

**Kenya:  
Business Preliminary Investigation  
(BOP Business Collaboration Promotion)**

**Final Report**

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**Independent Administrative Agency  
Japan International Cooperation Agency (JICA)**

**Takeda**

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## List of Abbreviations

AtM	Access to Medicines
BU	Business Unit
BOP	Bottom of the pyramid
GDP	Gross Domestic Product
GEM	Growth and Emerging Markets
GI	Gastro Intestinal
HISP	Health Insurance Subsidy Program for the Poor
HSS	Health Systems Strengthening
ICP	International Comparison Program
KDHS	Kenya Demographic and Health Survey
KEMSA	Kenya Medical Supplies Agency
KIHBS	Kenya Integrated Household Budget Survey
KSG	Kenya School of Government
Ksh	Kenyan Shillings
LCU	Local Currency Unit
LMG	Leadership, Management and Governance
LMIC	Low-middle income country
LPGW	Lowest Paid Government Worker
MoH	Ministry of Health
NCD	non-communicable diseases
NGO	Non-Governmental Organisation
NHIF	National Hospital Insurance Fund
OOP	Out-of-pocket
PAP	Patient Assistance Program
PPB	Pharmacy and Poisons Board
PPP	Purchasing power parity
SSA	Sub-Saharan Africa
TA	Therapeutic Area
UHC	Universal Health Coverage
US\$	United States Dollar

# 1. Executive Summary

The purpose of the BOP business survey was to conduct a medicines affordability assessment of the Kenyan population, in order to inform a business model where Takeda Pharmaceuticals can look to improve patient access to their relevant pharmaceutical medications for non-communicable diseases (NCDs).

A comprehensive understanding of the Kenyan health and economic profile was developed. This was followed by an in-country survey to collect baseline data and thereafter medicines affordability was calculated using three widely used methods to validate patient affordability of diabetes and hypertension medicines; and medicines for the treatment of breast and prostate cancer. The affordability factors validated during the field study were:

- At what price point are patients simply too poor to afford medicines
- At what price point does accessing medicines push a patient into poverty
- How many days' wages are needed to pay for a course of treatment

Findings revealed that the prevalence of NCDs and their risk factors in Kenya is high and increasing. Kenya's healthcare system is not adequately responsive to the prevalence of NCDs due to inadequate financing and infrastructure, leadership and governance challenges, as well as human resource challenges that hinder effective management and service provision. As a result, treatment for people living with NCDs is often costly and difficult to access for the majority of the Kenyan population

Treatments for these conditions are funded primarily through out-of-pocket payments, and where household choose to seek care, many incur high (catastrophic) health expenditure which leads to impoverishment.

Evaluation of pricing and commercialization data using economic modelling indicates that lowest possible price does not guarantee maximum access. Therefore alternative pricing models focused on driving access in a sustainable manner should be considered in order to realize greater impact. Pricing options to be considered include:

- Patient Assistance programs: A patient pays what they are able to afford for the purchase of higher-cost, patented medicines that have no generic equivalents or close therapeutic substitutes
- Price-volume deals on higher-cost innovative medicines with government,
- Lowest sustainable price to maximise access – e.g. set price of essential medicines at the lowest sustainable price (above cost of manufacturing if this is the price that maximises access/affordability.)
  - Zero-profit pricing models on selected essential medicines to maximise access
  - Agree with retailers/wholesalers/and/or government to limit their mark-up fee.
- Two-tier pricing strategy to maximise access – e.g. set a single price above cost, at a level that maximises affordability. The idea would be to plough profits generated back into donor/philanthropic programs in the lower part of the pyramid to maximise access.

The evaluation of both the qualitative information from the surveys and the quantitative outputs of the economic model will inform the business model and pricing mechanism / s to be used to improve access to Takeda's medicines.

## 1.1. Consistency between the summary of the investigation and the development issues

### 1.1.1. Investigation overview

Table 1: Investigation overview

Objectives	
Objectives	The objective of the BOP business survey is to conduct a medicines affordability

	assessment of the Kenyan population, in order to inform a business model, where Takeda can look to improve patient access to their relevant pharmaceutical medications for non-communicable diseases (NCDs) in Kenya.
Period	19 March 2018 to 31 March 2019
Activity region	Kenya
Summary of business targeted for commercialization	As an outcome of the BOP business survey, Takeda is investigating the implementation of sustainable medicines pricing initiatives, to improve access to their medicines in this market. For example, this could take the form of a patient-assistance program (PAP) or through offering medicines at a lower cost to the patient.
Development effects targeted and beneficiaries	This business case seeks to address these chronic diseases (mainly cancer, diabetes and hypertension) by looking to identify potential pricing initiatives to subsidize patients at the bottom-of-the-pyramid, thereby improving overall access to Takeda medicines in Kenya.

### 1.1.2. Background of investigation

Kenya is classified as a low-middle income country (LMIC) and in 2017 had a Gross Domestic Product (GDP) of US\$ 74.9bn with a GDP per capita of US\$ 1 507<sup>1</sup>. In LMICs, there is little or no health insurance, and as such people need to pay out-of-pocket (OOP) for medicines when they fall ill<sup>2,3</sup>. By definition, a person in a LMIC only has a limited amount of resources which needs to cover payment for basic services such as food and housing; and the amount of money they can spend on healthcare (including medicines) is very limited. Therefore if a medicine needs to be paid for, people simply do not purchase the goods/services, or forgo some essential services, and / or pay for the service and go into debt<sup>4,5,6</sup>.

This “affordability” to pay for essential healthcare services is becoming an increasingly important issue where there is a need to ensure that OOP payments are “affordable”. This problem is further being exacerbated by the increasing incidence of non-communicable diseases (NCDs) that require lifelong treatment<sup>5</sup>. Patient access to medicine, both diagnosis and treatment, is highly dependent on levels of affordability. In response to this, Takeda aims to sustainably provide affordable access to some of its medication for appropriate patients in Kenya, and expand it to the rest of sub-Saharan Africa (SSA) in the future.

Determining these affordability thresholds requires an understanding of the price of a particular product in a country, that country’s specific income levels and a clear definition of “unreasonable burden”. It is not just as simple as applying these measures from other countries, as there are vast variations in income within a region and often within the country itself. It is therefore, critical to determine this affordability by country and in some cases within regions / counties of a country. Whilst a number of studies have been completed across the world<sup>7</sup>, this has not been done recently in East Africa and for Kenya in particular.

### 1.1.3. Objective of investigation

The objective of this BOP business survey is to seek to implement sustainable pricing access strategies on some of Takeda’s medicines, with initiatives that improve access to their medicines in Kenya. For example, Takeda could offer a Patient-Assistance Program (PAP) or find another approach to offer medicines at a lower cost to the patient. This could take the form of a co-share payment system that will subsidise the cost incurred by the patient. This level of subsidisation needs to be relevant to the income level of the patient whereby those who:

- Have sufficient income to pay for the medicines pay for it in full
- Are already in poverty and / or will be pushed into poverty when they access medicines receive full subsidization
- Fall in between the above 2 categories are required to make a co-payment based on their level of affordability

In order to achieve this, Takeda need to define the “unreasonable burden” as it relates to local definitions of the affordability of medicines in Kenya. Critical to the effectiveness of the model displayed in

, is an accurate picture of the population’s income levels and health care affordability. Understanding the division of the population will provide a more precise indication of affordability and, ultimately, the viability of introducing sustainable pricing initiatives which will improve access to some of

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<sup>1</sup> World Bank, 2018. Available at <https://data.worldbank.org/country/kenya?view=chart>

<sup>2</sup> Dror DM, Preker AS, Jakab M. The role of communities in combating social exclusion. In: Dror DM, Preker AS, editors. *Social reinsurance: a new approach to sustainable community health financing*. Washington & Geneva: World Bank & International Labour Office; 2002

<sup>3</sup> Flores G, Krishnakumar J, O'Donnell O, van Doorslaer E. Coping with health-care costs: implications for the measurement of catastrophic expenditures and poverty. *Health Econ* 2008; 17: 1393-412 doi: 10.1002/hec.1338 pmid:18246595

<sup>4</sup> Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. *Lancet* 2009;373:240–9.

<sup>5</sup> Niëns LM, Cameron A, Van de Poel E, Ewen M, Brouwer WB, Laing R. Quantifying the impoverishing effects of purchasing medicines: a cross-country comparison of the affordability of medicines in the developing world. *PLoS Med* 2010;7:e1000333

<sup>6</sup> Flores G, Krishnakumar J, O'Donnell O, van Doorslaer E. Copingwith health-care costs: implications for the measurement of cat-astrophic expenditures and poverty. *Health Economics* 2008;17:1393–412

<sup>7</sup> Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. *Lancet* 2009; 373: 240-9 doi: 10.1016/S0140-6736(08)61762-6 pmid: 19042012

Takeda’s medicines for the Kenyan population. In order to do this, on-the-ground surveys in Kenya and health economic modeling was required to be conducted. The intention of this was to ascertain the affordability and health spend of households to healthcare and in particular medicines; how this differs between diabetes / hypertension and oncology; how people access medicines and what additional barriers patients’ face in accessing medicines (i.e. beyond the price of medicines).

### 1.1.4. Summary of business model

The goal of BOP business survey is to understand the ability of Kenyan patients to pay for medicines for the treatment of NCD’s (hypertension, diabetes and oncology) based on income class and the disease to be treated. This will help Takeda to construct pricing access strategies to improve access to their medicines in Kenya, whilst remaining sustainable.

Potential pricing access strategies to be considered as an outcome of the BOP Business survey:

- Patient Assistance programs: A patient pays what they are able to afford for the purchase of higher-cost, patented medicines that have no generic equivalents or close therapeutic substitutes
- Price-volume deals on higher-cost innovative medicines with government,
- Lowest sustainable price to maximise access– e.g. set price of essential medicines at the lowest sustainable price (above cost of manufacturing if this is the price that maximises access/affordability.)
  - Zero-profit pricing models on selected essential medicines to maximise access
  - Agree with retailers/wholesalers/and/or government to limit their mark-up fee.
- Two-tier pricing strategy to maximise access – e.g. set a single price above cost, at a level that maximises affordability. The idea would be to plough profits generated back into donor/philanthropic programs in the lower part of the pyramid to maximise access.

The outcomes will further help Takeda understand where best to position each product in the Kenyan market. See

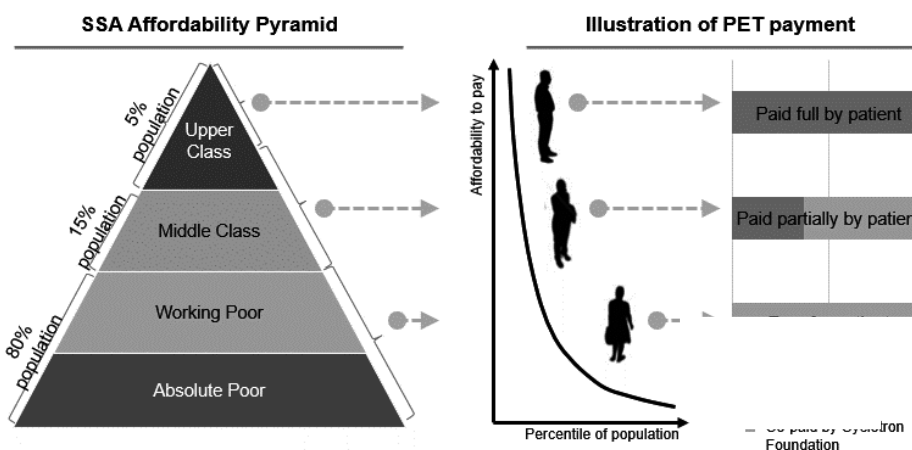


Figure 1: Proposed financial cross subsidization model

Determining the target Takeda medicines price points against patient affordability will be crucial in developing an effective and sustainable business model.

### 1.1.5. Consistency with development issues

A third of the global population, and half of the population in LMIC’s lack reliable, affordable access to medicines primarily affecting people living in Africa and Asia.

Due to economic constraints and poor financing of healthcare in LMIC's, 90% of the population pay for medication out-of-pocket (OOP), accounting for 25% to 70% of healthcare spending, compared to 10% in high income countries<sup>8</sup>.

Poor access to medicines and healthcare is most often exacerbated by low buying power of citizens and the perceived high cost of medicines and treatment. Developing countries generally experience great variability in the availability and purchase price of medicines – information of which is generally not publically available<sup>9</sup>. This prevents accurate benchmarking of medicine prices<sup>10</sup>. This lack of data poses a challenge for governments, NGO's and private sector companies to establish suitable pricing policies to increase access. In developing countries, this is further compounded by other factors such as supply chain challenges, government regulations, political / economic constraints and lack of appropriately trained health professionals.

Kenya is a typical LMIC and suffers all of the above-mentioned challenges.

In 2015 it was reported that 36.8% of the Kenyan population lives below the US\$1.90 (approx. 213 yen) poverty level (as defined by the World Bank)<sup>11</sup>, with large disparities in the poverty gap between the 47 counties. The population living below the poverty line of US\$1.90 in rural and urban areas is 50.5% and 33.5%, respectively.

A great proportion of the Kenyan population relies primarily on OOP as a source of healthcare financing, increasing poverty levels. The average annual OOP per capita healthcare spending in 2015 was estimated at US\$23 (circa Ksh 2,000 or 2 226 yen) and this has more than doubled since 2000<sup>12</sup>. Consequently, 4% of the population had accessed credit to pay for medical expenses in the same year.

The impact of income / affordability and price is clearly a barrier to most Kenyans accessing medicines; however the extent of this is not adequately understood. Takeda seeks to address the above development issues, and the business case aims to consider how Takeda's sustainable pricing initiatives and associated activities can strengthen access to medicines in this country.

## 1.2. Method of investigation

The investigation was designed to take place through six survey items, with the output of each item then forming part of the overall business case (See Figure 2).

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<sup>8</sup> World Health Organisation and Health Action International, 2008, "Measuring medicine prices, availability, affordability and price components", 2nd edition

<sup>9</sup> World Health Organisation and Health Action International, 2008, "Measuring medicine prices, availability, affordability and price components", 2nd edition

<sup>10</sup> Niëns L M. 2014, "Affordability in health care: Operationalisations and applications in different contexts

<sup>11</sup> Kenya National Bureau of statistics, 2013." Exploring Kenya's Inequality, pulling apart or pooling together, National Report"

<sup>12</sup> World Health Organization: <http://apps.who.int/nha/database/ViewData/Indicators/en>



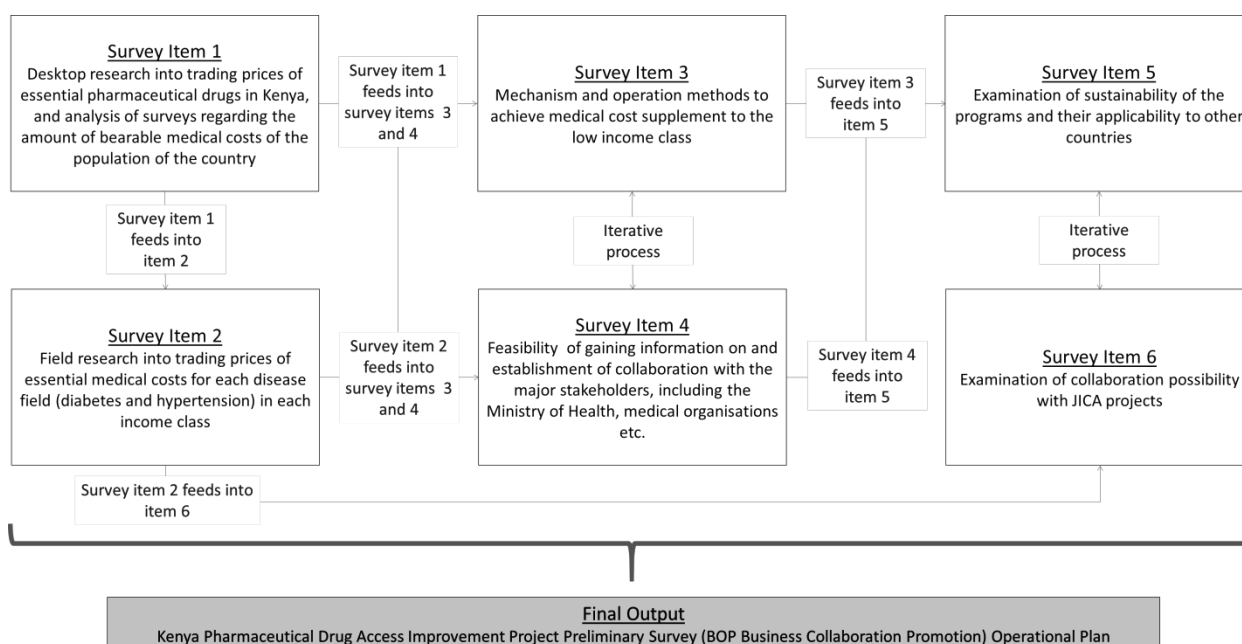


Figure 2: Approach to the development of the business case

### 1.2.1. Overall investigation plan

The BOP business survey was developed utilizing the “six survey items” outlined in Figure 2: Approach to the development of the business case. A detailed version of the project plan can be seen in “Appendix A – Detailed Project Plan”. Survey Items particular sought to provide information on:

- Medicine pricing and availability
- Patient access and affordability
- Poverty levels and the effect of purchasing medicines on poverty levels
- Potential pricing access models to enable patients to access medicines, without pushing them into poverty?

### 1.2.2. Period of investigation

The BOP business survey commenced in March 2018 and was completed on 01 April 2019. Originally the business case was to be completed in January 2019, however a two-month delay in Ethics Approval caused a delay in the commencement of the field based surveys. The project timeline was adjusted accordingly.

### 1.2.3. Regions of Investigation

Kenya was selected as the country for the development of the initial business case.

The secondary literature / data research for the business case was augmented by field research focusing on specific areas of related to access to medicines. A detailed selection procedure was followed to select the survey regions – this took into account the survey timeframe, demographic profile, ease of access and the prevailing security risks at the time. Nairobi, Kisumu and Mombasa were identified as the three counties where the survey would take place. Following security risk consultation with JICA, it was agreed that the following areas would be chosen as specific survey locations:

- Nairobi: Embakasi and Kasarani
- Kisumu: Kisumu Central and Kisumu East
- Mombasa: Chagamwe and Mvita

The approach and planning for the field surveys followed the recommendations of the WHO and HAI (2nd edition) “Measuring medicine prices, availability, affordability and price components”<sup>13</sup>. A household survey was also developed to understand patient experience in accessing NCD medication, and reasons for their health-seeking behavior.

The target was to complete between 315 and 360 households surveys, and between 40 and 56 pharmacies. This would allow for comparison between the different survey locations on an individual basis and/or permit the aggregation of data according to similar characteristics to improve statistical significance.

