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Assessment of effectiveness of existing oncology drug distribution model for the Kenyan market.

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ASSESSMENT OF EFFECTIVENESS OF EXISTING ONCOLOGY DRUG DISTRIBUTION MODEL FOR THE KENYAN MARKET

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DECLARATION

I declare that this work has not been previously submitted and approved for the award of a degree by this or any other University. To the best of my knowledge and belief, the dissertation contains no material previously published or written by another person except where due reference is made in the dissertation itself.

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ABSTRACT

The high mortality due to cancer in developing countries necessitates the development of drug distribution models that ensure effectiveness in delivery and pricing of oncology medication. This need is highlighted by the fact that developing countries like Kenya are most affected by cancer as indicated by the comparative proportion of deaths occurring among such countries. The main objective of the study was to examine the characteristics and effectiveness of existing oncology medicines drug distribution strategies and propose a model for expanding access in the Kenyan market. The study specifically sought to characterize existing oncology drug distribution strategies applied in Kenyan pharmaceutical industry; examine the effectiveness of the strategies based on the experiences and opinions of oncology and pharmaceutical industry experts and finally, develop a model for scaling up drug distribution for oncology medicines in the Kenyan healthcare industry. The study centred on an exploratory research design. Qualitative data was collected from three pharmaceutical firms (Novartis, Roche and Astra Zeneca), two medicines supplies organizations (the Kenya Medical Supplies Authority – KEMSA, and the Mission for Essential Drugs and Supplies – MEDS), and two hospitals serving high volumes of cancer patients (the Kenyatta National Hospital - KNH, a public hospital, and the Texas Cancer Centre – a private hospital. A total of 19 interviews were collected from the organizations. A content analysis approach, centring on transcribed interviews, was employed to address the study objectives. The main contribution of the study presents in highlighting a relatively more efficacious approach to distribution of oncological medicines to the needing population of cancer patients in Kenya. Findings point to three models as most dominant in the market – reduced wholesaler arrangement, direct sales to pharmacies and short-line wholesaling. The models were generally ineffective with respect to rapidity of delivery, continuity of supply and affordability. An ideal model is proposed following an assessment of responses suggesting the need for stakeholder engagement in the crafting of drug distribution models. Findings are of pertinence to policy makers, manufacturers, distributors, payers and patients involved in treatment in the oncology space.

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CHAPTER ONE
INTRODUCTION

The purpose of this chapter is to provide an exposition of the background of the study, to highlight the problem under consideration, and to stipulate the research objectives and questions. Discussed herein as well are the scope and significance of the study.

1.1 Background of the study

Statistics indicate that the cancer burden stood at 18.1 million cases, causing 9.6 million deaths in 2018 (World Health Organization, 2018). Of the new cases, the most common types were lung, breast and colorectal. Whereas the global trend in most cancers indicated a declining mortality rate, death rates were higher than incident rates in Africa and Asia. Reasons for the observation include limited access to diagnosis and treatment (World Health Organization, 2018). As highlighted by Kirton (2019) over 800 million individuals spend more than 10% of their monthly income on medical-related issues. Given the universal health coverage (UHC) goal of ensuring equitable access to quality health services, there is need to develop effective approaches to availing lifesaving medication for cancer.

Kumar, Juluru, Thimmaraju, Reddy and Patil (2014) defined pharmaceutical drug distribution models as comprising three main components – price, channel, and stakeholders. Notable stakeholders in the drug distribution setup include payers, patients, pharmacies, advocacy groups, physicians, and government agencies. To ensure effective access, all three aspects must be aligned. In an assessment of global trends in drug distribution, Siegal and Shah (2019) point out that there is increasing pressure to reduce spending on medication, hence payers are increasingly looking to formulary applications to improve drug distribution models. However, they noted that drug distribution models are convoluted, dynamic and ever-evolving, hence rendering the creation of effective strategies a herculean task.

In an assessment of drug distribution among developing countries vis-à-vis industrialized ones, Kumar et al., (2014) found that the models in the latter were often more defined than those in the former. Whereas the drug distribution models in industrialized nations are currently changing due to an appreciation of the value of existing treatments, pharmaceutical companies operating in low-

and middle-income countries (LMICs) struggle operating amid poorly structured regulatory systems. For that reason, companies in LMICs often focus on specific aspects of the drug distribution model, for instance, price, channels and stakeholders, in isolation. This contrasts with the approach taken in industrialized nations whereby drug distribution models are viewed as unitary systems.

Recent evidence shows that Kenya has the fastest growing pharmaceutical market in East Africa, with an estimated value of USD 740 million (Selvaraj, 2019). Yet the sector only contributes 1.2% to the national GDP (Selvaraj, 2019). As far as oncology medicines are concerned, reports suggest that the treatment cost for cervical and breast cancer may be as high as $1,500 in public facilities and more than $7,500 in the private facilities (Subramanian et al., 2017). This notwithstanding the fact that 35.6% of the population lives under the poverty line of less than USD 1.9 a day (The World Bank, 2019).

1.1.1 Drug Distribution Strategies and models

Thomas et al. (2018) define market access models as the strategies, activities and process employed by pharmaceutical companies in developing drugs, devices and technologies and making them available at affordable costs to health systems. In the current studies, the strategies are interactively considered as models that acts as conduits in the bid to avail medication to patients. It is therefore apparent that drug distribution models form a facet of market access apparatus utilized by pharmaceutical companies in availing cancer medications to patients. According to Kumar *et al.*, (2014) market access is the processes by which medication is delivered to patients in a rapid manner, made continuously available and provided at the right price. Kumar *et al.*, (2014) further posit that the concept involves a wide array of factors including – from a pharmaceutical company's perspective – regulatory, supply chain, marketing, medical, and corporate functions. It is thus apparent that market access strategies refer to processes involved in ensuring delivery of medication rapidly, continuously and inexpensively; it is this conceptualization of market strategies that is considered in assessing market access efforts employed in the distribution of medication in Kenya. The strategies therefore encapsulate regulatory, supply chain, marketing, medical and corporate operations (Kumar *et al.*, 2014). In the current studies, the strategies are interactively considered as models that acts as conduits in the bid

to avail medication to patients. The specific models considered are – Short-line wholesaling, Direct sales from manufacturers, Reduced Wholesale Arrangements (RWA), Direct to Pharmacy (DTP) arrangements (Walter, Dragosits and Said , 2012).

1.1.2 Effectiveness of market access strategies

The effectiveness of drug distribution strategies, as defined in the foregoing sections, is primarily assessed on account of the strategies' ability to avail mediation to patients in a rapid, continuous and inexpensive manner. Two billion people globally lack access to essential medication. A major contributor, as posited by Lee and Hunt (2012), is ineffectiveness of the current medicines supply strategies, and particularly so as is the case in developing countries. In the current study, the effectiveness of the drug distribution strategies is to be assessed in light of the regulatory, supply chain, marketing, medical and corporate operations functions of the supply mechanism. The specific models to be apprised are as follows - Short-line wholesaling, Direct sales from manufacturers, Reduced Wholesale Arrangements (RWA), Direct to Pharmacy (DTP) arrangements (Walter, Dragosits and Said , 2012).

1.1.3 Development of a multi-stakeholder effective strategy

The conflicting interests of regulators and stakeholders result in construction of typical drug distribution models that integrated such functions as distribution and financing within supply chains. For that reason, a blanket approach involving creation of full-line distributors in the mould of RISM may not be effective across emerging markets (Kumar *et al.*, 2014). Furthermore, as highlighted in the foregoing two sections, the strategies involved in drug distribution are numerous and involve multiple stakeholders. In particular the stakeholders include - Payers, Patients, Pharmacies, Advocacy groups, Physicians and Government agencies and regulators. An ideal drug distribution model, one structured to address the peculiar needs of the Kenyan context, would thus be one that incorporates the interests of the stakeholders in such a manner as to ensure delivery of medication in a rapid, continuous and inexpensive manner.

1.2 Statement of the problem

The underlying assertion of the UHC goals is that all individuals should have access to medical care without debilitating financial consequences. Healthcare services availed to individuals should furthermore encompass health promotion, prevention, treatment, rehabilitation and palliative care (World Health Organization, 2019). As evidenced in the background of the study, the challenge of cancer remains front and central with 18.1 million new cases reported in 2018 (World Health Organization, 2018). African countries are particularly more susceptible to death by cancer given the high incidence of cases with poor prognosis, a fragmented healthcare provision system, and a general scarcity of resources (Kumar et al., 2014; The World Bank, 2019). As highlighted by Subramanian et al., (2017), in Kenya, treatment cost for cervical and breast cancer may be as high as $1,500 in public facilities and more than $7,500 in the private facilities (Subramanian et al., 2017). Given that 35.6% of the population lives under the poverty line of less than USD 1.9 a day, incidence of the disease, to a large section of the population, often presents as a death sentence due to the inaccessibility of medication (The World Bank, 2019).

The World Health Organization reports that among the ten leading sources of inefficiency in health systems are three factors that pertain to medicines – under-use of branded and higher than necessary costing; use of substandard and counterfeit medicines, and inappropriate and ineffective use of medicines (World Health Organization, 2010). The development of efficiently priced and distributed medicines through leveraging a well-structured drug distribution model would thus serve to address the growing challenge of cancer deaths due to inefficient treatment. Issues relating to distribution of branded medicines, costing, and counterfeiting relate directly to the conduits used in availing mediation to patients. As noted by Kumar et al., (2014) the main challenge in drug distribution in Kenya emanates from the lack of a synchronized approach orchestrated by an overarching body as is the case with GRIPS in Europe. Kumar et al., (2014) therefore propose consideration of a unifying central body charged with the responsibility of acting as a conduit between manufacturers and consumers of medication with the benefit of such an entity being the streamlining of the process hence cost reduction for all stakeholders. Strother *et al.*, (2012) further highlights that the overreliance on donations towards cancer treatment results in a fragile medicine access framework as donations often prove unreliable in frequency and amount.

According to Slomiany et al. (2017) addressing stakeholder requirements in an integrative manner requires development of value-based models that incorporated the interest of multiple stakeholders of the industry; these sentiments are shared by McCabe et al., (2009) and Miller (2011). Viewing this assertion in light of Kumar et al., (2014) observation of a peculiar environment in developing countries as regards regulatory environment and stakeholders, it is apparent that specific studies aimed at addressing the needs of developing nations should be considered. The current study addressed this gap.

The main gap in drug distribution models employed in the distribution of cancer medications in developing nations, and Kenya by extension, is evidenced by the fact that most cancer deaths occur in developing countries, yet the region suffers the highest cost of medication and these medications are often inaccessible (World Health Organization, 2018). It is therefore apparent that the development of efficacious drug distribution models presents as an urgent need in the local context. This need is highlighted by the fact that treatment costs associated with breast and cervical cancer currently require astronomically high expenditure (Subramanian et al., 2017). Current drug distribution model can thus be inferred to generally be ineffective in addressing the needs of the region. As Lee and Hunt (2012) aptly observe, the challenge of distribution of medicines requires concerted effort from national, international, and private stakeholders with a stake in the industry. Such concerted effort is lacking in the current models employed in the distribution of medication in developing nations (World Health Organization, 2018).