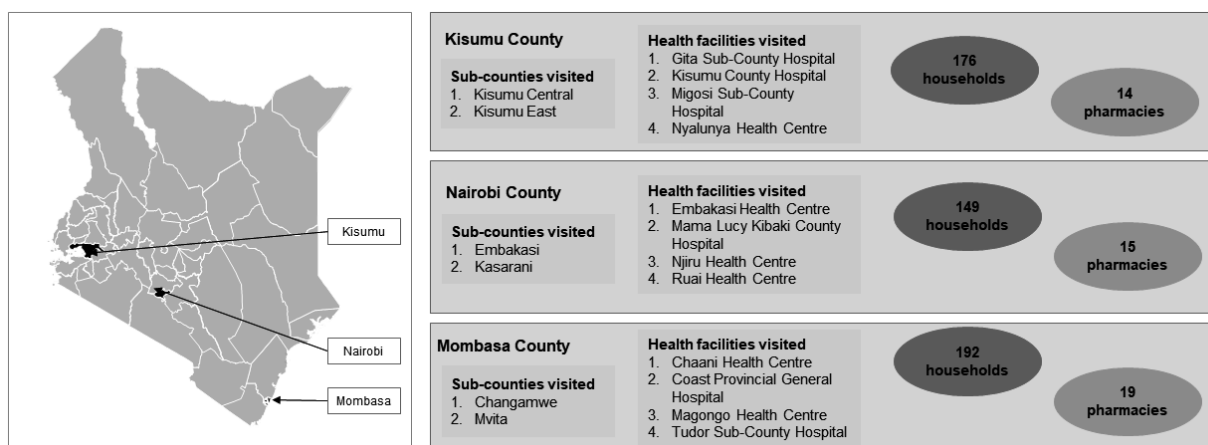


Figure 3: Regions included in the field surveys

#### 1.2.4. Approach to in-country Investigation

Prior to conducting the surveys it was learned that for any research involving human participants, it is necessary to obtain ethical approval from an Ethics Committee recognised by the Kenyan National Ethics Committee (NEC), before a study can commence.

Ethics according to the English Oxford Living Dictionary is the moral principles that govern a person's behaviour or the conducting of an activity.

*Note: there was a significant delay at the start of Survey Item 2 (field research) project while waiting Ethics Approval. This had a knock on effect into the timing of Survey Item 3. An application for Ethics Approval of the study was submitted on 3<sup>rd</sup> May 2018, with the understanding that the process would take approximately one month. However the approval process was severely delayed. Ethics Approval was eventually granted on 17<sup>th</sup> August 2018.*

Following gaining ethics approval, a letter of permission to conduct the research in the county and identified districts was obtained from the County Executive for Health in each of the survey counties. Their return letter of permission was then presented in each district and to each facility, along with the Ethics Approval document.

Once permission had been granted by the person in charge at each facility, the Community Health Education Workers (CHEWs) or Public Health Officers (PHOs) were engaged to support the survey and to understand the burden of hypertension, diabetes and cancer patients.

The in-country surveys comprised four main activities:

##### 1) Household survey

A household survey was conducted with the aim of describing a robust population profile of hypertension, diabetes and cancer patients, which would ultimately support an increased knowledge of the existing levels of medicines affordability within the Kenyan population.

<sup>13</sup> Accessed from [http://www.who.int/medicines/areas/access/OMS\\_Medicine\\_prices.pdf](http://www.who.int/medicines/areas/access/OMS_Medicine_prices.pdf)

The household survey would also provide the required evidence to support the modelling of the economic impact of medicine purchases to a typical Kenyan household

- 2) Pharmacy survey  
The pharmacy surveys were conducted in both public and private facilities, to determine trading prices of hypertension, diabetes and oncology medication. This would enable the modelling of patient affordability for specific medicines for each disease
- 3) Key informant interviews  
Key informant interviews were conducted with the health personnel at several health facilities and also with key personnel with good knowledge on the factors affecting availability and affordability of NCD medication
- 4) Focus group discussions  
Focus group discussions were conducted with groups of people suffering from hypertension, diabetes and cancer in order to obtain an in-depth understanding of health-related opinions and health seeking behaviour and practices. The qualitative data obtained during these sessions was used to compare and further enhance the more quantitative data collected in the household survey

The survey team engaged Community Health Volunteers (CHVs) at each health facility visited. CHVs are an important component of healthcare delivery within the community, working to provide health education and services to households. The CHVs identified patients and accompanied the survey team during household visits.

The survey team enquired if and when the facilities had clinic days so that a visit to the facility could be arranged on those particular days, in order to engage with many NCD patients, who would become the survey’s respondents.

Broad stakeholder consultation and partnerships were a crucial element for the success of the health surveys. Amref Health Africa, an organisation committed to bringing lasting health change in Africa by empowering communities and strengthening health systems was also actively engaged during the survey due to their extensive local knowledge and previous experience in conducting several surveys across Kenya.

### 1.2.5. Investigation structure and role

Please see Figure 4 and Figure 5 for the team structure. The team largely consisted of Takeda employed personnel. External personnel were hired to effectively conduct the field research in the local languages with abundant market survey experience in Kenya. The tasks of external personnel were limited to Survey Items 1 and 2.

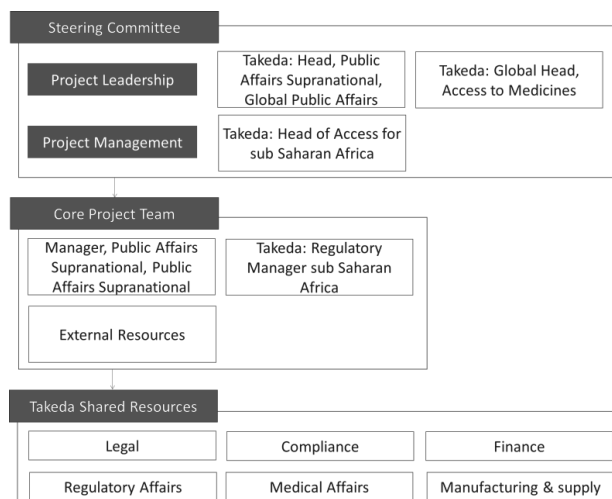


Figure 4: Project leadership team

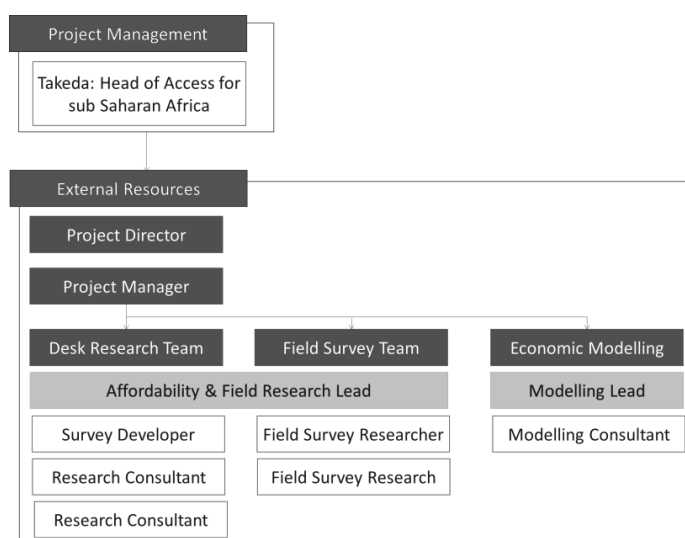


Figure 5: Project management team

### 1.3. Validation items

As part of the BOP business survey, Takeda were looking to validate patient affordability of diabetes and hypertension medicines; and medicines for the treatment of breast and prostate cancer. The affordability factors validated during the field surveys were:

- At what price point are patients simply too poor to afford medicines
- At what price point does accessing medicines push a patient into poverty
- How many days wages<sup>14</sup> are needed to pay for a course of treatment
- What other factors prevent access to medicines, for example:
  - Medicine availability at pharmacies
  - Medicine purchasing regimes of patients (e.g. frequency, volumes)
  - Ability to travel to a facility / pharmacy to get medicines
  - Other factors preventing access to medicines

There are several qualitative and quantitative methods that are widely used to understand affordability in developing countries. Each method has benefits and disadvantages and relies on the analysis of a predetermined set of country and medicine-related data.

#### Method for calculating the affordability of medicines

The following three methods were used to calculate the affordability of medicines in Kenya. Using more than one method simultaneously can enhance the accuracy of the understanding and assessment of the impact on individual affordability related to medicines:

- Catastrophic method: Defines that expenditure on healthcare [as a proportion of an income] that exceeds a pre-defined threshold
- Impoverishment method: Expresses how many people would be pushed below the poverty line should they access a particular medicine or treatment
- Lowest paid government worker (LPGW) method: Expresses the affordability [cost] of medicines in terms of the number of days' wages

The **catastrophic method** is based on the premise that the purchase of a medication should not take up more than a predetermined percentage of a household's non-food expenditure/income. The most common predetermined percentages (known as thresholds) adopted in the literature are 15%, 25% and 40%. The method helps to determine whether the price of medication is more than 15%, 25% or 40% of households' monthly non-food expenditure. If the medication price as a percentage of non-food

<sup>14</sup> Based on a day's wages for the lowest paid government worker

expenditure exceeds a chosen threshold, the purchase of the medication is considered "catastrophic" for the household.

At the 15% threshold what it means is that households should not be spending more than 15 percent of their non-food expenditure on medication; and that if the price of the medication constitutes more than 15% of the household's non-food expenditure, then buying the medicines will be catastrophic for the household. If the 40 percent threshold is chosen, it means that households should not be spending more than 40 percent of their non-food expenditure on medication, thus if the medication price exceeds 40% of non-food expenditure, then at the 40 percent threshold, purchase of the medication induces catastrophic expenditure.

The **impoverishment method** calculates how many people would be pushed below a defined poverty line should they choose to purchase a healthcare service / medicine. It considers the absolute quantity of available resources before and after paying for services/goods; and it works on the basis that there is a minimum level of income people need to cover their essential basics. If a household is above the poverty line before paying for the commodity, but falls below it after having made payment, they are said to have been "impoverished" by the transaction. Therefore, to calculate the affordability of medicines using the impoverishment method, the International Poverty line of US\$1.90 per day (2011 PPP) was used – this poverty line is based on International Comparison Program (ICP) purchasing power parity (PPP) calculations and represents the international equivalent of what \$1.90 could buy in the US in 2011. The PPP conversion factor was then used, GDP local currency unit (LCU) per international US\$ in Kenya 2011 = 34.298, so  $US\$1.90 * 34.298 = Ksh 65.1662$  per day (approx. 72.52 yen) which then works out at Ksh 1 955 or 2185 yen per month (30 days per month). Note: 36.8% of the Kenyan population fall below the international poverty line.

The **Lowest Paid Government Worker (LPGW)** method was developed by WHO and it expresses the cost of medicine as the number of days wage it would take the LPGW to pay for 1 month's supply of a chronic medication or in the case of oncology medicines – the average cost of 1 month's treatment in a typical year-long cancer treatment regime. The advantage of this method over the previous two methods is that it is a relatively simple expression of medicine affordability and so it is relatively easy to compare the affordability of medicines across a large range of medicines and/or countries. The disadvantage is that in Kenya the LPGW falls in the top 20% of income earners (assuming post-tax income equals expenditure). In other words, 80% of the population earn and spend less than the LPGW. The LPGW is therefore not a particularly good benchmark for affordability in the population as a whole. The LPGW got an after-tax salary of roughly Ksh 13 419 (approx. 14 932 yen) in 2015/16 and Ksh 16 473 (approx. 18 331 yen) in 2018/19. Tax was estimated at 10% based on analysis of income tax bracket and exemptions for annual taxable income (which are very low at roughly first Ksh 15 000 or approx. 16 692 yen).

The three affordability study methods offer various benefits (see "Appendix B – Comparison of Methods used to Calculate Affordability"), but they also have certain limitations and the use of the methods to assess affordability were based on a thorough understanding of the Kenyan health and economic environment.

### Selection of medicines

Studies in the literature on the affordability of medicines, typically focus on a few medicines (per disease category) to illustrate the case.

As part of this study, the price of the most relevant available comparator medicines was captured during the field surveys. The choice of medicines identified for benchmarking was informed by the results of the survey of 48 pharmacies, conducted as part of the field survey and Takeda's own knowledge on comparator products. This information will also support Takeda in understanding which segment of the market Takeda should focus, to ensure maximum access, taking into consideration competitors as well as Takeda's pricing in other markets.

In order to reduce the complexity, Takeda limited the number of medicines used to benchmark affordability in Kenya to a maximum of three per disease category (diabetes, hypertension and oncology). The reason for limiting the selection is to streamline the way in which affordability could be analysed.

#### 1.4. Validation of results

A total of 517 household [patient] surveys and 48 pharmacy / medicine price surveys were completed across the three counties (Nairobi, Kisumu and Mombasa). All of the household respondents in the field survey were being treated for hypertension, diabetes, cancer, or a combination thereof, and from here on are respected as being patients.

There was an average of 3.9 people per household, which is similar to what was found in the 2014 Kenya Demographic and Health Survey (KDHS). The average age of patients was 56 years which indicates that hypertension, diabetes and cancer mostly afflict the elderly population in Kenya; and 38% of the patients were self-employed, 10% had some form of formal employment and more than half of the respondents were unemployed with unemployment highest in respondents aged over 65 years.

Of those patients surveyed, hypertension was the most prevalent disease with 65% of the patients being treated for the condition, and 21% of the patients being treated for a combination of one or more of the investigated diseases.

More than half (71%) of the surveyed patients sought treatment from public healthcare facilities and this was highest amongst cancer patients but 64% of patients reported that they did not receive any or all of their medication at the facility where they received healthcare services; mainly because their usual facility did not have the medicine available. As a result 74% of those patients purchased medication at private pharmacies close to their homes that had stock of the required medicine.

The majority of patients (59%) did not have any form of health insurance. Of those with health insurance, 94% were covered by National Hospital Insurance Fund (NHIF); Nairobi had the highest proportion of patients with health insurance. However, even if patients had a form of health insurance, a significant number of patients still had to pay for their medication out-of-pocket (or top-up), suggesting that health cover might be insufficient for patient needs.

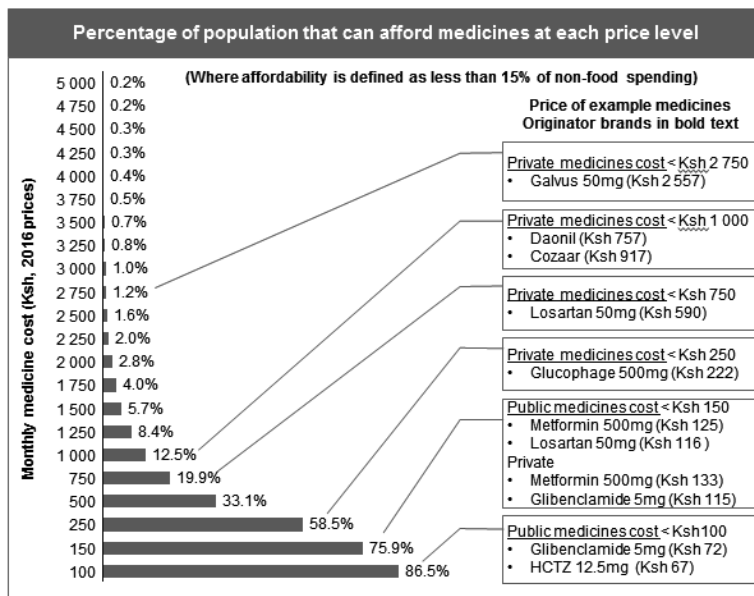
Most pharmacies stocked medicines for hypertension and diabetes but did not stock cancer medicines. Very few originator medicines were stocked – almost all medicines were generics. Patients do not always buy the needed medicines either because they cannot afford to pay the price, there is a shortage of the medicine, or they feel ashamed by having the disease or a combination of these.

The survey also gathered pricing data on 20 brands of hypertension medicines and eight brands of diabetes medicines. The diabetes and hypertension medicines were typically generics and most commonly sold in tablet form. The most frequent [generic] hypertension medication cost less than Ksh 5 (approx. 5.56 yen) per tablet, but the most expensive cost more than Ksh 100 (approx. 111 yen) per tablet. The diabetic medication was priced between Ksh 4 (approx. 4.45 yen) and Ksh 20 (approx. 22.26 yen) per tablet, whilst the originator brands were priced at more than Ksh 50 (approx. 55.64 yen) per tablet. 44 cancer medicines were found at public health facilities and none in private pharmacies. Almost all were generics except for Capecitabine which was available in both originator (Xeloda) and generic versions; the average price of cancer medication was Ksh 13 727 (approx. 15 275 yen) per vial.

##### Overview of affordability modelling results

The **catastrophic method** of calculating affordability, defines expenditure on medicines where if the spending on medication out of non-food expenditure exceeds a chosen threshold, the purchase of the medication is considered "catastrophic" for the household.

For diabetes and hypertension, Takeda felt that a household should not exceed 15% of a patient's total non-food expenditure. The logic for this is that these conditions are treated with chronic medications that must be taken daily and typically for the remainder of the patient's life.

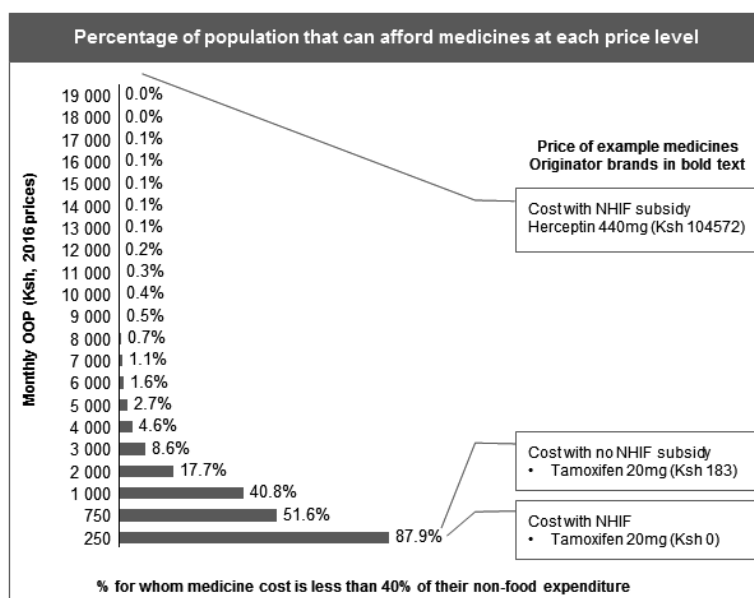


As reflected in Figure 6: Diabetes and hypertension; Affordability of medicines (Catastrophic method) Figure 6 findings revealed that at Ksh 150 (approx. 167 yen) for a month's supply of medicine, 76% of the population can afford to purchase the medication without it being "catastrophic". Whereas at Ksh 250 (approx. 278 yen) about 58% of the population can afford the medication but at Ksh 2 500 (approx. 2 782 yen) only 1.6% of the population can afford it without falling into poverty.