The main purpose of this study was to understand the process and challenges around availing oncology medicines and using the information to propose a pharmaceutical drug distribution model for the distribution of oncology drugs in Kenya. The emerging market structure thus addressed the challenge of inaccessibility and high costing of medication by proposing ways by which to optimize the distribution channels hence lowering the cost of availing needed medicines to the population of patients in the country.

1.3 Objectives of the study

General Objective

To examine the characteristics and effectiveness of existing oncology medicines drug distribution strategies and propose a model for expanding access in the Kenyan market.

Specific objectives

I. To characterize existing oncology drug distribution models applied in Kenyan pharmaceutical industry.
II. To examine the effectiveness of the models based on the experiences and opinions of oncology and pharmaceutical industry experts.
III. To assess stakeholder-value-based model to support efforts towards effectively scale up drug distribution for oncology medicines in the Kenyan healthcare industry.

1.4 Research Questions

The research questions forthcoming from the research objectives are subsequently presented:

I. How can the existing oncology drug distribution models applied in the Kenyan pharmaceutical industry be characterized?
II. What is the effectiveness of the models based on the experiences and opinions of oncology and pharmaceutical industry experts?
III. How can a stakeholder-value-based model for scaling up drug distribution for oncology medicines in the Kenyan healthcare industry be developed?

1.5 Scope of the study

The study focuses on pharmaceutical companies with drug distribution operations in Kenya and specifically those involved in the distribution of oncological medication. The study was conducted through a case-study approach. Novartis International AG is a Swiss multinational pharmaceutical company with a large operation base in Kenya. Novartis constituted the primary case. Novartis was specifically chosen due to its experience and expertise in developing and marketing medicines for cancer treatments. It is a major distributor to both government and private healthcare facilities

in Kenya. However, interviews also sought to understand other distribution models used by Roche, Astra Zeneca, KEMSA, MEDS in other regions, as well as the main distributors supporting Novartis towards expanding drug distribution to the cancer medicines and Cancer hospitals (KNH, Texas Cancer Centre). The study employed an interview approach in keeping with that employed by McCabe et al., (2009) in their assessment of market and patient access to new oncological products in Europe. The current study however employed the use of four additional interviews to account for the multi-stakeholder views.

1.6 Significance of the study

The study was expected to deliver insights on policy, academic and industry practice contributions. At policy level, information will contribute towards government actors' understanding of drug distribution barriers and opportunities for cancer medicines. Cancer has gained prominence in Kenya over recent years, and as discussions on UHC continue, it is important that policy is well informed on options available for supporting the private pharma industry, either directly, or through adjustments to the business regulatory environment.

For academia, the study will contribute towards understanding how pharma markets can be studied, particularly in aspects that intersect with public health. Focus of pharma research has often been pricing and regulatory aspects. Little effort has gone towards understanding the interplay between the industry and community/public health, which is enhanced through drug distribution programs.

At industry level, the study provided insights into the current drug distribution strategies debate, and how the pharma industry can better serve the public whilst remaining profitable. There is a scarcity of evidence on effective mechanisms for distribution medicines, particularly those for non-communicable diseases such as cancer.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter looks at theories that touch on distribution of medicines, summarizing current evidence in the area. The chapter also looks at literature touching on access to essential medicines through drug distribution programs and related initiatives. In addition, the researcher, through this chapter explores experiences within the Kenyan market, with a stronger focus on oncology medicines. The chapter ends by highlighting gaps in research and presenting an analytical framework to guide the inquiry.

2.2. Theoretical review

This section looks broadly at literature around access to commodities. The drug distribution models are fundamentally conduits to supplying of utility products. In the case of the pharmaceutical industry, drug distribution models strive to optimize the supply function to meet demand at an optimal price point – one that achieves adequate compensation for investors while integrally meeting the basal objective of stakeholders involved. The theory of supply and demand thereby forms the premise of the discussion with dispersions of the model, that characterize the pharmaceutical distribution model, described. It is these idiosyncrasies that render essential the development of optimal models of supply, in an established oncology medicines demand market.

2.2.1 Theory of supply and demand

Early notable proponents of the theory of supply and demand include Sir James Stewart (1767) and Adam Smith (1776). The law of supply and demand emanates from the independent associations between demand and price and supply and price. The relationship between demand and price is captured in the law of demand which stipulates that increases in price result in decrease in demand with the inverse, to a point, being true (Beattie & LaFrance, 2006). The law of supply, in turn, stipulates the interaction between supply and pricing positing that increase in price results in increase in supply as manufacturers seek to increase profits (Beattie & LaFrance, 2006). In viewing the two laws in concert – hence the law of supply and demand – it is apparent that increase

in demand would result in supply to a point of equilibrium where price does not prove a restriction to either supplier or consumer of product. This balance is however not apparent in the pharmaceutical industry in Kenya given that the pricing of cancer medication remains hindering to a wide market of consumers (Subramanian et al., 2017).

The most noteworthy criticism of the theory of supply and demand is presented by Mosley (2010) in a critique of depictions of aggregate demand and aggregate supply as put forward by Mankiw's presentation of the law of supply and demand. According to Mosley (2010), the two concepts, supply and demand, are mutually exclusive and should therefore not be included as a single law. Factors affecting supply and the reaction of markets to supply fluctuations differ from those related to demand and the two constructs – supply and demand – as pertains to market reactions need not be discussed concurrently. Furtherment, Mosley (2010) posits that the current environment of regulation and restrictions curtails the interpretability of the laws of supply and demand. As an example, increased demand, due to regulatory constraints, may not necessarily result in increasing prices with the inverse being true as well. It is however noteworthy that despite the criticism the theory remains valid in evaluations of supply and demand vis-à-vis price of goods and services as modifications to the theory account for the difference between markets and factors affecting different markets.

The high incident rate of cancer results in a high demand for cancer medication (Bray et al., 2018). The resulting dynamic, as stipulated in the law of supply and demand, would thus be an increase in production to meet demand and a lowering of costs in light of increasing demand. The European Association of Pharmaceutical Full-line Wholesalers, (2009) however indicates that the pharmaceutical market is atypical with regard to supply and demand factors as physicians, charged with the role of prescribing medication, are the main determinants of demand as opposed to the typical scenario whereby patients would drive demand. Bureau of Labor Statistics price index indicate that the rate of increase in the price of pharmaceuticals far outpaces that of other products thus indicating that the market does not abide the laws of supply and demand (Scherer, 1993). In viewing this observation in light of the law of supply and demand, it is apparent that the machinations of the pharmaceutical system are atypical. It is thus necessary, in the current study, to evaluate the dispersions of the entails of the industry and their implications in structuring a drug distribution model aimed at addressing the needs of the context.

The atypical nature of the supply and demand function is further highlighted by the fact that most cancer deaths occur in Lower and Middle-Income Countries (LMICs) yet the regions have the lowest supply of oncology medication on account of the high costs associated with acquisition of the drugs (Dey, 2014). It is thus apparent that the peculiarities of the pharmaceutical industry predicate construction of ad hoc drug distribution models that consider these peculiarities of the market in question and thus construct supply mechanisms that effectively address the challenges of the specific environments within which they operate.

2.3 Empirical Review

This section looks at studies on drug distribution strategies, with some bias towards oncology medicines.

2.3.1 Characterizing oncology drug distribution models applied in the pharmaceutical industry

2.3.1.1 Concepts and factors

The general state of medico-economic value assessment mechanism in place as pertains to the development and mainstreaming of oncology diagnostic tests and medication is lacking (Miller et al, 2011). This lack is characterized by the inability of researchers to accurately access validation data for new remedies developed to combat the growing threat of cancer. Funders of technologies developed in the space lack an effective way of estimating the reimbursement paradigm that would be used to compensate their efforts following the resource consuming efforts of identifying nascent oncological therapies. As Miller et al., (2011) note, whereas a burgeoning framework to drug distribution of tests and medicines is apparent in the United States, the same is not apparent in the EU with the difference emanating from shortcomings in the integration of the various strategic functions involved in drug distribution.

Kumar *et al.*, (2014) defined drug distribution as the processes by which medication is delivered to patients in a rapid manner, made continuously available and provided at the right price. The authors further posit that the concept involves a wide array of factors including – from a pharmaceutical company's perspective – regulatory, supply chain, marketing, medical, and

corporate functions. The stakeholders are identified to include payers, patients, pharmacies, advocacy groups, physicians, key opinion influencers, and regulatory bodies. The wide scope of the concept therefore necessitates a segmented understanding of the drug distribution function as pertains to the various stakeholders.

Whereas drug production companies focus efforts on the development of new therapies that can be utilized in the fight against cancers, these efforts manifest within the context of strict regulatory provisions. It is therefore necessary to ensure alignment between drug development, regulations and drug distribution models (Martinalbo et al., 2016). The tradeoff between early access of medications in dependent on the availability of evidence on the benefit-risk details of the intervention, relative cost and effectiveness as well as the ability of sales not only be affordable to patients but also to recoup the investments of the manufacturer. These multiplicity of needs as expressed by different stakeholders necessitates early dialogue initiatives between regulator and other stakeholder in the treatment chain to align evidence requirements and discuss perceptions of unmet needs in the market as viewed from different perspectives(Martinalbo et al., 2016).

In assessing the integration of the drug distribution function, Kumar et al (2014) argued that two main factors contributed to changes in the distribution of medicines – escalating healthcare costs, and a challenging pricing and reimbursement environment. The pricing aspect often triggered increased scrutiny by regulatory bodies, in a bid to minimize health expenditure, and, a counter-force from manufacturing companies to ensure sustainability of business models. The two forces impact the disbursement of medicines differently. In the industrialized world, where the healthcare function is well established, the various functions are often orchestrated with various stakeholders operating in light of their effect to the distribution channels. However, in the less developed healthcare systems characteristics of emerging markets, the various functions are handled differently often leading to inefficient systems that result to high expenditure for patients. It is therefore apparent that the factors dictating the selection of distribution models developing markets differ significantly from those applied in industrialized nations.

Javalgi and Wright (2003) assessed business prospects of pharmaceutical companies looking to expand operations to international jurisdictions. They point at foreign market analysis, consumer and government obstacles, and method of entry as the three most pivotal points of focus. Pertinent

to the ongoing study is the importance of market entry models. The authors put forward a conceptual framework comprising of market analyses, selection of drug distribution model, and entry into target markets. Five main drug distribution models are identified – export/import, subsidiary, merger/acquisition, joint venture and licenses. The selection process for the various options, they argued, was dependent on the three main aforementioned factors. As an example, jurisdictions with a high involvement of government in the industry would necessitate exploration of licencing options with the dominant players as opposed to direct acquisitions. The focus of the models put forward however centre less on the provision of affordable medication and more on the business performance of the manufacturing and distribution entities. It is thus apparent that the applied drug distribution models are not appreciative of the multiplicity of stakeholders in health provision.