Figure 6: Diabetes and hypertension; Affordability of medicines (Catastrophic method)

For oncology medicines Takeda felt that a household should not exceed 40% of a patient's total non-food expenditure. The logic for this is that a patient may only seek treatment for cancer once or twice in their lives, but would be prepared to spend a greater proportion of their income to ensure their health and productivity for longer.

An important consideration when assessing affordability for oncology medicines is that NHIF subsidize up to Ksh 25 000 or approx. 27 820 yen per cycle (for up to a maximum of six cycles per financial year) for first line cancer treatment and up to Ksh 150 000 or approx. 166 915 yen per cycle (for up to four cycles per financial year) for second line treatment.



Findings represented Figure 7 in revealed that Tamoxifen (Nolvadex) 20mg, produced by generic manufacturers, is affordable to the majority of Kenyan's (87.9%), without a subsidy from the NHIF. This may be because a multinational pharmaceutical company reportedly supplies it at a very low cost (\$1 per month) via its generics division.

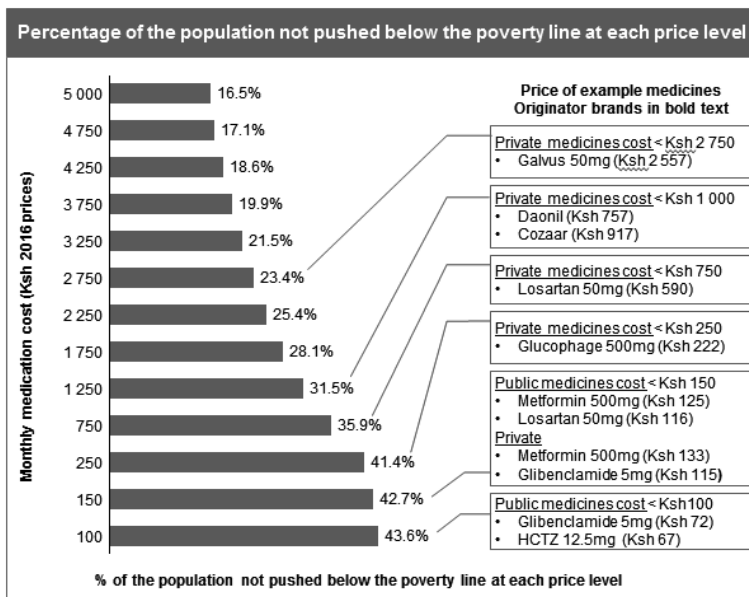
Herceptin (trastuzumab) by contrast is a drug patented by a / other multinational pharmaceutical company and it is unaffordable for almost all Kenyans, even with a subsidy from the NHIF. This multinational pharmaceutical

company has therefore reportedly entered into a unique pricing agreement with the Kenya government, whereby they will support access to the medicine for treatment of HER2-positive patients.

Figure 7: Oncology; Affordability of medicines (Catastrophic method)

The **impoverishment method** calculates how many people would be pushed below a defined poverty line should they choose to purchase a healthcare service / medicine. If a household is above the

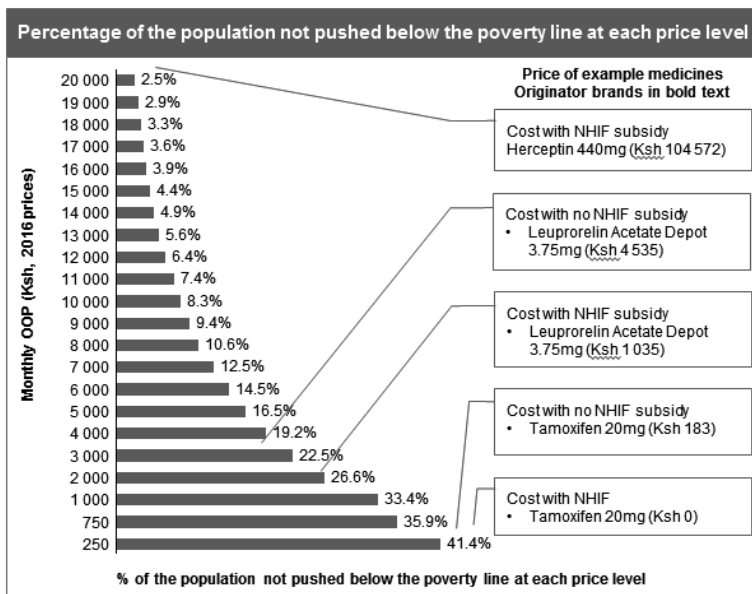
poverty line before paying for the commodity, but falls below it after having made payment, they are said to have been “impoverished” by the transaction.



For diabetes and hypertension, according to the catastrophic method 76% of households can afford a medicine that costs Ksh 150 (approx. 167 yen) a month while more than 86% can afford a medicine that costs Ksh 100 (approx. 111 yen) for a month’s supply. However, as represented in Figure 8 when placed in the context of the impoverished method, medicines costing Ksh 100 (approx. 111 yen) per month leave only 43.6% of the population above the poverty line, and medicines costing Ksh 150 (approx. 167 yen) leave only 42.7% of the

population above the international poverty line.

Figure 8: Diabetes and hypertension; Affordability of medicines (Impoverished method)



For oncology medicines, the catastrophic method suggests that 41% of households can afford a medicine that costs Ksh 1 000 (approx. 1 113 yen) a month, the impoverishment method shows this monthly cost leaves around 33.4% of the population living above the international poverty line.

Purchase of Tamoxifen (Nolvadex) 20mg, only produced by generic manufacturers, leaves around 40% of the Kenyan population above the poverty line, though is deemed affordable for the majority of Kenyans without a subsidy (87.9%) from the NHIF in the context of the catastrophic method.

Purchase of a month’s treatment of Herceptin (trastuzumab) would leave virtually all Kenyans living below the international poverty line.

Figure 9: Oncology; Affordability of medicines (Catastrophic method)

The **Lowest Paid Government Worker (LPGW)** method expresses the cost of medicine as the number of day’s wage it would take the LPGW to pay for one month’s supply of a chronic medication or in the case of oncology medicines – the average cost of 1 month’s treatment in a typical year-long cancer treatment regime.



For diabetes, Insulin will cost a LPGW an average of 1.1 days' wage in private sector pharmacies and 0.8 days in public sector facilities (that charge). The most affordable type 2 diabetes medicine currently available is Glibenclamide 5mg (only available as a generic, is under many brand names including Gliben-J, Daonil, Diabeta, Euglucon, Gilemal, Glidanil, Glybovin, Glynase, Maninil, Micronase and Semi-Daonil), would cost the LPGW 0.2 days wage. Galvus (Vildagliptin), which is a type of medicine, called a dipeptidyl peptidase-4 (DPP-4) inhibitor and is used to treat type 2 or non-insulin dependent diabetes (NIDDM) would cost the LPGW 5.0 days to buy, when purchasing from a private pharmacy.

For hypertension, the number of days' wage it will take the LPGW in Kenya to pay for a month's worth of hypertension medication currently supplied in Kenya range from 0.1 days for HCTZ 12.5mg to 2.4 for a branded product like Tenormin (atenolol). Medicines supplied by public facilities would typically cost an LPGW an average of between 0.1 and 0.2 days wage. Generic medicines supplied by private pharmacies in Kenya would typically cost an LPGW an average of between 0.2 and 1.2 days wage, and branded medicines typically cost an LPGW an average of between 1.8 and 2.4 days wage.

For oncology, Tamoxifen (Nolvadex) 20mg would cost 0.4 days wage for one month's treatment if the patient were not to have NHIF coverage. With NHIF coverage, the full cost of such a medicine would be covered by NHIF (at least for duration of the first six treatment cycles). A medicine such as Herceptin (trastuzumab) even for a patient with NHIF coverage would cost 222 days wage for one month's worth of treatment.

#### 1.4.1. Forecast of commercialization

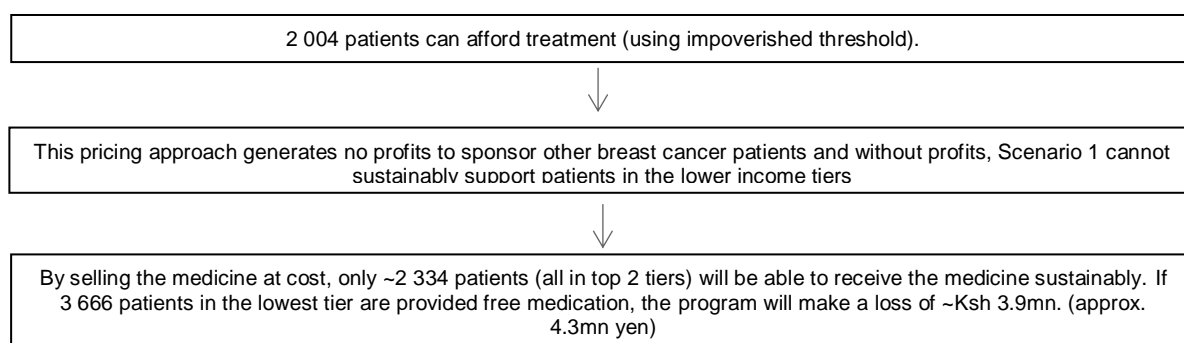
A pricing simulation based on the affordability modelling was performed on a hypothetical oncology medicine, in order to consider the effects of various pricing scenarios on access.

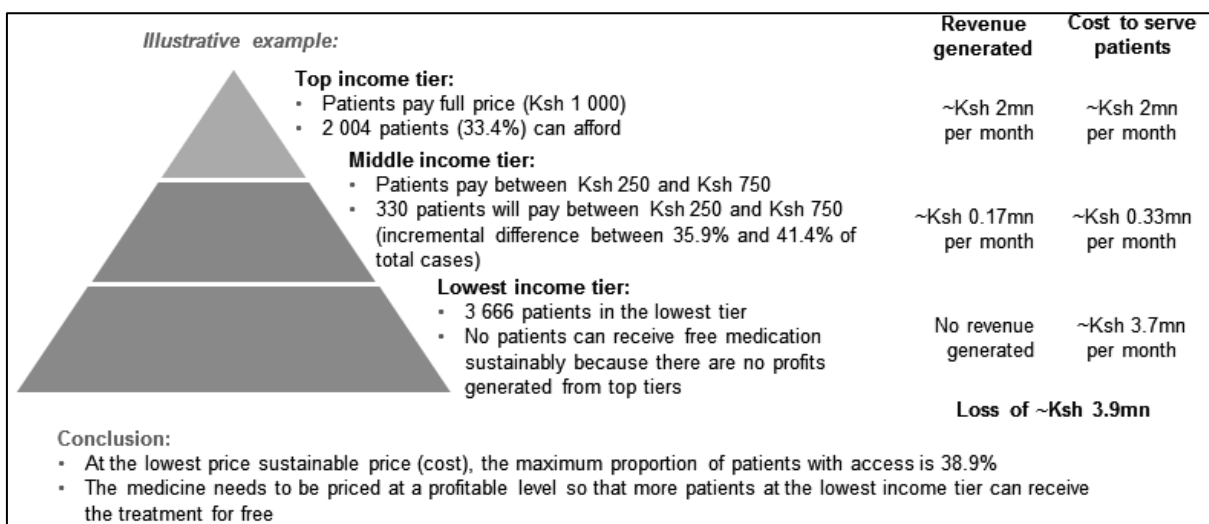
##### Pricing and access maximization simulation for hypothetical "Medicine A"

Assumptions made for pricing simulation:

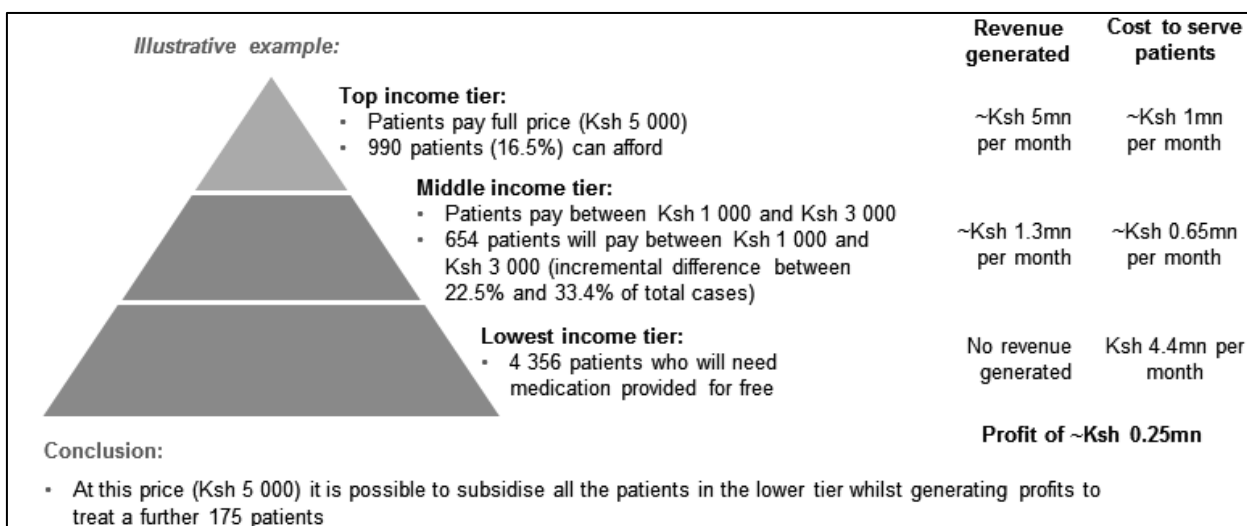
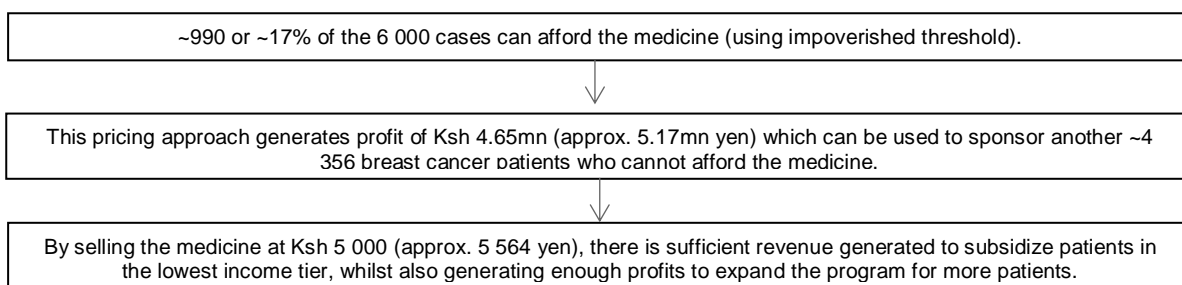
- An essential oncology medication "medicine A" costs a Pharmaceutical Company ~ Ksh 1 000 or approx. 1 113 yen (per vial, which is a month's dose) to get to the patient
- There are approximately 6 000 new cases of breast cancer a year that require treatment
- Patients at the lowest income tier are given treatment for free; middle income tier pay ~50% of the price of the medicine; and top income tier patients pay full price

**Hypothetical Modelling Scenario 1:** Pharmaceutical company sells "Medicine A" at a price of Ksh 1 000 or approx. 1 113 yen (cost)





**Hypothetical Modelling Scenario 2:** Pharmaceutical company sells “Medicine A” at a price of Ksh 5 000 or approx. 5 564 yen (Ksh 4 000 above cost)



The results of the hypothetical modelling reiterates that when making a judgement on pricing and commercialization, offering medicines at the lowest possible price does not guarantee maximum access, and there could be alternative pricing initiatives which could realize a greater impact.

**1.4.2. Basis for judgment on commercialization prospects/validation results**

The BOP business survey highlighted a definite need for sustainable medicines pricing initiatives, to improve access to originator medicines for non-communicable diseases (NCDs) in the Kenyan Market.

Hypertension and Diabetes:

To make a judgement on providing access and the type of access pricing initiative to adopt for Type 2 diabetes and hypertension medicines, the catastrophic method at a threshold of 15% will be used to understand affordability and to calculate how and if it is possible to offer sustainable pricing access initiatives for these products. This means the monthly cost of one type of medication should ideally not exceed 15% of a patient's total non-food expenditure. The reason for choosing a lower threshold (and not 25% or 40%) is that these conditions are treated with chronic medications that must be taken daily and typically for the remainder of the patient's life. It is also critical to consider that there is often co-morbidity meaning the patient may have to purchase both hypertension and diabetes medicines (in which case they may actually have to outlay 30% of non-food expenditure).

The impoverishment method, which shows the proportion of the population that does not fall below the poverty line at a particular medicine price, will be used to provide more nuanced insights into the preceding results from the catastrophic affordability analysis. For instance, while the catastrophic method suggests that 75.9% of households can afford a medicine that costs Ksh 150 a month, the impoverishment method shows that at a monthly cost of Ksh 150 (approx. 168 yen), only 42.7% of the population remain above the international poverty line.

Further considerations include understanding availability of supply and pricing of similar medicines for the treatment of type 2 diabetes or hypertension. For instance, private pharmacies stock only a limited supply of originator brands such as Glucophage at price of less than Ksh 250 (approx. 280 yen), which roughly 58% of the population can afford. Very few private pharmacies supply the more expensive originator brands – for example only two of 28 pharmacies visited supply Galvus (Vildagliptin) 50mg and this is because at a price of more than Ksh 2 500 (approx. 2 795 yen) only 1.2% of the population can afford it. It is however understood that in some urban areas originator brands are more common.

#### Oncology:

When considering providing access and the types of access pricing initiative to adopt for oncology medicines, the catastrophic method at a threshold of 40% will be used to understand affordability and to calculate how and if it is possible to offer sustainable pricing access initiatives for this range of products. The cost of a month's supply of medication in a typical year of treatment will be affordable if it does not exceed 40% of total non-food expenditure. The reason for choosing a higher threshold (and not 15% or 25%) is that oncology medicines treat an acute condition over a limited number of cycles, and so the patient would not have to continue to bear the monthly cost for the rest of his/her life. A course of treatment would typically be for a finite period of between 6 months and 5 years, and is potentially lifesaving so patients would be willing to pay a higher proportion of total expenditure than for a chronic medication.

When making a judgment on pricing and provision of a pricing access initiative, another important consideration for oncology medicine is the financing support provided under the NHIF. NHIF is however not used solely for the purchase of medication, and so it is likely that out-of-pocket payments will still be necessary, but will affect affordability.

Further considerations include understanding availability of supply and pricing of similar medicines for the treatment of oncology. Only a few oncology medicines are currently stocked by private pharmacies and private hospitals. From this list Tamoxifen (Nolvadex) 20mg and Trastuzumab (Herceptin) 440mg, which are good comparator medicines for Takeda products, will be used for benchmarking purposes as part of the judgement for providing a sustainable pricing access initiative. Tamoxifen (Nolvadex) 20mg, only produced by generic manufacturers, is affordable to the majority of Kenyan's without a subsidy (87.9%) from the NHIF. This may be because a / other multinational pharmaceutical company supplies it at a low cost via its generics division<sup>15</sup> and as part of its Access Program.