2.3.1.2 Distribution mechanisms

Walter, Dragosits and Said (2012) provided a systematic evaluation of drug distribution mechanisms in six European Union countries – France, Germany, Italy, Netherlands, Spain and the United Kingdom. The authors put forward four main drug distribution models – Short-line wholesaling, Direct sales from manufacturers, Reduced Wholesale Arrangements (RWA) and Direct to Pharmacy (DTP) arrangements. The focus of the study was to evaluate the effectiveness of the various systems from a multi-stakeholder approach. This study contrasts with that by Javalgi and Wright (2003) in the scope of involved stakeholders. Short-line wholesaling companies are defined as those that carry a specific set of medications and engage in direct distribution of the medications to wholesaling companies. Full line distributions involve wholesaling and logistic organizations that encompass a wide range of smaller entities that work in a concerted effort to result in distribution of the full-range of medications necessary for a population (Walter, Dragosits & Said, 2012).

Reduced wholesale arrangements involve the distribution of medicines through a pre-identified narrow set of distributors in the bid to leverage the efficiencies of the identified distributors. Direct to pharmacy models, involve ownership of the distributed medicines by the manufacturer up until the sale to retailers. Finally, direct sales from manufacturers involve channelling of medications from manufacturing entities straight to retailers for final consumption by patients (Walter,

Dragosits and Said, 2012). The analysis thus provides an all-encompassing approach to distribution models; it is this demarcation of distribution channels that is used in operationalizing distribution models in the current study.

In expounding on the role of full-line pharmaceuticals, (European Association of Pharmaceutical Full-line Wholesalers, 2009) points to the role of Groupement International de la Répartition Pharmaceutique (GIRP) as a central player in guaranteeing the availability of medicines via pharmaceuticals to the EU general public. GIRP is an umbrella organization housing an association of wholesales operating in various jurisdictions of the EU. The organization is responsible for both the warehousing and logistics involved in availing medications to the various retail pharmacies scattered across the European Union. As of 2009, the organization supplied 170,000 retail pharmacies with over 100,000 products. The members of the organization commit to carrying and distributing the complete assortment of products, ensure product availability to patients, create and maintain quality standards, and generally fulfil the public function of dissemination of medication to retailers. To achieve these objectives, the organization plays the role of purchasing, warehousing, storing, order preparation, and delivery of medicines. The centralization of all functions involved in drug distribution thus allows for the running of a streamlined model that ensures a high level of satisfaction among stakeholders in the industry. This high performance is exemplified by the high satisfaction ratings of retailers currently serviced by the GIRP (Walter et al., 2012). It is however noteworthy that s Kumar *et al.*, (2014) observe, the success of the model is highly dependent on the regulatory framework of the EU and the lack of such a framework in emerging markets - among which lies Kenya – prevents curtails efficiency in drug distribution and particularly so in distribution of medication to patients.

Davis, Kanagat, Sharer, Eagan, Pearson and Amanyeiwe (2018), in a study focusing on HIV drug distribution opine that the approach to distribution is of pivotal importance in determining the effectiveness of treatment and adherence to regimens. Basing their research on 13 key publications focusing on distribution models, the authors conclude that a mixture of facility-based and community-based distribution models present as effective in reaching affected patients. Effectiveness of the mixed approaches is evidenced in reduced patient wait times, reduced time cost and improved patient outcomes. The study thus shows the importance of adherence to effective drug distribution models in the bid to improve patient outcomes. It is however noteworthy

that whereas HIV drugs are generally readily available for the public, cancer treatment drugs are both unavailable and costly. This difference must thus be factored in in selection of the most appropriate models fitting the idiosyncrasies of cancer treatment in Kenya.

Lymphatic filariasis still presents as a major disease particularly in rural Kenya. The most efficacious approach currently exercised in dealing with the challenge is the mass administration of drugs to the populace. In Kenya, the exercise of mass drug administration is achieved through the use of mass drug administrators. Njomo, Njenga, Amunynzu-Nyamongo, Magambo and Ngure (2012) study this approach to drug distribution with the intention of highlighting the deterrents and motivators to effective drug distribution in the coastal region of Kenya. The study involved a retrospective qualitative approach with data collected through the use of interviews and focus groups. Findings reveal that high education, trust, and familiarity aided in enhancing the distribution exercise whereas such factors as inadequate training, shortage in drug supply, lack of community sensitization, and lack of supervision deterred the distribution exercises. In viewing these findings in light of cancer drug distribution, it is apparent that there are marked differences – whereas lymphatic filariasis patients often present no symptoms, those suffering cancer seek out remedies as symptoms present and are thus more likely to embrace treatment options. The difference not-withstanding, such factors as shortage in drug distribution and a lack of sensitization among the populace do present as hindrances to effective treatment. It is thus necessary to not only focus on the logistical factors affecting cancer drug distribution but also to consider the socio-cultural influences and preferences that should be addressed to ensure that medication reaches the affected.

In a study of drug distribution in Kenya, Shretta, Omumno, Rapuodo and Snow (2000) posit that there are parallel distribution channels that exists particularly in the treatment of such diseases as malaria. The researchers focus on the change in malaria treatment policy in which chloroquine was replaced as the primary drug for malaria on account of widespread resistance. The authors opine that the shift was encumbered with uncertainty due to the lack of consensus on the metrics to be used in rendering a drug ineffective. That notwithstanding, the switch to an alternative drug was challenged by the fact that the bulk of the population received medication from retailers as opposed to central medical facilities in the various locations. The consequence of this was a disjoint between medical policy and the distribution channels availed to the population. Whereas cancer treatment

medications are specialized an expensive and thus unlikely to be distributed as prevalently by retailers in the country, the lack of congruence between policy and distribution remains a factor of concern in assessing patients' access to needed medications. A well-crafted intentional distribution model should follow from a progressive nation-wide treatment policy that aims to make cancer treatment both affordable and available to the affected. Failure in the policy would thus have an unfettered effect on the eventual distribution of drugs to the affected.

2.3.1.3 Models in the United States

According to Iacocca, Zhao and Fein (2013) drug distribution models employed in the United States can be categorized into two – resell models and direct drug distribution models. Whereas direct drug distribution models render wholesalers as entities involved with the distribution of drugs at a fee, resell models involve the transition of ownership of drugs, upon purchase by the wholesaling body, from the manufacturer to the wholesaler. The latter model comprises two approaches – buy-and-hold and fee-for-service. The two models, as expounded upon by the authors, emanate from the steady increase of drug prices as effected by yearly increases in the wholesale cost put forward by manufacturers. To take advantage of the increasing costs, wholesaling entities maintain a higher inventory than is needed. The increase of price in subsequent years therefore results in higher profit margins for the distributor but not for the manufacturer as the distributing wholesale companies disburse inventory bought at a lower cost and preserve the newly acquired stock for future sale. To curb this approach, the second model, fee for service, allows for payment of fee, by the manufacturer, to prevent holding of excess inventory. The highlighted approaches thus indicate the role of self-interest in the distribution of medication to the public in that entities in the distribution channels put in place mechanisms that ensure maximum profit making often at the expense of the final consumer of the drugs.

Short-line wholesalers differ from their full-line counterparts on account of stocked medication. Whereas full-line providers include all medication in their inventory, short-line wholesalers focus on fast moving medication. The focus on such medication by short-line wholesales in the increase in profit margins given that slower-moving product, which lends itself to losses associated with inventory charges and expiry, do not bear a toll on profits (Macarthur, 2007). As highlighted by Macarthur (2007) short-line wholesalers in the UK stock 10 percent of the inventory of their

counterpart full-stock companies. Given their smaller size and their leveraging on generic products, short-line wholesalers are able to negotiate less expensive deals with pharmacies albeit with the loss of such value-add services as prompt delivery and carriage charges. Macarthur highlights that there is a negative perception of the distribution approach in the UK as the short-term wholesalers are viewed as aligning themselves to reap the benefits of the industry without taking on the risks associated with the stocking of slow-moving medication. It is noteworthy that the existence of short-term wholesalers is determined by the legal framework of the countries involved. The practice, in the EU, is most prevalent in the UK due to the relatively less stringent regulatory framework as compared to such countries as Belgium and Finland where wholesalers are required to hold the full range of medications (Macarthur, 2007).

2.3.1.4 Models in Europe

In an exposition on the entails of the Direct to Pharmacy approach to medicine distribution, Kanavos, Schurer and Vogler (2011) reported that the model involved the restriction of the wholesaling function to a limited group responsible for the delivery of medication to retail pharmacies. This definition reflected the reduced wholesale arrangement put forward by Walter, Dragosits and Said (2012). Between 10-20% of pharmacies operating in Denmark, Greece, Ireland, Luxembourg, Netherlands and the UK were supplied by the model. The authors pointed at the model as a solution to low revenue accruals by manufacturers seeking to increase their profit margins by selecting specific wholesalers that are aligned with the manufacturers business interests. The direct to pharmacy approach, as defined by Vogler (2011) thus involved creation of competencies for competitive advantage; these competencies emanated from the interactions between the manufacturing entity and the selected wholesalers involved in the distribution of medication.

The final model considered in this study, as posited by Walter, Dragosits and Said (2012), involves direct sales from manufacturers. This approach, as the name suggests, involves the cutting out of the middle man in the distribution process thus allowing for direct management of the distribution function by the manufacturer. The obvious benefits of the approach involve the lowering of costs for the retailer by virtue of doing away with the percentage margins that would be collected by such intermediary players as wholesalers. The reduction in price is however not a foregone

conclusion for purchasers given that direct distribution would involve the taking on of logistic challenges by the two parties – the manufacturer and the retailer – functions that would otherwise lie with the wholesaler (except for short-line wholesaling). These additional functions would thus present additional expenditure points that previously did not exist for the two parties.

2.3.2 Effectiveness of the oncology drug distribution models

The World Health Organization argues that the provision of quality healthcare is a fundamental right for all individuals (Lee & Hunt, 2012). Yet, two billion people globally lack access to essential medication. A major contributor, as posited by Lee and Hunt (2012), is ineffectiveness of the current medicines supply models, particularly in developing countries. The authors posited that the challenge of distribution of medicines requires concerted effort from national, international, and private stakeholders with a stake in the industry.

McCabe et al. (2009) highlight the implications of oncology drug drug distribution models as assessed from the vantage point of pharmaceutical companies, academicians, regulators and post regulators by exploring the outcomes of a Biotherapy Development Association's meeting encompassing the mentioned stakeholders. As evidenced from the meeting, the notion of effectiveness is multifaceted. The central outcome is however to ensure delivery of mediation at an affordable rate and in an accessible manner – this thus forms the basis of assessment of effectives as viewed by each stakeholder. Among the factors explored in effective delivery of medications included evidenced of cost effectiveness as a prerequisite for reimbursement. This requirement presents over and above that for proven safety and relative effectiveness of the drugs in question (McCobe et al., 2009).