By contrast, Herceptin (trastuzumab) (a medicine patented by a / other multinational pharmaceutical company) is unaffordable for almost all Kenyans, even with a subsidy from the NHIF. This is why the multinational pharmaceutical company had reportedly entered into an agreement with the Kenya

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<sup>15</sup> <http://www.pharmexec.com/novartis-supply-low-cost-drugs-kenya-ethiopia-and-vietnam>

government where they will support the treatment of HER2-positive patients, as a stop-gap measure until further government funding can be found.

### 1.4.3. Business model targeted for commercialization

The challenge that Takeda faces is to balance the desire to increase access to its innovative medicines, and at the same time ensure the long-term sustainability of the pricing structure so that their medicines will remain available to future generations.

Various potential pricing initiatives and access models are being considered as an outcome of the BOP business survey.

#### Medicine access strategy: Diabetes and hypertension

For diabetes and hypertension, Takeda defines affordable medicines as those which do not exceed 15% of a patient’s total monthly non-food expenditure; only 33.3% of Kenya’s population can afford a medication if it costs less than Ksh 250 (approx. 279 yen) a month (See Figure 10). Diabetes and hypertension are distinct conditions, requiring their own specific therapeutic interventions and medicines. However, for the purposes of assessing their affordability for the Kenyan population, these medicines were grouped together because they are similarly priced (i.e. the effect on affordability is the same for both these medicines, but this is not to imply that the medicines are always sold in combination or in a bundle).

Potential access strategies being considered as an outcome of the BOP business survey include:

- Lowest sustainable price to maximise access– e.g. set price of essential medicines at the lowest sustainable price (above cost of manufacturing if this is the price that maximises access/affordability.)
  - Zero-profit pricing models on selected essential medicines to maximise access
  - Agree with retailers/wholesalers/and/or government to limit their mark-up fee.

Results of the BOP business survey have however highlighted that by offering medicines at the lowest possible price, it does not guarantee maximum access, and there could be alternative pricing initiatives which could realize a greater impact.

- Two-tier pricing strategy to maximise access – e.g. set a single price above cost, at a level that maximises affordability. The idea would be to plough profits generated back into donor/philanthropic programs in the lower part of the pyramid to maximise access.

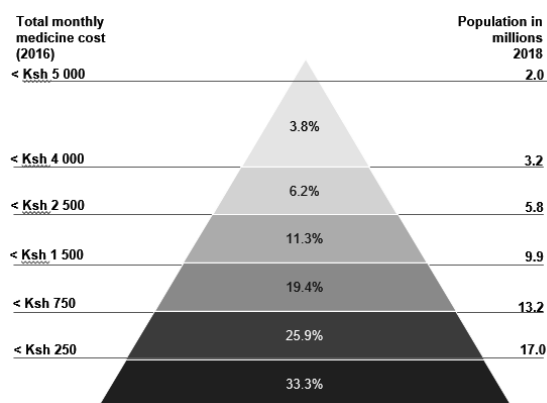


Figure 10: Percentage of population that can afford diabetes and hypertension medicine at each price level

### Medicine access strategy: Oncology

For oncology, Takeda defines affordable medicines as those which do not exceed 40% of a patient's total monthly non-food expenditure; in the pyramid below, only 48.4% of Kenyan's population can afford medicine if it costs less than Ksh 250 (approx. 279 yen) a month (See Figure 11).

Potential access strategies being considered as an outcome of the BOP Business survey:

- Patient Assistance programs: A patient pays what they are able to afford for the purchase of higher-cost, patented medicines that have no generic equivalents or close therapeutic substitutes
- Price-volume deals on higher-cost innovative medicines with government, such as a / other multinational pharmaceutical companies 50-50 deal on Herceptin (trastuzumab) (this has reportedly stalled)<sup>16,17</sup>
- Lowest sustainable price to maximise access– e.g. set price of essential medicines at the lowest sustainable price (above cost of manufacturing if this is the price that maximises access/affordability.)
  - Zero-profit pricing models on selected essential medicines to maximise access
  - Agree with retailers/wholesalers/and/or government to limit their mark-up fee.
- Two-tier pricing strategy to maximise access – e.g. set a single price above cost, at a level that maximises affordability. The idea would be to plough profits generated back into donor/philanthropic programs in the lower part of the pyramid to maximise access.

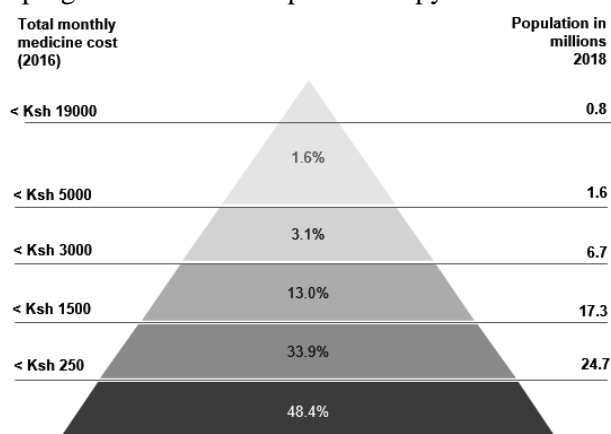


Figure 11: Percentage of population that can afford oncology medicine at each price level

When making a judgment for commercialization of oncology medicines, financing support provided to the patient under the NHIF will be considered. NHIF is not used solely for the purchase of medication, and so it is likely that out-of-pocket payments will still be necessary, but will affect affordability.

#### 1.4.4. Remaining issues and countermeasures

Table 2: Remaining issues and countermeasures related to progressing Takeda's business strategy for diabetes, hypertension and oncology

No.	Name	Remaining Issues	Countermeasures	Resolution Period
	Product Registration	Time to product registration can take anywhere between 12 and 18 months.	Takeda intend making applications for fast track registration. Despite this expect Marketing Authorization (MA) is 12 months following	Through fast track application, the timeline to receiving Marketing Authorization

<sup>16</sup> <https://www.standardmedia.co.ke/article/2001286614/shortage-of-vital-drug-pushes-cancer-patients-beyond-their-means>

<sup>17</sup> <https://www.nation.co.ke/news/Cancer-patients-cling-on-hope-as-drug-runs-out/1056-4621186-wn4q93z/index.html>

			filing with the local regulatory body.	could be reduced by as much as 6 months.
	Distribution	Pricing control strategies in the supply chain will be essential to minimize pricing distortions and enable access to medicines efforts	Takeda are working with their distribution partners to ensure products are made available at the best price to the patient	Takeda will include a clause in contracting with distributors, to ensure they work together to strive towards maximising access to Takeda products.
	Sales/Marketing	Finding a single distribution partner that could fulfill both sales and marketing and distribution	Finding a single partner who could fulfill all distribution requirements in terms maintaining cold chain, as well as sales a marketing function was not possible.	Takeda are developing a hybrid distribution model, where they have identified multiple partners to work together to fulfill and meet both the distribution and sales and marketing requirements.
	Affordability of innovative products	Takeda's innovative specialty medicines are sold at a price that most people in the Kenyan market are unable to afford.	A patient Assistance Program has been developed, whereby the costs of treatment is shared between the National Insurer, the patient and Takeda, thereby ensuring the patient is able to complete their full course of treatment, even if they cannot afford it in full.	A PAP for Adcetris has been piloted in two not for profit private hospitals in Kenya and following a successful pilot, they are now being expanded to local public hospitals. This is expected to be complete by quarter 2 of 2019.

### 1.4.5. Investigation plan for the future

#### Medicine access strategy: Diabetes and hypertension

As key pillars of the strategy, Takeda need to further investigate the following:

- Affordability
  - Pricing model options:
    - Lowest sustainable price to maximise access– e.g. set price of essential medicines at the lowest sustainable price (above cost of manufacturing if this is the price that maximises access/affordability.)
    - Two-tier pricing strategy to maximise access – e.g. set a single price above cost and use profits from the sale to middle and upper income levels to subsidise medicines to BOP patients.

The results of the BOP business survey suggest that by offering medicines at the lowest sustainable price does not guarantee maximum access, and for this reason the two-tier pricing strategy may be more effective in maximising access. This needs to be modelled accounting for a number of additional criteria including potential demand etc.

- Access and Availability
  - Private vs public
    - Identify opportunities to collaborate with both public and private facilities and distributors to reduce their margins
    - Develop an engagement strategy for sales to the public sector (e.g. collaboration with KEMSA and MEDS for wider coverage and find opportunities to access government funding)
    - Develop a strategy for selling to the private market (i.e. to reach upper / middle income segments, to potentially subsidise the BOP)
- Capacity-building
  - Training, education and awareness: continue to identify opportunities to support hypertension and diabetes professional capacitation programs
  - Supply chain support: consider supporting in-country supply chain efficiency projects

#### Medicine access strategy: Oncology

When looking into the various initiatives across the cancer care continuum, it is clear that pharmaceutical companies share an opportunity to address all levels of health service across the cancer care continuum since no company addresses all stages of the care continuum and value chain (See Figure 12 エラー! 参照元が見つかりません。 ).

Effective cancer management requires a sequence of health services, referred to as "the cancer continuum of care", and the care continuum starts with raising awareness and education. It continues with prevention, screening, diagnosis, pricing, treatment and ends with pain management / palliative care.

No one company addresses all stages, but many pharmaceutical companies address multiple stages of the cancer care continuum. Takeda has cancer initiatives around training, diagnosis, pricing, product distribution, treatment and pain management / palliative care.

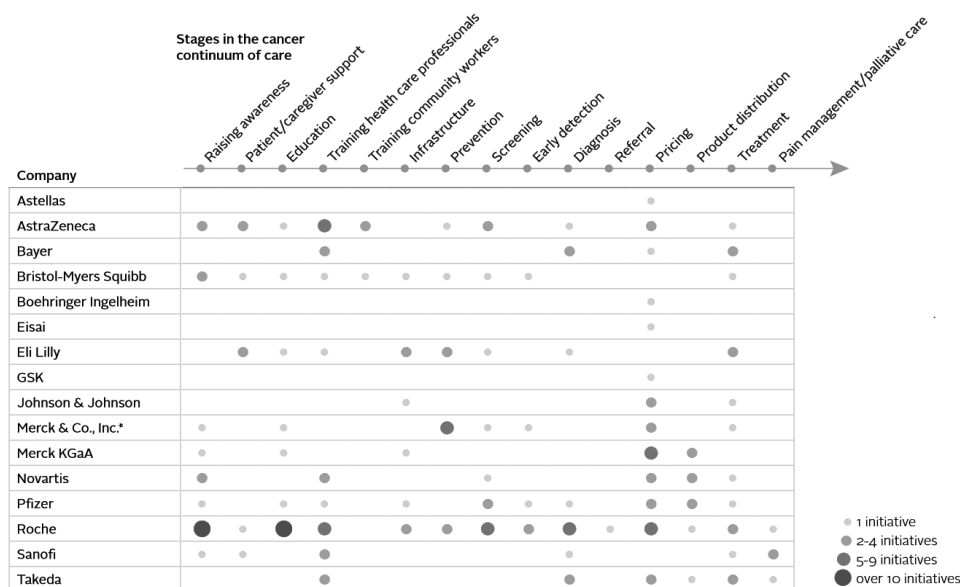


Figure 12: Pharmaceutical company initiatives across the cancer care continuum<sup>18</sup>

With regards to sustainable pricing, Takeda is considering various pricing initiatives. The key assumptions linked to this are:

1. Oncology medicines treat an acute condition over a limited number of cycles and the patient would not have to continue to bear the monthly cost for the rest of his/her life
2. The mortality rate of cancer makes patients less price sensitive
  - As key pillars of the strategy, Takeda need to further investigate the following:
    - Affordability
      - Pricing model options:
        - Patient Assistance programs: A patient pays what they are able to afford for the purchase of higher-cost, patented medicines that have no generic equivalents or close therapeutic substitutes
        - Price-volume deals on higher-cost innovative medicines with government, such as a / other multinational pharmaceutical companies 50-50 deal on Herceptin (trastuzumab) (this has reportedly stalled) ,
        - Lowest sustainable price to maximise access– e.g. set price of essential medicines at the lowest sustainable price (above cost of manufacturing if this is the price that maximises access/affordability.)
        - Two-tier pricing strategy to maximise access – e.g. set a single price above cost, at a level that maximises affordability. The idea would be to plough profits generated back into donor/philanthropic programs in the lower part of the pyramid to maximise access
          - Recommendation for an engagement strategy with NHIF, first to ensure Takeda medicines, e.g. Leuprorelin (leuprolide acetate) , are on the authorized list of treatments
          - Secondly, to support NHIF’s registration drive (will increase volume of diagnosed cancer patients getting support from NHIF)
    - Access and Availability
      - Identify opportunities to distribute the medicine via public hospitals in order to reach patients at the lowest income level.

<sup>18</sup> Improving access to cancer care (2017), [https://accessmedicinefoundation.org/media/atmf/Access-to-Medicine-Foundation\\_Cancer-care-study\\_22May2017.pdf](https://accessmedicinefoundation.org/media/atmf/Access-to-Medicine-Foundation_Cancer-care-study_22May2017.pdf)



- Identify opportunities to work with the private not for profit hospitals to help relieve the pressure from public hospitals and so should be included in the patient assistance programme
- Capacity-building
  - Training, education and awareness: Continue to identify opportunities to support oncology professional capacitation programs

Takeda will need to continue to evaluate the sustainability and effectiveness of each of the programs being delivered on an ongoing basis. In addition to managing the P&L, Takeda will need to monitor and audit all partners supporting this business model, to ensure their effectiveness in supporting this program.

## 2. Detailed Investigation Results

### 2.1. Investigation on macro environment

#### 2.1.1. Political / economic status

##### Political

The Republic of Kenya is located in East Africa, and it covers a surface area of 580 367km<sup>19</sup>. Kenya's population is estimated to be over 50.7 million (2018) with an annual growth rate of 2.52%. The population is spread across 47 counties, and it is the 140<sup>th</sup> most densely populated country in the world with a population density of 87.8 people/Km<sup>20</sup>. The Kenyan population living in rural and urban areas is 73.9% and 26.1% respectively, with an urban population growth of 4.2% annually<sup>2, 19</sup>. The five most populated cities in 2018 were [in order of population size] Nairobi, Mombasa, Nakuru, Kisumu and Eldoret.

Since 2014, Kenya has been ranked as a lower middle income country (LMIC) because the Gross National Income (GNI) crossed the World Bank threshold of \$1 045<sup>21, 22</sup>. In 2017, Kenya's Gross Domestic Product (GDP) in Kenya was \$74.94 billion, which has grown significantly since 1994 (CAGR of 10.8%). The GDP per capita in 2017 was \$1 507.81, which is just below the average Sub-Saharan GDP per capita which was \$1 553.775<sup>23</sup>. The government has initiated a broad range of business reforms including the areas of starting a business, obtaining access to electricity, registering property, protecting minority investors and streamlining insolvency rules<sup>24</sup>.

Kenya is also experiencing one of the fastest rises in Foreign Direct Investment in Africa (47% increase since 2015)<sup>24</sup>. Most of the foreign organizations' investments are in the energy sector; 24% of the total investment consists of mineral fuels, oils and distillation products. 2.7% of the total foreign investment consists of pharmaceutical products<sup>25</sup>.

In December 2017 President Kenyatta said that his administration would focus on food security, affordable housing, manufacturing and affordable healthcare as key pillars during his second term in office<sup>26</sup>. These pillars are listed in Table 3. Regarding healthcare, the ambition is to gradually increase the budget allocation to health from 7% in 2017 to 10% in 2022; and to implement Legal reforms to align NHIF to Universal Health Coverage (UHC).

<sup>19</sup> World Population Review, 2018. Available at <http://worldpopulationreview.com/countries/kenya-population/>

<sup>20</sup> World Bank, 2018. Available at <https://data.worldbank.org/country/kenya?view=chart>

<sup>21</sup> Kenya Economic Profile 2018 (Index Mundi)

<sup>22</sup> <http://www.worldbank.org/en/news/press-release/2014/07/24/kyrgyz-republic-becomes-lower-middle-income-country>

<sup>23</sup> World Bank, 2018. Available at <https://data.worldbank.org/country/kenya?view=chart>

<sup>24</sup> Export Gov

<sup>25</sup> <https://tradingeconomics.com/kenya/imports-by-category>

<sup>26</sup> <http://www.president.go.ke/>

Table 3: President Kenyata's "Big Four" topics (201)<sup>19</sup>

<b>City</b>	<b>County</b>
Universal Health Coverage	100% of Kenyan population is covered by National Hospital Insurance Funds, by 2021
Food security and nutrition	Decrease the cost of food as a percentage of income from 47% (2017) to 25% (2022)
Affordable Housing	Construct 500 000 new affordable homes
Enhancing manufacturing	Growth of the manufacturing GDP by 2022 from 9.2% to 20% of total GDP

## Socio-economic profile

The World Bank defines extreme poverty as living on less than US\$1.90 (approx. KSh200 or 223 yen) per day and moderate poverty as less than \$3.10 (approx. KSh330 or 367 yen) a day<sup>27</sup>. In 2015, 36.8% of the Kenyan population was living on US\$1.90 or less, and 66.2% on less than US\$3.20<sup>28</sup>. Poverty is highest in the north but most severe in the coastal areas.

The Gini-coefficient is a measure of statistical dispersion intended to represent the income or wealth distribution of the population of a country, and is the most commonly used measurement of inequality. The Gini-coefficient map of Kenya illustrates the inequality of counties in Kenya where 0 represents complete equality and 1 represents complete inequality (see Figure 13). Whilst income distribution in Kenya has become more equal since 1992, there is still a high level of inequality across the country with lowest income/expenditure inequality in the northern regions of the country and the highest along the coast<sup>29</sup>.

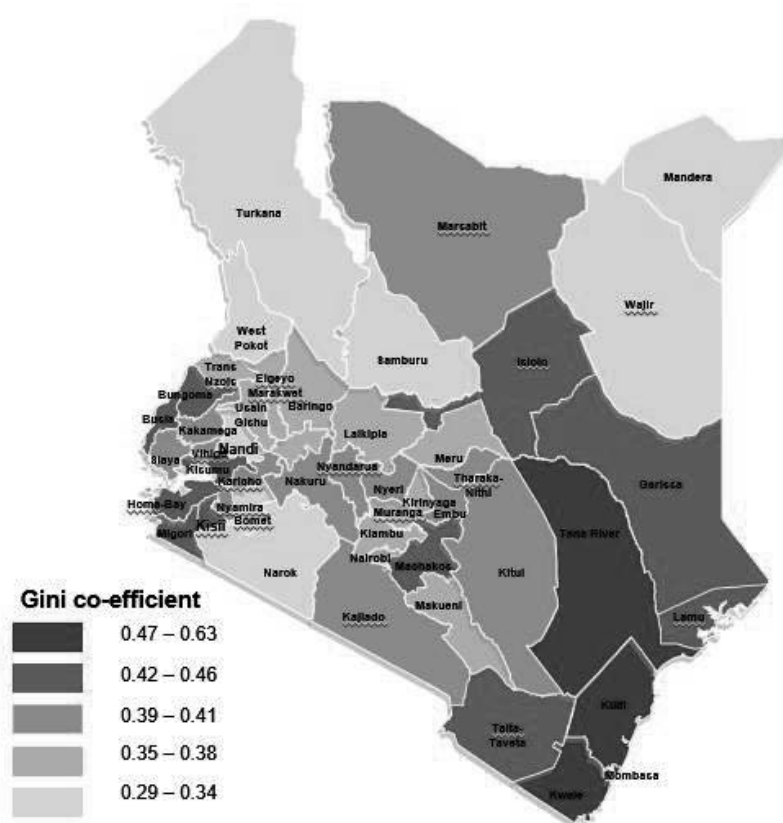


Figure 13: Kenyan inequality expressed through Gini Coefficient ratios per county (2013)<sup>29</sup>

Approximately one third of households (34%) sought credit or a loan in the 12 months preceding the 2015 / 2016 Kenya integrated household Budget Survey; and of that, 4% of the credit or loans were accessed in order to cover medical expenses<sup>30</sup>.

<sup>27</sup> <https://www.worldbank.org/en/topic/poverty/overview#3>

<sup>28</sup> World Bank Data Set

<sup>29</sup> Kenya National Bureau of statistics, 2013. "Exploring Kenya's Inequality, pulling apart or pooling together, National Report

<sup>30</sup> 2015/2016 Kenya integrated household Budget survey (KIHBS)

## Poverty levels

Kenya is considered to be a lower middle income country (LMIC). In 2015, 36.8% of the Kenyan population lived below the poverty line of US\$1.90 a day<sup>31</sup>; however by January 2018 14.8 million people (or 30% of the population) was living below the poverty line. And the poverty levels are predicted to continue to fall (see Figure 14).

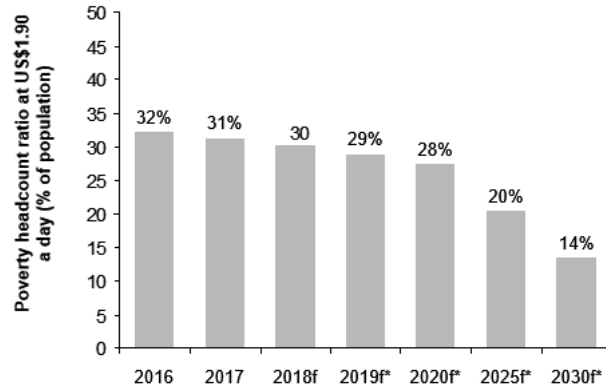


Figure 14: Poverty headcount ratio at US\$1.90 a day (% of population)<sup>32</sup>

There are large disparities in the poverty gap between the 47 counties; the population living below the poverty line in rural and urban areas is 50.5% and 33.5% respectively. Poverty in Kenya is higher in the northern and coastal parts of the country and it is low in the central and southeast regions of the country but most severe in the northern areas of Kenya.

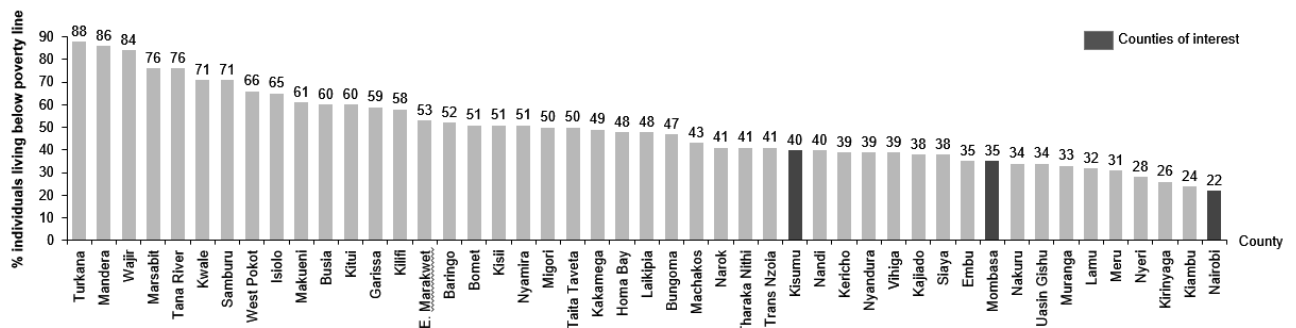


Figure 15: Percentage of individuals living below the poverty line of US\$1.90 per county (2013)<sup>33</sup>

<sup>31</sup> World Bank, 2018. Available at <https://data.worldbank.org/country/kenya?view=chart>

<sup>32</sup> World Poverty Clock: <https://worldpoverty.io/index.html>

<sup>33</sup> Kenya National Bureau of statistics, 2013. "Exploring Kenya's Inequality, pulling apart or pooling together, National Report"

## Expenditure levels

Results from the Kenya Integrated Household Budget Survey (KIHBS) survey from 2015 / 2016<sup>30</sup> shows that expenditure distribution in the country is very unequal, with the average monthly total consumption expenditure of the richest 10% of the population exceeding the combined average monthly expenditure of 50% of population. The poorest 10% of Kenya's population spend, on average, Ksh 1 591.64 (approx. 1 772 yen) per month. Ksh 1 123.50 or approx. 1250 yen (70.6%) of their total monthly expenditure is allocated to food; compared to the richest 10% of the population who spend an average of Ksh 19 767.32 (approx. 21 997 yen) per month and allocate Ksh 10 186.98 or approx. 11 336 yen (51.5%) of this expenditure to food.

In Kenya, average monthly expenditure per adult equivalent is Ksh 7 811 (approx. 8 692 yen); 54.3% of this expenditure (Ksh 4 239 or approx. 4 717 yen) is allocated toward food, and the remaining 45.7% (Ksh 3 572 or approx. 3975 yen) is allocated toward non-food items.

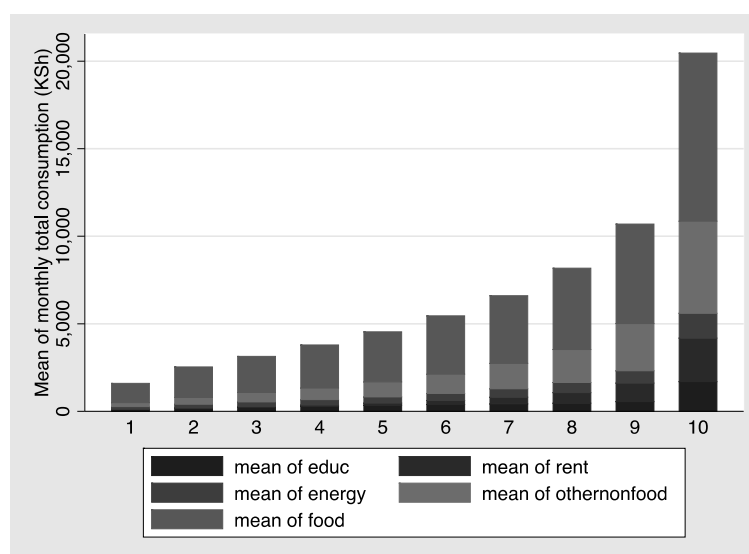


Figure 16: Composition of monthly per adult equivalent expenditure by income decile in Kenya

## **2.1.2. Legal system and healthcare related regulations**

### Legal system

The Constitution of Kenya, 2010 created a decentralized system of government wherein two of the three arms of government; namely the Legislature and the Executive are devolved to the 47 Political and Administrative Counties<sup>34</sup>. The constitutional mandate of the Ministry of Health (MOH) includes the development of public health policy; The Ministry, under the control of the Cabinet Secretary, is conferred legislative powers and control of six operating departments and various operational subdivisions<sup>35</sup> (see Figure 17).

### Healthcare related regulations

The Health Policy 2014 to 2030, developed by the National MOH, aims to achieve improvement in overall status of health in Kenya in line with the Vision 2030 objectives<sup>36</sup>. The role of the National MoH is anchored in policy development and the management of national health facilities, while that of

<sup>34</sup> Kenyan Government Website, <http://mygov.go.ke>

<sup>35</sup> Kenya Ministry of Health, [http://www.health.go.ke/?page\\_id=134](http://www.health.go.ke/?page_id=134)

<sup>36</sup> Kenya Health Policy 2014 – 2030; Kenya Ministry of Health

the County Departments of Health is focused on the administration and service delivery at a more localized level<sup>37</sup>.

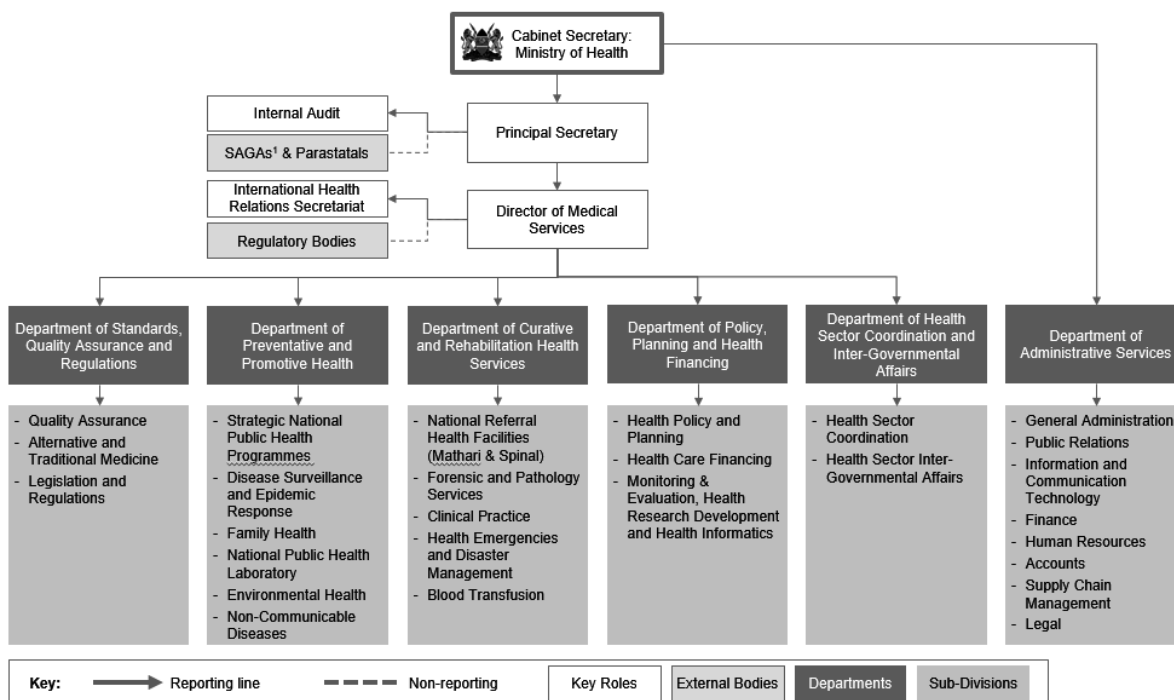


Figure 17: Ministry of Health organizational structure and operating divisions

The Pharmacy and Poisons Board (PPB) is the Medicine Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the practice of pharmacy, and manufacture and trade in medicines and poisons. The PPB is tasked to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for all medicines, chemical substances and medical devices, locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the laws regulating medicines in force in Kenya<sup>38</sup>.

<sup>37</sup> "Devolution and the Health System in Kenya", Devolution and Health Consultative Meeting Presentation, Oct 2012; [https://www.healthpolicyproject.com/ns/docs/Kenya\\_Kipchumba\\_Presentation.pdf](https://www.healthpolicyproject.com/ns/docs/Kenya_Kipchumba_Presentation.pdf)

<sup>38</sup> <https://www.pharmacyboardkenya.org/about-us>

### 2.1.3. Status of development and of infrastructure related facilities

#### General infrastructure related facilities

Kenya has performed well in the past decade in terms of improving its infrastructure (see Table 4). The country is currently focused on making improvements to its infrastructure to create a modern and efficient transport system for within the country and between other countries. In addition, and various national electrification projects have been undertaken recently and Kenya is one of the fastest countries to increase access to electricity.

Table 4: Kenya's infrastructure and access indicators<sup>39,40,41</sup>

<b>Infrastructure Indicators</b>	<b>Value 1 to 7 (best)</b>	<b>Rank x/137</b>	<b>Access indicators</b>	
<b>Infrastructure</b>			Access to electricity (% population)	73 (end of April '18)
Quality of overall infrastructure rank	4.3	56	Access to water (% population)	85
Quality of roads	4.3	60	Mobile users (% population)	81.3
Quality of railroad infrastructure	3.2	56	Internet users (% population)	26
Quality of port infrastructure	4.5	55		
Quality of air transport infrastructure	4.9	47		
<b>Electricity &amp; telephony infrastructure</b>				
Quality of electricity supply	4.1	94		

#### Healthcare related facilities

The health service delivery system in Kenya is organized across six levels of care, beginning at the community level (Level 1) and continuing all the way to the national referral health services (Level 6)<sup>42</sup> – see Figure 18.

<sup>39</sup> World Bank, 2018. Available at <https://data.worldbank.org/country/kenya?view=chart>

<sup>40</sup> World Economic Forum, 2018. "Global Competitiveness Report"

<sup>41</sup> <https://www.capitalfm.co.ke/business/2018/05/kenya-has-highest-access-to-electricity-in-east-africa-wb-research/>

<sup>42</sup> Kenya Health Service Referral Implementation Guidelines

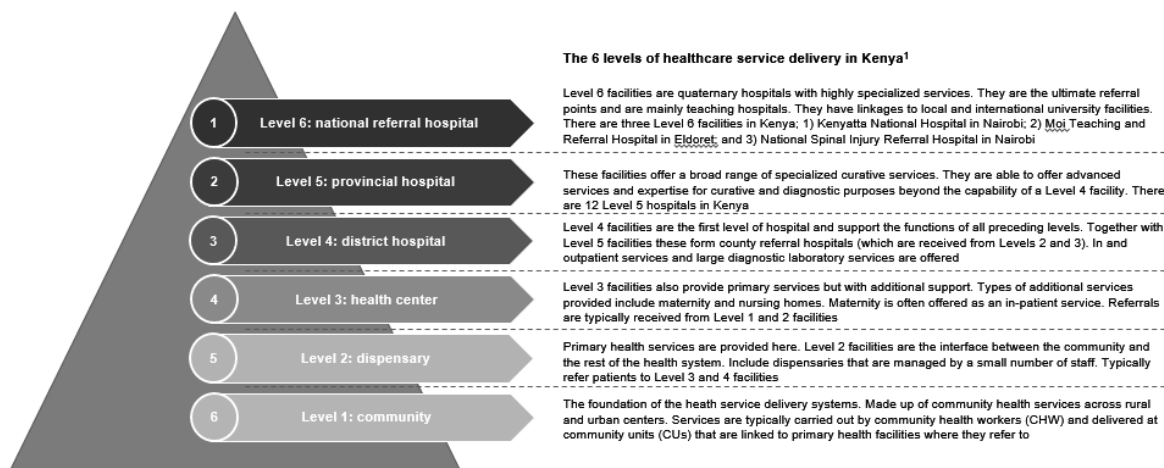


Figure 18: The six levels of health care service delivery in Kenya indicators

Kenya has a wide range of health facilities operated by the Government, Faith-based Organizations (FBOs), Non-Governmental Organizations (NGOs), international organizations and private sector<sup>43</sup>. Rural counties have very few health facilities compared to the more urban counties and Nairobi has the highest number of healthcare facilities<sup>44</sup> (see Figure 19).

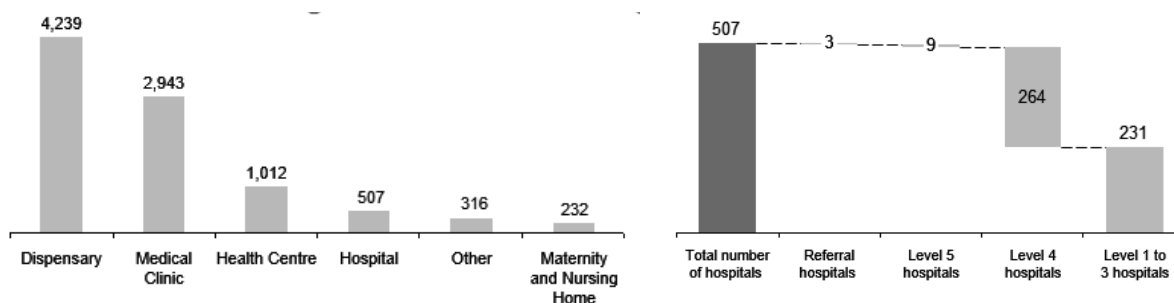


Figure 19: Distribution of facilities by type and level

The number of healthcare facilities is unevenly distributed across the 47 counties in Kenya.

Private hospital groups in Kenya have embarked on developing more capacity, particularly in non-communicable disease specialties such as cardiology and oncology and vary on their specialist facilities, diversity of services, size and geographical footprint<sup>45,46</sup>.

### Healthcare system challenges

**Healthcare facilities** - According to the WHO there should be two healthcare facilities for every 10 000 people. Based on this ratio, Kenya has sufficient healthcare facilities to support the Kenyan population. However, there is a disproportionate distribution of facilities between the counties. Those counties with a lower ratio of healthcare facilities results in patients having to travel further distances to reach their nearest facility (ranges between 20.2% and 87.5%)<sup>47</sup>

**Healthcare workers** - There is a reported shortage of healthcare workers – Kenya has 13 healthcare workers per 10 000 people which is below the ratio recommended by the WHO. According to this ratio, there should be 23 healthcare workers per 10 000 people for the healthcare system to function

<sup>43</sup> Kenyan Healthcare Sector Opportunities for the Dutch Life Sciences & Health Sector, 2016

<sup>44</sup> Health Sector, Human Resources Strategy 2014-2018

<sup>45</sup> Moi Teaching and Referral Hospital falls under the public care system, but has capacitation of varied specialist facilities

<sup>46</sup> Company Websites

<sup>47</sup> Kenya Service Availability and Readiness Assessment Mapping (SARAM) 2013



optimally. The number of physicians per 1 000 Kenyans is also too low. In addition, healthcare workers have historically focused on the treatment of communicable diseases, and there is a need to upskill them to diagnose and treat NCDs<sup>48</sup>.

Health product and equipment scarcity - There is a reported shortage in health products supply in most healthcare facilities, particularly in rural areas. There is a limited variety in medicine provision, and generics are more prevalent. There is a shortage in the availability and supply of essential medical equipment such as cryotherapy machines, pathology and laboratory equipment to screen and diagnose NCDs<sup>47</sup>.

Social and cultural factors - Traditional medicine is still commonly used as a primary source of healthcare in Kenya. The low level of education in rural areas may also be preventing individuals from seeking medical attention, as they are unaware of NCDs. Additionally, the fear of the unknown, and the stigma surrounding disease, also prevents the population from seeking medical help<sup>49</sup>

Cost of healthcare services - Through the Abuja Declaration (2001), where African countries pledged to spend 15% of their annual budget on healthcare; Kenya currently spends between 6 and 8% of its budget on healthcare. Many people spend out-of-pocket to access healthcare treatment, and it is reported that 44% of the population does not access medical services because they cannot afford it<sup>47</sup>.