Principle to this collaboration is the positioning of pharmaceutical companies as pursuers of public health goals rather than profit. Such an alignment, as posited by Lee and Hunt (2012) requires that the industry adhere to a set of guiding principles that reflect this essential need. Through reconfiguration of the industry, efforts such as accountability in assessment of extant policies and protocols in drug distribution would result in a streamlined system that both ensures efficacious delivery and business soundness of the manufacturing and distribution entities in the space. The measure of effectiveness of a drug distribution model involved in distribution of drugs is thus to

be assessed, primarily, on account of its ability to ensure minimization of expenditure to the end user and to ensure fair addressing of stakeholder concerns; it is this approach that is applied in the assessment of the effectiveness of oncology drug distribution models.

This call for greater collaboration in the approval and distribution of medication is further highlighted by Pauwels et al., (2016) who call for collaborative efforts in identifying value in the drug manufacturing and distribution process. Pauwels et al (2016) however also note that the process of identification of value is hampered by the multiple conceptualizations of the concept by different stakeholders. Further to this, Slomiany et al., (2017) in assessing value frameworks applied in the oncology industry conclude that multiple points of misalignment are apparent. In Keeping with Pauwels et al (2016), Solamiany et al (2017) propose a wider value assessment approach involving the inclusion of each stakeholder involved in oncological treatment. This assertion is addressed in the current paper by inclusion of multiple stakeholders in the scope of respondents. Efforts of collaborative treatment development have however been apparent in the market. As an example, McCabe et al., (2009) report on a meeting in Belgium involving pharma representatives, academics and European regulatory bodies with the main aim of the meeting being increase all parties' understanding of counterparts roles in the development, licensing and approval of new treatments. Such efforts though not applied to the current market should be considered with the main focus being the tail end of the distribution process given the death of research conducted in the continent.

Walter, Dragosits and Said (2012) provided a systematic evaluation of the effectiveness of various distribution systems employed in the EU. The authors report that full-line pharmaceutical companies are responsible for the supply of up to 74% of medical products sold in the EU. The main entity responsible for this function is the GIRP an entity that above ensuring availability of medication in various pharmacy outlets, provides logistic services for member pharmacies. The authors indicate that in the EU, the full-line pharmaceutical model proves most efficacious on account of its ability to streamline the health provision process for multiple stakeholders in the industry. The organization is observed to pre-finance up to € 10.2 billion over a period of 41 days. This pre-financing provision allows for payment of pharmaceutical companies and delivery of products to pharmacies with later financing following sales.

Walter, Dragosits and Said (2012) argued that elimination of the pre-financing option facilitated by GIRP would result in an annual increased expenditure of between € 164,922.43 and € 171,510.06 per year. Furthermore, pharmaceutical respondents involved in the space indicated that they were most satisfied with the delivery model employed by the GIRP thus pointing to an overall successful drug distribution distribution model in the EU. It is however noteworthy that the absence of such overarching bodies in most developing countries – as is the case in Kenya – indicate that the approach cannot be applied to reduce medical costs for final consumers.

In an assessment of direct to market vis-à-vis resell drug distribution models employed by pharmaceutical companies in the United Sates, Iacocca, Zhao and Fein (2013) posited that the former approach allows for better business prospects as compared to the latter approach and as viewed from the vantage point of pharmaceutical companies. The assertion stems from the observation that the direct to market approach allows the manufacturing company to maintain control over the product hence allow for the reaping of the benefits of price increments. In comparison, the latter model leads to a one-way benefiting model in that the wholesaling entity reaps all the benefits of subsequent sales of drugs at higher prices. The arbitrary benefit of sales by both manufacturer and distributor thus enables for improved business performance as viewed from the manufacturer's vantage point.

Kanavos, Schurer and Vogler (2011), in an assessment of the effectiveness of direct to pharmacies models posited that the approach, from a manufacturer's perspective, may allow for streamlining of the sales and distribution function thus resulting in the gaining of additional revenue. However, in a counter argument from the public's perspective, the fragmentation of the market through self-selection of wholesalers is anticipated to result in reduced economies of scale thus resulting in fragmentation of the distribution function and eventual higher costs to end-purchasers. The authors further posited that direct to pharmacy models escalate the interest-seeking behaviour of the various stakeholders involved in the distribution function – manufactures, wholesalers, retailers – in that each seeks to achieve maximum benefit at the expense of the served population. As compared to postulations by Walter, Dragosits and Said (2012) regarding the benefits of full-line pharmaceutical models, the direct to pharmacies model appears to serve interests of one stakeholder, the pharmaceutical company, with other players being secondary.

In a National Pharmaceutical Services Association (NPSA, 2011) submission to the Senate Standing Committees on Community Affairs, the organization advocates for the amendment of the National Health Act of 1953 which allows for the distribution of drugs directly from the manufacturer to retailing pharmacies. The argument put forward is that wholesaling outlets operating in the space are required, as a provision of law, to make available all medication to all retailing outlets within the space of 24 hours hence margins gained through delivery of standard medication serve to offset the expenditure incurred from slow-moving inventory. This argument is thus similar to that put forward by Macarthur (2007) in an exposition on short-line distributors operation in the UK. The concern over the approach to drug distribution followed a 2011 decision to supply medication directly to consumers as effected by the biggest pharmaceutical Benefits Scheme (PBS) supplier in Australia. This move saw the distribution function shifted from wholesalers to a logistics company that was not required to adhere to PBS stipulations – for example the delivery of medication within 24 hours.