#### **2.1.4. Status of applicable disease burden (non-communicable disease)**

The burden of disease in Kenya has historically been dominated by communicable diseases such as HIV/AIDS, Malaria and TB; however in the last decade there has been an increase in the prevalence of non-communicable diseases (NCDs)<sup>50</sup>. In 2016, non-communicable diseases accounted for 27% of all deaths reported in Kenya (77 100 out of 284 000 total deaths)<sup>51</sup>.

The Kenyan Ministry of Health is focused on targeting four main NCDs – cancer, cardiovascular diseases, chronic respiratory diseases and diabetes.

- The prevalence of diabetes in adults is estimated to be 4.56% of the population, and accounts for 750,000 affected persons and 20,000 annual deaths. 14% of the Kenyan population also have impaired glucose levels which could lead to diabetes
- The number of cardiovascular disease related deaths account for 6.1% to 8% according to the NSHHP and WHO, respectively. The prevalence of hypertension has increased by 20% over the last two decades and continues to increase with 12.6 to 18% of the Kenyan adult population being affected by hypertension
- Cancer accounts for 7% (28 000) of national deaths in Kenya, with an incidence rate of 37 000 new cases yearly, with the leading causes of cancers being
  - In women: Breast, cervical and esophageal cancer
  - In men: Esophageal, prostate and Kaposi's sarcoma

Due to the low awareness and diagnostic capabilities of cancer and consequently lower reporting of cancer incidence, it is likely that 7% is an underestimation

#### **2.1.5. Status of applicable health system financing (NHIF)**

Kenya is trying to reform its healthcare system by moving away from out-of-pocket payments towards financing through the National Hospital Insurance Fund (NHIF), Private Insurance and Social Insurance and Universal Health Coverage (UHC)<sup>52</sup>. The UHC is a new health package being developed by the Government. The main focus will be on preventable and primary health care. The planned interventions (e.g. 100% immunization coverage and prevention of non-communicable diseases, particularly diabetes and hypertension) should be included in the essential health service package that should be available to all Kenyans at no further cost<sup>53</sup>

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<sup>48</sup> [http://www.who.int/hrh/fig\\_density.pdf](http://www.who.int/hrh/fig_density.pdf), August 2010

<sup>49</sup> Healthcare Utilization in the Kenyan Health System: Challenges and Opportunities, Turin, D.R. 2010

<sup>50</sup> Kenya STEPwise survey for non-communicable disease risk factors, 2015

<sup>51</sup> World Health Organization: Non-communicable Diseases (NCD) Country Profiles, 2018

<sup>52</sup> Kenya Healthcare Sector. Market Study Report: Opportunities for the Dutch Life Sciences and Health Sector. 2016

<sup>53</sup> <http://www.ipsnews.net/2018/03/accelerating-universal-health-coverage-kenya-get/>

The NHIF is Kenya's primary hospital insurer. It is a state parastatal established in 1966 under the Ministry of Health. NHIF is currently managed by NHIF Act No. 9 of 1988 which transformed NHIF from a department under the Ministry of Health to a state corporation, and its core mandate is to provide medical insurance cover to all its members and their declared dependents at NHIF approved hospitals (both private and public)<sup>54</sup>.

NHIF membership is open to all Kenyans who have attained 18 years and have a monthly income of more than Ksh 1 000 (approx. 1 113 yen), and there are two types of NHIF cover:

- A National Scheme which is for salaried employees (all formal sector / salaried employees are required to contribute to NHIF) and those on "Supa Cover"
- A Managed Scheme which is for civil servants, police and other government parastatals that have an agreement with NHIF

A Health Insurance Subsidy Programme for the Poor (HISP) has also since been established to cater to the informal sector in Kenya. In 2016 it was reported that there were 2.9 mn formal sector employees registered with NHIF, and 4 mn registered with HISP (16% of the Kenyan population)<sup>54</sup>. The NHIF originally provided inpatient insurance, and in 2015 they started to provide insurance for outpatient healthcare.

#### NHIF cover for oncology

In 2016, NHIF reviewed its benefits packages after a review of monthly contribution rates. These limits cover the full cost of the session including consultation fees, chemo-administration fees, cost of medicines, etc.:

- Radiotherapy Ksh 3 600 (approx. 4 006 yen) per session for up to 20 sessions
- Brachytherapy Fee varies from Ksh 20 000 – Ksh 40 000 (approx. 22 255 – 44 511 yen) per session for up to 2 session.
  - Usually determined on case-by-case basis
- CT Scan Ksh 8 000 (approx. 8 902 yen) per session for up to 2 sessions
- PET Scan Not yet incorporated. However, they currently sponsor selected patients to get PET scans abroad
- Chemotherapy cover
  - First line treatment: up to Ksh 25 000 (approx. 27 819 yen) per session for up to 6 sessions
  - Second line treatment: up to Ksh 150 000 (approx. 166 916 yen) per session for up to 4 sessions

There are currently 31 hospitals that have been approved by NHIF to offer oncology services, nine of which are public facilities:

- Coast Provincial General Hospital (Mombasa)
- Jaramogi Oginga Odinga Teaching and Referral Hospital (Kisumu)
- Kenyatta National Hospital (Nairobi)
- Kisii Level V Hospital (Kisii)
- Meru Teaching and Referral Hospital (Meru)
- Moi Teaching and Referral Hospital (Eldoret)
- Nyeri Provincial General Hospital (Nyeri)
- Rift Valley Provincial General Hospital (Nakuru)
- Thika Level V Hospital (Kiambu)

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<sup>54</sup> Kenya Healthcare Sector, 2016. "Market Study Report: Opportunities for the Dutch Life Sciences and Health Sector"

Table 5: Fees incurred by patients for chemotherapy per visit (over and above the cost of the medication)

Service	Public facility	Private facility
Professional fees	Ksh 300 – 600 (approx. 334 – 668 yen)	Ksh 10 000 – 15 000 (approx. 11 128 – 16 672 yen)
Lab costs	Ksh 1 000 – 2 000 (approx. 1 113 – 2 226 yen)	Ksh 6 500 – 6 700 (approx. 7 233 – 7 456 yen)
Chemo-administration fees	Ksh 500 – 600 (approx. 556 – 668 yen)	Ksh 8 950 – 11 100 (approx. 9 959 – 12 352 yen)
Consumables	Ksh 3 000 (approx. 3 338 yen)	Ksh 3 000 (approx. 3 338 yen)
Pre- and post-chemo medication	Ksh 4 500 – 12 000 (approx. 5 008 – 13 353 yen)	Ksh 4 500 – 12 000 (approx. 5 008 – 13 353 yen)
<b>Total</b>	<b>Ksh 9 300 – 18 200</b> <b>(approx. 10 349 – 20 252 yen)</b>	<b>Ksh 32 950 – 47 800</b> <b>(approx. 36 666 – 53 190 yen)</b>

#### NHIF cover for diabetes and hypertension

Unfortunately, currently there is no benefits package available for either diabetes or hypertension. NHIF has defined a package of services, but are concerned about the financial impact on the Fund of rolling these services out. They are also currently working out how to deal with co-morbidities (patients with both diabetes and hypertension)<sup>55</sup>.

<sup>55</sup> Interview with the Principal for Benefits and Claims at NHIF

### 2.1.6. Market status

Pharmaceutical companies are facing increasing pressure to expand availability and affordability of their medicines, while balancing the need to preserve incentives for innovation. As such, companies are wrestling with how to consider access earlier in the product life-cycle.

Access to medicines is a multi-faceted issue that can be defined – and approached – in a variety of ways. The approaches being deployed by pharmaceutical companies today can be categorized according to where they fall on the continuum between philanthropy and the core business (see Figure 20).

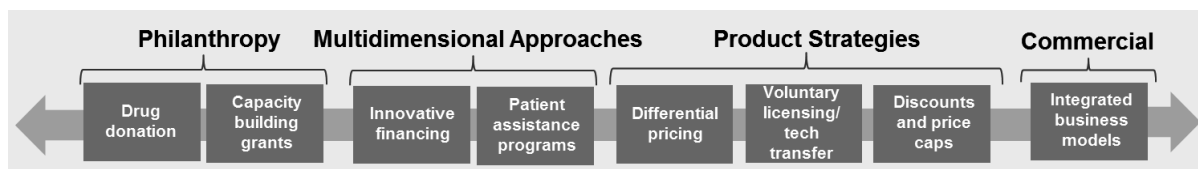


Figure 20: Access approaches

There continues to be a lot of innovation in the access to medicines arena across the continuum, with industry experimenting with diverse approaches to reach more patients. As part of this, industry are rethinking how they engage governments, providers, patient groups and stakeholders to foster environments that enable the sustainable delivery of affordable medicines and potentially life-saving products to improve health worldwide

There is also a growing interest and need to measure the outcomes and impact of access initiatives, but there has been limited movement in this area to date. Although the number of industry-led access initiatives has substantially increased few companies have rigorously evaluated access initiatives despite claims of positive impact<sup>56</sup>.

#### Market Overview:

There are a number of multinational pharmaceutical companies with originator brand presence in Kenya (see Table 6: Competitor products by disease and it is important for Takeda to consider in developing their access strategy if there are already similar products in the market and level of access to these products that is already available.

Table 6: Competitor products by disease

	Take da	GSK	Nova rtis	Pfize r	Merc k & Co.	Sano fi	Eli Lilly	John son & John son	Novo Nord isk	Gilea d
Oncology	●		●	●		●	●			
Gastro-intestinal Diseases		●								
Diabetes	●	●	●	●	●	●	●		●	
Respiratory Diseases		●	●			●		●		
Malaria		●	●	●		●				
Mental & Behavioral disorders						●	●			

56 Rockers, Peter C., et al. "Industry-Led Access-To-Medicines Initiatives In Low-And Middle-Income Countries: Strategies And Evidence." Health Affairs 36.4 (2017): 706-713. <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2016.1213>

HIV/AIDS		●			●			●		●
Nutritional Deficiencies										
Musculoskeletal Disorders		●								
Cardiovascular & Circulatory Disease	●	●		●		●				
Maternal Diseases								●		

Below are just a few examples of access programs that are already being delivered by other multinational pharmaceutical companies related to their presence in these countries:

#### **Novartis Access/Novartis Social Business**

- Offers portfolio of 15 treatments for high-burden conditions at \$1/day to governments and NGOs in low-income countries
- New business unit – Novartis Social Business – operates in six lower income countries and offers a range commercial health solutions<sup>57</sup>.

#### **Lilly’s 30x30 (30 million people by 2030)**

- 5-year, \$90 million investment in Lilly Global Health Partnership to improve access to treatment in target countries for diabetes, cancer, and TB<sup>58</sup>.

#### **AstraZeneca’s Healthy Heart Africa**

- AZ has partnered with the Ministry of Health in Kenya since inception of this signature hypertension initiative
- Approach integrates hypertension screening into existing infectious disease programming and operates in public, social franchise and faith-based facilities

Most of the companies are supporting local government initiatives in diagnosis, screening and treatment. Some examples include:

## **2.2. Investigation regarding development issues**

### **2.2.1. Status of development issues regarding region targeted for business**

#### Overview of Kenya’s burden of disease<sup>59, 60</sup>:

Kenya, similar to other countries in the region and Low Middle Income Countries (LMICs), is troubled by a double burden of disease; communicable and non-communicable diseases. However, over the last two decades Kenya has made progress in decreasing the rates of mortality and health loss.

Life expectancy has increased because Kenya has made substantial progress in reducing the burden of communicable diseases such as TB, HIV and Malaria with a 40%, 50% and 80% decrease, respectively. The increase in life expectancy has led to a shift in the burden of disease from CDs to NCDs. In the year 2013 it was reported that NCDs were responsible

57 Novartis, Corporate Responsibility Report, 2017: <https://www.novartis.com/sites/www.novartis.com/files/novartis-cr-performance-report-2017.pdf>

58 The Lilly Global Health Partnership countries include: Brazil, China, India, Kenya, Mexico, Russia, South Africa and the U.S. <https://investor.lilly.com/news-releases/news-release-details/lilly-announces-ambitious-new-commitment-expand-global-access>

59 IHME, 2016 “The Global Burden of Disease: Generating Evidence, Guiding Policy in Kenya”

60 Kenya STEPwise survey for non-communicable disease risk factors, 2015

for 30% of deaths in Kenya and over 50% of hospital admissions. The NCDs that are notable are depression, congenital heart disease, low back pain and chronic obstructive pulmonary disease (COPD) which is the reason the MoH NCD strategy is focusing on cancer, cardiovascular diseases (CVDs), chronic respiratory disease and diabetes.

The Kenyan MoH has addressed some of the gaps caused by the increase in NCDs in their healthcare systems through the provision of medicines and healthcare technologies using private public partnerships.

The Kenyan National Strategy for the Prevention and Control of Non-Communicable Diseases 2015 – 2020, seeks to address the challenges faced by Kenyans through a roadmap for stakeholders.

#### Kenya's Healthcare Challenges:

The Kenyan Healthcare system faces a number of challenges that impact the efficient delivery of adequate healthcare services and medicines to the Kenyan populations. These include:

- **Healthcare facilities:** According to the WHO there should be two healthcare facilities for every 10 000 people. Based on this ratio, Kenya has sufficient healthcare facilities to support the Kenyan population. However, there is a disproportionate distribution of number facilities between the counties. Those counties with a lower ratio of healthcare facilities results in patients having to travel further distances to reach their nearest facility (ranges between 20.2% and 87.5%)<sup>61</sup>.
- **Healthcare workers:** There is a reported shortage of healthcare workers – Kenya has 13 healthcare workers per 10 000 people which is below the ratio recommended by the WHO. According to this ratio, there should be 23 healthcare workers per 10 000 people for the healthcare system to function optimally. The number of physicians per 1 000 Kenyans is also too low. In addition, healthcare workers have historically focused on the treatment of communicable diseases, and there is a need to upskill them to diagnose and treat NCDs<sup>62</sup>.
- **Health product and equipment scarcity:** There is a reported shortage in health products supply in most healthcare facilities, particularly in rural areas. There is a limited variety in medicine provision with generics more prevalent. There is a shortage in the availability and supply of essential medical equipment such as cryotherapy machines, pathology and laboratory equipment to screen and diagnose NCDs<sup>63</sup>. Recently the MoH has embarked on a process of improving medical equipment supply across the country.
- **Social and cultural factors:** Traditional medicine is commonly used as a primary source of healthcare in Kenya. The low level of education in rural areas may also be preventing individuals from seeking medical attention, as they are unaware of NCDs. Additionally, the fear of the unknown, and the stigma surrounding disease, also prevents the population from seeking medical help<sup>64</sup>.

#### **2.2.2. Detection scenario of development effectiveness via business**

Takeda shares the view that access to medicine and quality healthcare is a vital part of the right to health; and improving health outcomes across the world is one of the key measures of human development. Awareness, diagnosis, affordability and accessibility have been identified as key barriers to health care and treatment in Kenya.

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61 Kenya Service Availability and Readiness Assessment Mapping (SARAM) 2013

62 [http://www.who.int/hrh/fig\\_density.pdf](http://www.who.int/hrh/fig_density.pdf), August 2010

63 Kenya Service Availability and Readiness Assessment Mapping (SARAM) 2013

64 Healthcare Utilisation in the Kenyan Health System: Challenges and Opportunities, Turin, D.R. 20101

A new impact framework approach will be delivered which is more comprehensive, and explicitly supports gap analysis and program design, to ensure that access programs understand the current context and their impact on health system capacities as well as patient experience and outcomes. This approach can be applied at program, portfolio, and industry levels

Each initiative to be launched in Kenya will be measured across short, medium and long terms Indices and other target values for detection of development effectiveness. These include but are not limited to:

Short Term Outcomes (0 – 3 Years):

- Changes in knowledge, attitudes, skill of healthcare workers

The idea behind including some of these indicators is to show that by having a more knowledgeable HCP that you are able to diagnose patients sooner, treat them sooner, etc.

- Health provider knowledge - Percentage of providers that pass the assessment examining their skills or knowledge
- Community knowledge - Percent of target community members who indicate their knowledge or awareness of a certain disease-specific topic
- Early referrals to treatment - Number of referrals to treatment
- Increased treatment initiation - Ratio of patients screened to patients treated
- Increased disease identification - Incidence of disease (in local area)
- Patients properly diagnosed - Median time between first symptoms and diagnosis
- Patients properly diagnosed - Correctly diagnosed disease

Medium Term Outcomes (4-6 years):

- Changes in behavior, procedures, practices, policies
  - Health service utilization (patient indicator) - Percent of population accessing health services for specific disease at least once per year out of total population in need of services
  - Care coordination (health system indicator) - Median time between diagnosis to receiving treatment initiation
  - Patient adherence to treatment - Percentage of patients that are on treatment as prescribed by their health care provider

Long Term Outcomes (also described as meaningful change or “Impact”):

- Changes in social, economic, health, environmental factors
  - Patient survival • atient survival , economic, health, enviro
  - Quality of life (patient indicator) environmental factors “Impact
  - Population health atient indicator) environmental factors “Impact”
- Timeframe: 7-10 years

## **2.3. Value chain investigation**

### **2.3.1. Investigation results regarding procurement**

The national procurement system is still tender-based. The procurement phase of the supply chain involves a number of varying stakeholders at any given point including International Donor Agencies (IDAs). Key stakeholders in this phase include, but are not limited to: the manufacturer, prospective patient, healthcare service provider and sales agents. Kenya’s regulatory framework covers the

activities of these stakeholders via a number of key regulations created and monitored by the Pharmacy and Poisons Board.

Before devolution (statutory delegation of powers from the central government of a sovereign state to government at a sub-national level, such as a regional or local level) of the healthcare system in Kenya, medicines procurement was handled at a national level – hospitals would send their orders to the Ministry of Health (MoH), and once procured they would be distributed to the hospitals. The MoH was responsible for the payment of suppliers. After devolution, this responsibility moved to the county governments. National government allocates funds to the counties who are then responsible for the running of all services in the county, including health. As a result, there are different priorities, budgeting levels and processes for the purchasing of medicines, and as such the availability of medicines differs between counties.

The public and private not-for profit supply chains are controlled by two players, namely KEMSA and MEDS. They are responsible for the procurement, warehousing and distribution of pharmaceutical products for the government and donor partners, respectively. The counties procure medicines mainly through Kenya Medical Supplies Agency (KEMSA) market. Counties are however no longer obliged to source from the government-run KEMSA and can source from other areas they deem to be superior.

This has opened an avenue for corruption, mismanagement and perennial scarcity of drugs at health facilities. This compromises not just the list of essential medicines, as provided by the Ministry of Health, but also the quality of the medication procured.

In addition to this, there are no regulations for the pricing of medicines in Kenya and although prices are monitored for retail patient pricing in public, private and faith based facilities, there is also no legal obligation for medicine price information to be publicly accessible.

### 2.3.2. Investigation results regarding manufacturing

Takeda is not currently considering manufacturing any medicines in Kenya, and therefore, no investigation was made into the pharmaceutical manufacturing environment in Kenya.

### 2.3.3. Investigation results regarding distribution

The entry and distribution of medical products in Kenya is controlled by the public, private for profit and non-profit stakeholders – See Figure 21.

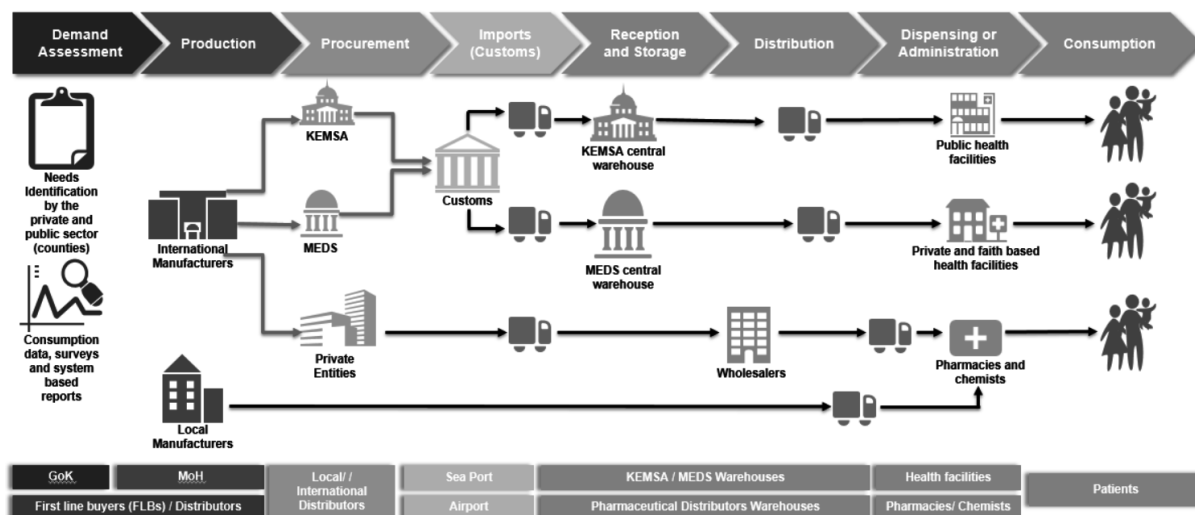


Figure 21: Pharmaceutical supply chain in Kenya

The public and private not-for profit supply chains are controlled by two players (KEMSA and MEDS). They are responsible for the procurement, warehousing and distribution of pharmaceutical products for government and donor partners.



KEMSA is the sole public sector supplier of pharmaceuticals and it is considered a public sector authority, and distributes products to over 4,000 public sector facilities. The KEMSA supply chain system, used to be based on a push model (medicines are delivered as part of an “essential package” and not need) and it has now been changed to a pull model in most regions. The counties request the medicines they need and KEMSA supplies through one of their nine regional depots. The transportation of medical supplies from KEMSA warehouses to public facilities occurs through courier services from the private sector. KEMSA and MEDS also supply commercial health facilities as part of the strategy to help reduce the cost of pharmaceuticals at these facilities – this is achieved by them leveraging the bulk order discounts that they get from manufacturers and importers.

### 2.3.4. Investigation results regarding sales/marketing

A number of key factors on how patients access medicines were identified during the field research, and these will be incorporated into improvements from the current sales and marketing in the next phase of the business case development.

Hypertension was the most prevalent disease with 21% of patients being treated for a combination of one or more of the diseases, and more than half (71%) of survey patients sought treatment from public healthcare facilities. Patients seeking treatment in public health facilities were particularly high amongst cancer patients (see Figure 22). 64% of patients reported that they did not receive any or all of their medication at the facility where they received healthcare services; the main reason patients did not obtain medication at their usual facility was due to medicine unavailability.

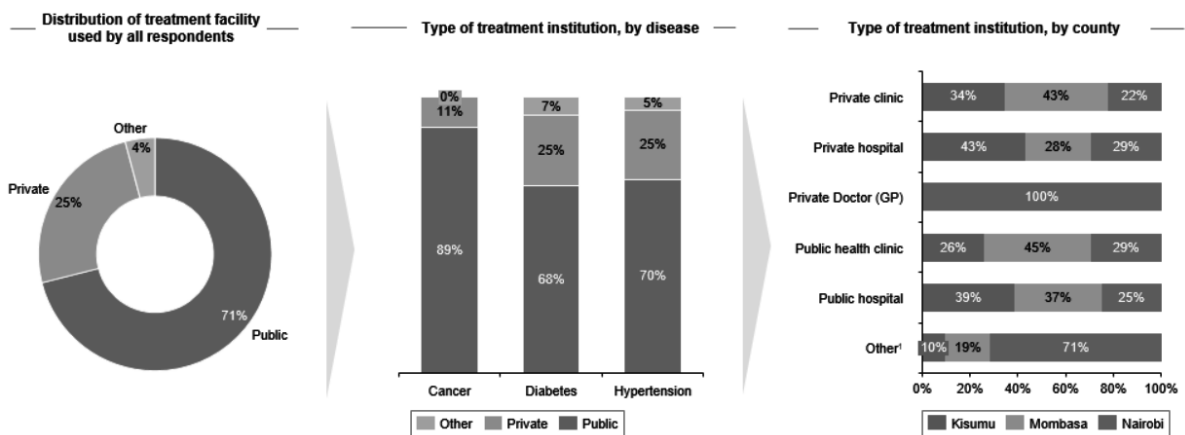


Figure 22: Where patients sought medical treatment

## 2.4. Formulation of project plan

### 2.4.1. Business model targeted for commercialization

The targeted business model for Kenya will be to offer both innovative specialty care products and primary care medicines. The strategy is to create a sustainable business model, in which the work Takeda do around Access to Medicines (AtM) will be supported by an income stream derived from two elements: modest contributions made by patients who are able to pay part or all of the cost of the innovative specialty (oncology) and primary (diabetes and hypertension) treatments provided as part of AtM. A new business model will also be created in Kenya in which Takeda will provide non AtM / non-essential medicines on a normal commercial basis, to help further support the sustainability of the business model in Kenya.

Many essential specialty and primary medicines are inaccessible to patients in Kenya due to cost. Takeda intends to improve this situation through medicines access pricing initiatives, including:

<p><b>1) Patient Assistance Program for essential <u>innovative speciality oncology</u> medicines*</b></p> <p>A patient pays what they are able to afford for the purchase of higher-cost, patented medicines that have no generic equivalents or close therapeutic substitutes</p>	<p><b>2) Lowest sustainable pricing strategy for <u>established oncology medicines</u> *</b></p> <p>Set the price of these essential medicines at the lowest sustainable price (above cost of manufacturing if this is the price that maximises access / affordability.)</p> <ul style="list-style-type: none"> <li>• Zero-profit pricing models on selected essential medicines to maximise access</li> <li>• Agree with retailers/ wholesalers/ and/ or government to limit their mark-up fee</li> </ul> <p>This will allow us to fit within the National health insurance rates</p>	<p><b>3) Targeted price strategy for <u>diabetes and hypertension</u> medicines</b></p> <p>Set a single price above cost, at a level that maximises affordability. The idea would be to plough profits generated back into donor/philanthropic programs in the lower part of the pyramid to maximise access.</p>
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**Business as usual for non-access products**

A new business in Kenya, in which non-AtM / non-essential medicines will be sold on a normal commercial basis, which will help financially support AtM activities.

*\*An important consideration when assessing affordability for oncology medicines is that NHIF subsidize Ksh 25 000 or approx. 27 820 yen per cycle (for up to a maximum of six cycles per financial year) for first line cancer treatments*

*Ksh 150 000 or approx. 166 915 yen per cycle (for up to four cycles per financial year) for second line treatment.*

*Figure 23: Approaches to addressing affordability*

#### 1) **Patient Assistance Programs for innovative speciality oncology medicines:**

Takeda's Patient Assistance Programs (PAPs) will form the cornerstone of Takeda's business model for their innovative speciality oncology medicines in Kenya. The PAPs are designed to ensure that eligible appropriate patients prescribed some of Takeda's potentially life-saving oncology medicines,

are able to access them through innovative, affordability-based approaches. The PAPs will use a collaborative model where patients, Takeda, local authorities and at times, foundations, medical associations, charities and other parties, share the cost of treatment.

Takeda’s PAPs are designed to be sustainable through the use of affordability-means assessments using a validated tool designed and administered by an independent, external third-party organization. A patient’s financial situation is assessed based on an individual’s National and personal insurance cover, their income, family circumstances and other financial obligations. Patients, through their insurance or through their own personal payments, contribute based on their ability to pay.

In select cases, for patients with no affordability, and where appropriate and feasible, Takeda may also explore other potential routes available for them to access medicines included in the PAPs. The progress, effectiveness, and sustainability of the PAPs will continuously be monitored by Takeda’s local teams in Kenya as well as through the third-party who assist with means and affordability assessments of the patients.

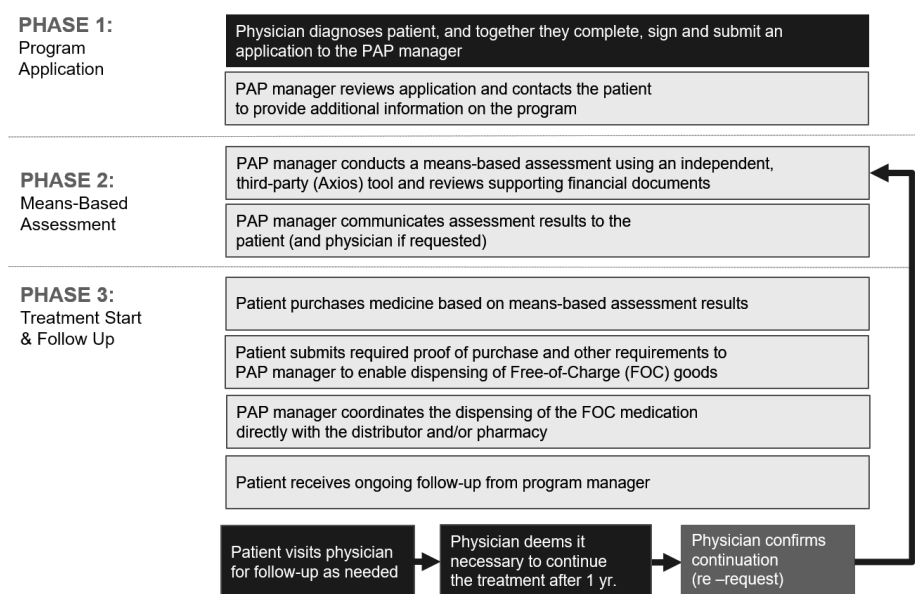


Figure 24: PAP third party model flow

Takeda’s Innovative oncology products to be included in the patient assistance program include Adcetris® and Ninlaro® for the treatment of Hodgkin Lymphoma and Multiple Myeloma. In the future, Takeda aim to include other specialty medicines if appropriate and feasible.

**2) Lowest sustainable pricing strategy for established oncology medicines :**

In addition to Takeda’s innovative speciality care oncology product portfolio, Takeda recognize the importance of making their “established” oncology products available in Kenya, including Leuprorelin (leuprolide acetate) for breast and prostate cancer. This product type, although more affordable, still remain largely inaccessible to the majority of the population in Kenya. As a result, Takeda are striving to increasing access to this product in the Kenya by setting the price of this essential medicine at the lowest sustainable price:

- Zero-profit pricing models on selected essential medicines to maximise access
- Agree with retailers/ wholesalers/ and/ or government to limit their mark-up fee

Through this approach, Leuprorelin (leuprolide acetate) as a first line treatment for breast and prostate cancer, is anticipated to be covered by NHIF for up to Ksh 25 000 (approx. 27 819 yen) per session for up to 6 sessions. By ensuring the pricing for this product is aligned within these limits, it is anticipated that anyone diagnosed and prescribed this medicine will be able to access it through this fund.

Takeda will further target listing on NHIF for re-imburement in 2021 or end of 2020 as well as possible KEMSA listing in 2021.

### 3) **Targeted price strategy for diabetes and hypertension medicines:**

Since currently there is no benefits package available for either diabetes or hypertension, the access pricing initiative for these products needed to be more considered. It became evident through this study that offering medicines at the lowest possible price, with no margin does not guarantee maximum access, and there could be alternative pricing initiatives which could realize a greater impact. For this reason Takeda will follow a targeted approach to its pricing strategy for these products. Setting a single price above cost, at a level that maximises affordability. The idea would be to plough profits generated back into donor/philanthropic programs in the lower part of the pyramid to maximise access, which would help support patients at the Bottom-of-the-pyramid (see ).

When considering product pricing, sustainability is a critical principle of any business strategy for Kenya, which is why Takeda will provide non-AtM / non-essential medicines on a normal commercial basis, which will help further support AtM activities. Putting in place initiatives that are both, operationally sustainable through local ownership, and financially sustainable, are important in ensuring the greatest health impact for patients, in the long term.

Affordability, and the provision of medicines, is however not the only access to medicines barriers that patients face. For this reason an access business model should go beyond the provision of medicines, by seek solutions for a wide range of patient access barriers – to enhance healthcare capacity, increase access to diagnosis and treatment, and address access barriers for diseases.

#### **2.4.2. Manpower requirement plan, human resource development plan**

Aligned to the business strategy, Takeda is the first Japanese headquartered pharmaceutical company to have a physical presence in Kenya (the hub for the SSA region), where they are adopting a sustainable not-for-profit approach for the region.

Because of Takeda's partnership approach in the Kenyan and SSA markets, anticipated man power requirement will be kept to a minimum. As Takeda have progressed through the course of this study, certain positions have already started to be filled, to ensure progress is maintained against the strategy. These positions include:

- Head of sub-Saharan Africa
- Regulatory Manager for SSA
- Compliance and Program Manager for SSA

One further position which is still to be recruited to complete the human resource requirements for the Takeda Kenya office is that of a medical manager. Takeda anticipate that they will have this position filled by mid-year 2019.

### 2.4.3. Fund procurement plan

Funding for the initial implementation and advancement of the Takeda Access to Medicines Strategy in Kenya will be supported internally by the AtM Office through Takeda's Growth & Emerging Markets Business Unit (GEM BU).

The financial, product and activity flow has been mapped, and Takeda's AtM office will work closely with both the manufacturing site and also the local partners on the ground to ensure a seamless product, financial and activity flow.

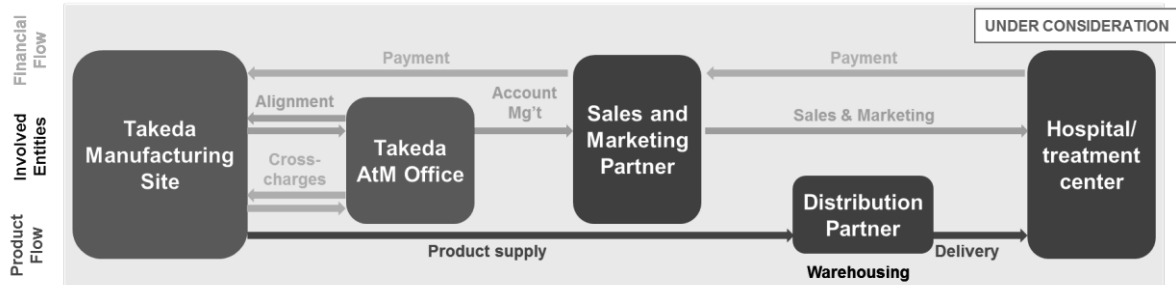


Figure 25: Financial, product and activity flow

### 2.4.4. Schedule through commercialization

Commercialization of each product is dependent on product filing and receiving Market Authorization (MA) from the Pharmacy and Poisons Board (PPB) of Kenya. Although an application has / will be made for fast track authorization on certain products being registered, receiving market authorization can still take as long as 12 to 18 months.

The Access to Medicines office in Kenya has already been established and certain staff appointed. Furthermore, Takeda has finalized the bespoke distribution model with the partners involved, and where product MA has been received, Takeda will finalise / update the pricing based on the innovative pricing access initiatives and commence with commercialization of those products.

Activity	Details	2016年				2017年				2018年				2019年				2020年				2021年			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Access to Medicine</b> Product Filing & Registration (Innovative Speciality Care)	Mepact 4mg																								
	Entyvio 300mg																								
	Adcetris 50mg																								
	Ninlaro 2.3mg, 3mg and 4mg																								
<b>Access to Medicines</b> Product Filing & Registration (Primary Care)	Leuprorelin 1M 3.75mg, 3M 11.25mg																								
	Edarbi 40mg																								
	Edarbygol																								
	Vipidia 25mg																								
	Vipdomet 12.5/1000mg																								
<b>Business as usual</b> Product filing & Registration	Xefo Rapid 8mg																								
	Xefo IV 8mg																								
	Vocinti 10mg,20mg																								
	Zafatec 100mg																								
	Pantoloc																								
	Pamntoloc IV																								
Human Resource Recruitment	Head of Sub Saharan Africa appointed																								
	Regulatory Manager appointed																								
	Program & Compliance Manager appointed																								
	Medical Manager appointed																								
Supply Chain implementation	Appoint distributor																								
	Finalise new direct route to market supply chain																								
	Finalise Cost of Goods for each product																								
	Introduce product protection																								
Finalize innovative affordability financial mechanisms	Patient Assistance Programs (PAPs) for all speciality care products																								
	Access pricing initiative for non-speciality care products																								
	Pricing for new business as usual products																								
	Update pricing for those business as usual products already registered																								

## 2.5. Possibility of collaboration with JICA business

### 2.5.1. JICA business for expected collaboration and collaboration details

Takeda met with representatives of JICA Kenya office in Nairobi on three occasions during the course of the study. The purpose of these meetings was to describe the approach and findings of the business case and for Takeda to gain an understanding of the current focus of JICA, their targeted activities in Kenya as regards healthcare, NCDs and to discuss potential opportunities for collaboration.

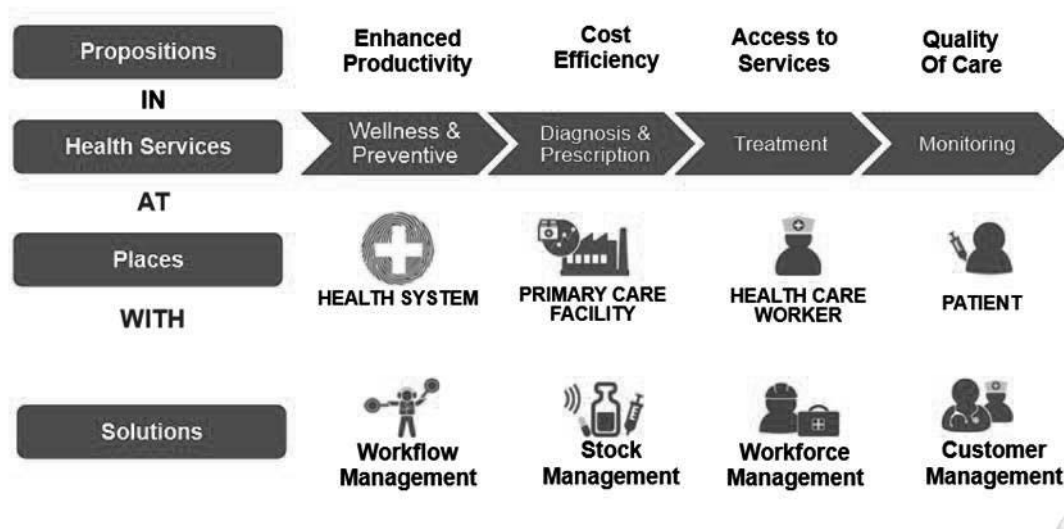
Through these meetings, Takeda learnt that globally, JICA is developing a position paper on NCDs, but this has not yet been circulated / rolled out. Locally, JICA in Kenya is focusing on three pillars - promoting structural economic transformation through economic diversification and industrialization, promoting resilient health systems for quality of life and promoting social stability for shared prosperity<sup>65</sup>. The healthcare projects largely focus on health systems strengthening (HSS) training in order to scale up training to attain a critical mass of human resources for health (HRH) towards the achievement of universal health coverage (UHC) and aligning to Government Policy for UHC.

It was further learnt that the JICA office in Kenya is supporting Amref to deliver a capacity development program focusing on Leadership, Management and Governance (LMG) for Health Systems Strengthening (HSS). The goal is to strengthen and harmonize regional training and collective learning capacity for sustainable HSS in Africa. It is implemented under the auspices of the Africa Health Leadership and Management network (AHLMN) and aimed to create a critical mass of professionals with state-of-the-art knowledge on leadership, management and governance (LMG) for HSS in Africa. This training is designed for planners; policy makers, health facility staff and program managers, newly recruited health managers, public health association managers, academics and researchers in health systems in private, public and non-governmental institutions. This would then promote sustainable health development in their respective countries across Africa.

Aligned to this project (supported by JICA), and to a Supply Chain and Stock Management initiative which Amref is implementing with the support of Takeda, Takeda is proposing to expand their Supply Chain and Stock Management project and to work with Amref and JICA to build LMG capacity within the medical supplies agency, including performance management and monitoring that are critical to achieving the success of the Organization's seamless flow of commodities. This approach will be implemented in conjunction with expert institutions to strengthen government involvement and ownership. The role of each entity is critical in ensuring a holistic approach to management of supply chain processes across health facilities in the country. In partnership with the Kenya Medical Supplies Agency (KEMSA), Amref International University (AMIU) and the Kenya School of Government (KSG), supply agency staff and county government officials will be equipped with the competencies they need to maintain effective and efficient commodity supply systems, co-ordination.

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<sup>65</sup> JICA 2017 Japan International Cooperation Agency. Annual Report Kenya Office



The future of every supply chain organization depends on developing and retaining good leaders. However, no standard supply chain leadership model exists. Research shows that supply chain leadership encompasses more than supply chain management and operation; it includes satisfying personal, professional, and organizational strategic goals and requirements. Every supply chain professional is a potential supply chain leader, whether formally—where leader is part of a position title—or informally, as it pertains to his or her job responsibilities. Takeda are proposing to embed leadership qualities in supply chain staff by improving their capacity in management of staff, commodities, relationships and resources. This will be achieved through a comprehensive training program for the Kenya Medical Supplies Agency (KEMSA) staff, county government officials directly involved in supply chain management and commodity management. The trainings will be delivered through blended approach combining face to face and eLearning training methodologies for improved learning outcomes.

Beyond JICA and Takeda, other proposed partners on this project would include:

- KEMSA**  
 Kenya Medical Supplies Authority (KEMSA) is a state corporation under the Ministry of Health established under the KEMSA Act 2013 whose mandate is to procure, warehouse and distribute medical commodities to public health facilities. KEMSA obtained ISO 9001:2008 Certification in 2010 and has subsequently successfully been re-certified every two years. KEMSA is currently on its 3rd cycle of recertification.
- Kenya School of Government (KSG)**  
 KSG is a State Corporation established to offer management training, research, consultancy and advisory services to the public sector. The School has been instrumental in setting up fast track management strategies through observance of high standards of integrity, competence, ethics and a culture of transparency whilst implementing the provisions of her mandate. Today it offers services to both National and County governments, private sector players as well as those from the Non-Governmental Organizations (NGOs). The Government recognizes the need to have a competent, well skilled and motivated workforce in the public service. The human resource must at all times have its potential developed to the maximum through effective training and capacity building. This will in turn give the Public Service the impetus necessary for it to deliver improved services to its clients and provide an enabling environment for other sectors of the economy to operate.
- Amref International University**  
 Amref International University (AMIU) is an accredited institution of higher learning focused on training in health sciences and is fully owned by Amref Health Africa. AMIU is founded



on the experience and intellect of Amref Health Africa, which is reputed with over 60 years of quality and innovative public and community health interventions, training and education. It has nurtured leaders and shaped the future of public health practice in Africa for over 40 years under its predecessor Amref International Training Centre (AITC). Amref lead the way in health sciences education with a breadth of programmes. AMIU focuses primarily on health sciences with a commitment to progressively develop innovative programmes catering to the present and future needs of African populations.

The following activities will be undertaken:

1. Advisory group set up– this activity is intended to establish a Kemsu operational and technical advisory group to support organizational development and institutionalize best practice.
2. Content Adaptation -existing content for leadership, management and governance will be adapted to the supply chain context in conjunction with subject matter experts and built into e-Learning modules that will be deployed through the content management and e-learning platform.
3. Training delivery – LMG training will be conducted for Kemsu and county staff
4. Secondment of a Technical Expert in Supply Chain Management and Delivery- Part of the ongoing support to Kemsu will be a secondment of a Technical expert to support the institution in strengthening the supply chain management for a period of 5 years.

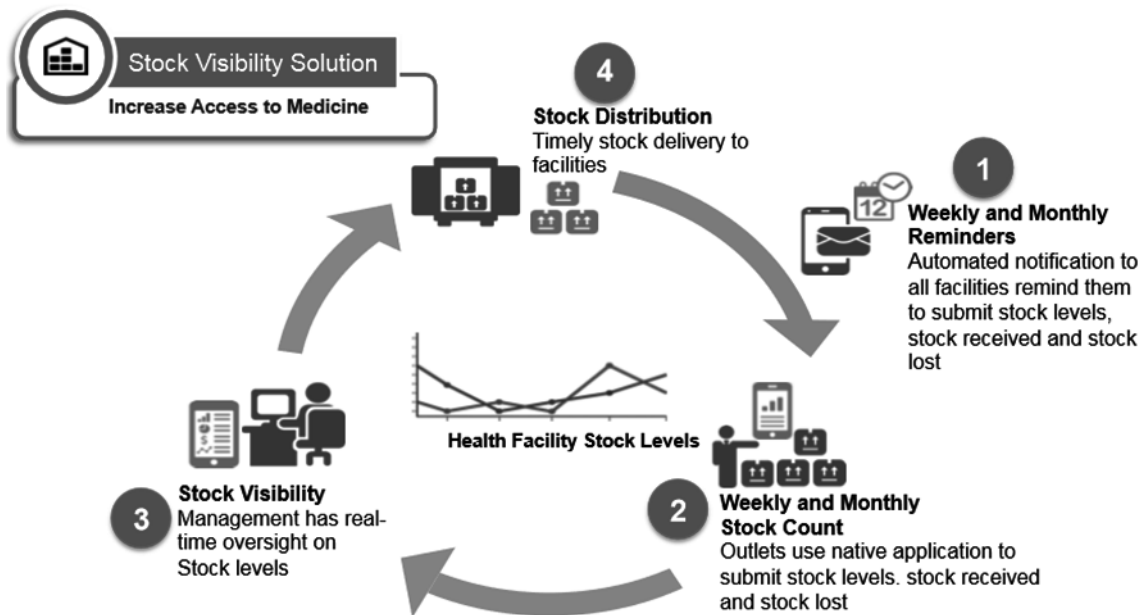
### **2.5.2.Effectiveness anticipated from collaboration and necessity of collaboration**

The stock management ecosystem is fragmented with many organisations in Kenya creating multiple platforms that address donor needs which are placed in health facilities all over the country. Lack of appropriate management skills for staff deployed to handle supply chain management, compounds these challenges, bringing lack of uniformity, regular stock-outs, overstocking of some commodities and wastage. Non-existent or poor stock control including poor forecasting are the major causes of stock outs and shortages reported in literature at the health facility level when stock is available at the central or depot level (Barrington et al., 2010). Discrepancies have been found between the reported stock levels and actual stock on hand at health facilities implying that the health workers do not follow protocols on the management of medicine stock. It is therefore important to build their capacity in this.

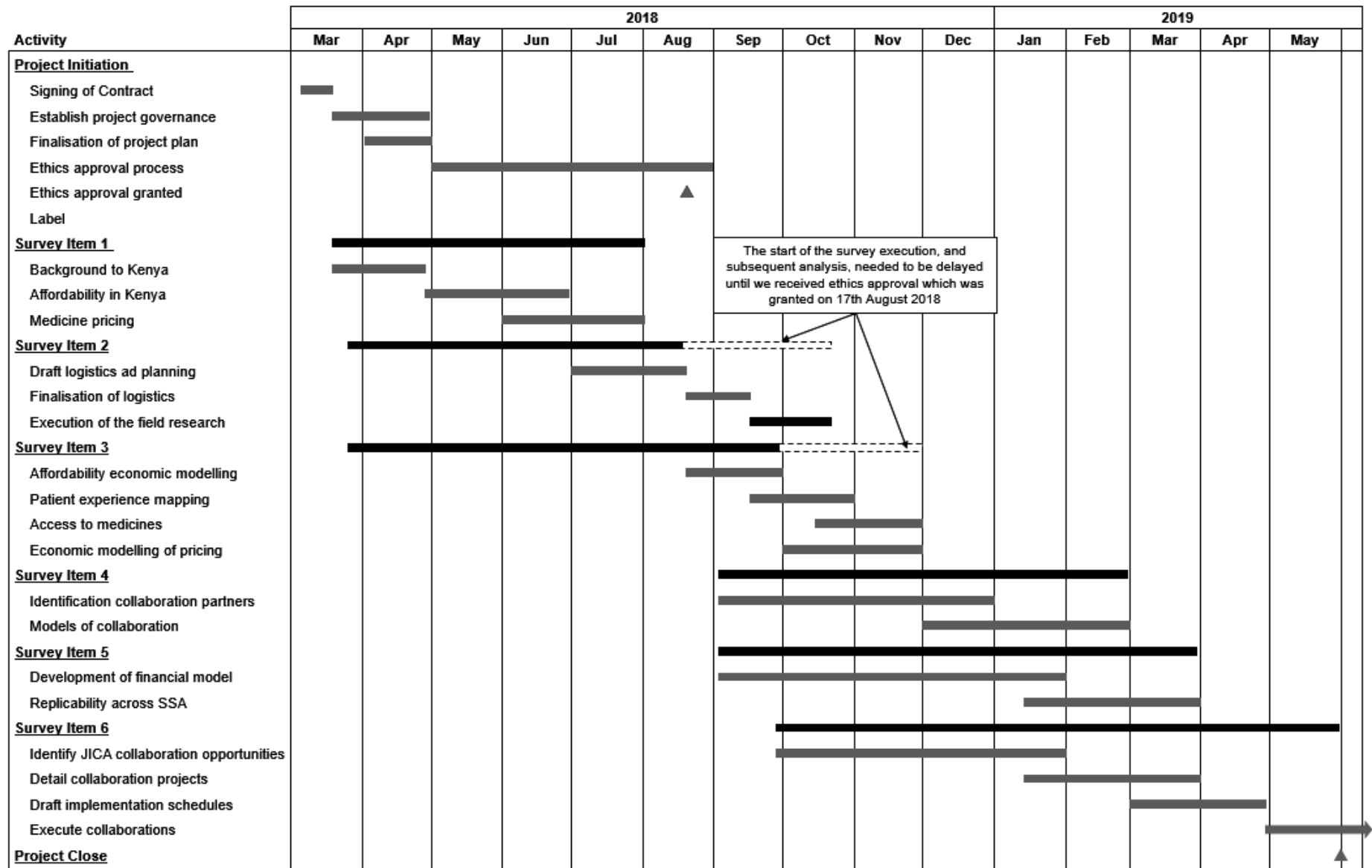
The consequences of the unavailability of medicines are widespread and can have detrimental effects on individual and public health (Barrington et al., 2010). Unplanned treatment interruptions could lead to adverse events and could eventually be fatal with a ripple effect of increased costs to the health system. Another important consequence of the unavailability of medicines to governments is the loss of confidence in public health systems by citizens (Honda et al., 2015) as well as impoverishment of patients and families when they must buy medicines from costly private providers. Research conducted confirms the supply chain challenges and lack of essential medication in lower level public health facilities such as medicines for hypertension, metformin for diabetes and other NCDs. Further, the study confirms that despite most private hospitals having anti-bacterial and anti-malaria medicines, they most likely did not have ARVs and other chronic disease medication due to shortages and supply gaps. Other study findings from the NCD screening supported by Takeda Pharmaceuticals indicated that follow-up patients identified with elevated BP was not consistent and recurrent stock outs in the public facilities is a major cause of noncompliance.

Beyond the Stock Visibility Solution depicted below, the proposed program will support the drugs supply agency in Kenya and county governments in strengthening leadership and management in the supply chain management for pharmaceutical and non-pharmaceutical commodities across health facilities in the country. This will enhance the management, co-ordination and control of commodities and ensure constant availability, limiting stock-outs, oversupply and wastage. Successful supply chains rely on strong leaders who can spur top performance from those around them. Leaders contribute their own talents, interests, styles and goals to help their respective institutions reach their full potential. Maximizing efficiency, service and managing people and relationships is an integral

part of supply chain management. This initiative will target supply chain managers at sourcing, distribution and utilization points for drugs and commodities to create a seamless flow and availability.



## Appendix A – Detailed Project Plan



## Appendix B – Comparison of Methods used to Calculate Affordability

	<b>Catastrophic<sup>66</sup></b>	<b>Impoverishment<sup>67</sup></b>	<b>Lowest Paid Government Worker (LPGW) r<sup>68</sup></b>
<b>Brief Overview</b>	The catastrophic expenditure method is based on a pre-determined threshold of household expenditure and considers at which point the price of a medication exceeds a certain proportion of a household's income causing a catastrophic impact on the ability of the household to meet other basic needs. After meeting basic needs, when out-of-pocket payment on healthcare exceeds the defined threshold, the medication is considered unaffordable.	The impoverishment method calculates the number of and the amount by which households or individuals are pushed below a pre-defined poverty line by accessing healthcare. If a household is impoverished by the procurement of the medication and / or treatment, then the medicine is deemed unaffordable.	The LPGW method assesses an individual's ability to pay by calculating how many days' wages, using the country's wage rate of the lowest paid unskilled government worker, are required to procure a particular medication / treatment. The threshold at which a medicine / treatment is deemed unaffordable is determined by local policy makers based on an understanding of average local income and the economic context.
<b>Benefits</b>	<ul style="list-style-type: none"> <li>• Takes into account the amount necessary to purchase healthcare services and medication and can have catastrophic consequences for poorest in society</li> <li>• The measures used in the catastrophic methods make it useful in making comparisons across societies and / or countries</li> </ul>	<ul style="list-style-type: none"> <li>• Multiple poverty lines can be used to gain a more accurate representation of households impoverished by OOP payments. Using one poverty line can narrow the findings, because national poverty lines are often considerably below the basic cost of living</li> <li>• The impoverishment method focuses on society's poorest individuals for whom a treatment's price point is critically important</li> </ul>	<ul style="list-style-type: none"> <li>• It is simple and straightforward to understand and apply</li> <li>• People in any country can position themselves relative to the LPGW. Essentially it allows international comparisons of price levels that are not affected as much by differences in economic structures and exchange rates (though this is still a consideration)</li> </ul>
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• Comparisons across countries (especially LMICs) and over time are difficult, due to the data intensive nature, and also because of the methodological differences in individual household surveys</li> <li>• Thresholds (percentage of income spent on OOP payments) used are subjective with no firm consensus in the literature</li> </ul>	<ul style="list-style-type: none"> <li>• Comparisons across countries are difficult due to the inconsistencies and limitations in the available data and also because of the methodological differences in individual household surveys</li> <li>• It is designed for use with aggregated data rather than individual household data, hence to ensure applicability the method requires several</li> </ul>	<ul style="list-style-type: none"> <li>• Knowing the number of daily wages the LPGW needs to pay for a course of medicines does not provide a clear indication of how many people for whom the medicine is deemed unaffordable</li> <li>• The LPGW overestimates the affordability of medicines because a substantial proportion of the population in some countries earn less than</li> </ul>

<sup>66</sup> Wagstaff A. & van Doorslaer E. 2003, "Catastrophe and impoverishment in paying for health care: with applications to Vietnam 1993-1998", Health Economics

<sup>67</sup> Niëns LM, et al. 2012, "Practical measurement of affordability: An application to medicines", Bull World Health Organ

<sup>68</sup> Niëns LM, 2014, "Affordability in health care: Operationalisations and applications in different contexts

	<p>and consequently influence the outcome of the study. This risk may be mitigated through the use of a range of thresholds</p> <ul style="list-style-type: none"> <li>• Does not consider households that postpone their healthcare for the lack of financial resources</li> <li>• Due to a lack of differentiation between rich and poor households this method does not give an adequate comparison of catastrophic expenditure i.e. a catastrophic payment for a rich household may not result in the impoverishment of that household but will be deemed catastrophic nonetheless</li> </ul>	<p>assumptions e.g. the assumption that per capita income is smoothly distributed across income groups. In reality most people in an income group are more likely to earn less than the average</p> <ul style="list-style-type: none"> <li>• For those people who are not pushed below a poverty line, but nonetheless experience a significant income drop, the pharmaceutical product or health service is not deemed unaffordable, which may impact outcomes recorded</li> </ul>	<p>the LPGW (treatments that appear relatively affordable may still be out of reach for much of the population)</p> <ul style="list-style-type: none"> <li>• Non discretionary expenditures such as food and housing are not taken into account</li> <li>• Many poor people experience seasonal fluctuations in income</li> <li>• A number of dependents may live on this wage, who themselves may require medicines, or one person may need more than one medicine for treatment of one disease</li> </ul>
Requirements	Household income and expenditure data (for food and basic needs), Defined threshold(s) and Price of medications / treatment in focus for the study	Household income and expenditure data, Country and global poverty line(s) and Price of medications / treatment in focus for the study	Country government wage data and Price of medications / treatment in focus for the study