In an elaboration of the proportions of sale by distribution approach, Walter, Dragosits and Said (2012) reported that direct sales by manufacturers account for 34% of sales in France, 19% in Europe, 16% in Italy, 8% in the Netherlands, 10% in Spain and 3% in the UK. It is thus apparent that the approach is responsible for a significant proportion of the distribution proportions. Furthermore, the authors report that the distribution approach is gaining traction given the lucrative opportunities enjoyed by companies engaging in the practice and the lowering of costs incurred by the retailing pharmacies. However, in an assessment of the impact of the distribution approach on the efficiency of service, Walter, Dragosits and Said (2012) reported that retailing pharmacists in the UK and Germany were concerned that opting for the approach would results disrupt service rendering through complications in challenges in increasing stock and order effort.

In a Pharmaceutical Services Negotiating Committee (2007) address regarding Pfizer's decision to adopt a direct-sales-to-manufacturer model, concerns over limited supply of medication, reduced service levels to pharmacies and patients and increased distribution costs were projected to result from the distribution approach. This concern is similar to that raised by the NPSA (2011) in Australia. It is thus apparent that the main challenge associated with the market model, as assessed from a pharmaceutical and patient perspective, is the disruption of the full-line function achieved through such organizations as the GIRS in Europe. It is therefore worth assessing the

implications of the direct-from-manufacturer approaches in environments without or with few full-line wholesale suppliers as is the case in most emerging markets as observed by Kumar *et al.*, (2014). The current study seeks to address this gap.

2.3.3 Stakeholder-value-based approach to effective oncology drug distribution models

Slomiany, Madhavan, Kuehn and Richardson (2017) highlight four main stakeholders in the development and distribution of oncology drugs – patients, physicians, policymakers and payers. The authors posit that effective development of oncology drugs and remedies pivots on the ability to identify frameworks that address the interests of each of the stakeholders in a satisfactory manner. An assessment of existing frameworks, to this end, as applicable in the U.S. market reveals a lack of integrated understanding of the various frameworks and a preference for different frameworks as a function of stakeholder perspective. This study therefore indicates that the creation of an effective drug distribution model depends on the ability to generate buy-in from all four stakeholders.

Meijboom and Obel (2007) ran simulations on the ideal structuring of market distribution models for internal supply chain structuring of pharmaceutical manufacturing companies with an international scope. The essence of the assessment was to generate a model that results in maximum efficiency from the distributors point of view. Two main models were compared – an IT-based centralized model and a transfer-price model. Findings from the study indicated that maximum efficiency was achieved through a transfer pricing approach, whereby business units sold products to other units operating in different markets in order to shield the main company from implications of taxation. This ideal structuring thus results in the recouping of expenditure incurred in high-tax areas through offsetting losses by gains in low-tax areas. This finding thus suggests that arriving at an ideal drug distribution model in emerging markets would require low taxation of drugs to incentivize manufacturing to consider the distribution approach.

Kumar *et al.*, (2014) in their seminal publication on drug distribution in emerging markets, argued that the complex and dynamic healthcare context in emerging markets hindered effective delivery of medication at affordable prices. The conflicting interests of regulators and stakeholders resulted in construction of typical drug distribution models that integrated such functions as distribution

and financing within supply chains. For that reason, a blanket approach involving creation of full-line distributors in the mould of GIRP may not be effective across emerging markets. To navigate this challenge, Kumar et al., (2014) argued that the drug distribution models for emerging markets must consider peculiarities within their contexts.

Strother *et al.*, (2012) in a study on cancer treatment in Western Kenya, highlighted that the bulk of oncology medication distribution in the region emanates from donations. The main reason for this is the high cost associated with treatment of cancer. It is thus apparent, from this observation, that there is a need for construction of drug distribution models that allow for uptake of oncology medication within resource restricted regions. Of concern to the authors, as well, was the lack of adequate training of staff involved in the issuance of medication. To address the various challenges involved, Strother et al., (2012) point to a need for oncology pharmacies that specialize in the treatment of cancer through chemotherapy. Such pharmacies aim to ensure patient and practitioner safety, inventory and procurement centralization and containment of hazardous materials (Strother et al., 2012). Findings from this study thus serve to emphasize the implications of resource limitation as a hinderance to drug distribution. An ideally structured drug distribution model, in the Kenyan context, would thus primarily have to centre on lowering of costs so as to achieve uptake by the majority resource-strained population.

Strother *et al.*, (2013) in an exposition on cancer treatment in Kenya highlight the need by reporting that the country is considered by the World Bank a low-income country with a gross national income per capita of USD 769. The budgetary allocation on healthcare as of 2008 accounted for 8% of the total budget, a figure which amounted to USD 8.30 per-capita spend allowance for the year. It is thus apparent that self-funding and insurance options are impractical as the primary approach in addressing matters cancer. To address the challenges presenting in the context, Strother et al., (2013) point to the AMPATH Oncology model deriving from a partnership between North America, European, and Kenyan partners centred on providing affordable healthcare to the populace through high-income-low-income funding. It is thus apparent, as was the case in Strother et al., (2012) that the main point of market entry for manufacturing organizations looking to serve the populace, would be through collaboration with such NGOs as AMPATH. Given the not-for-profit nature of the set-ups, however, manufacturing and distribution companies would likely have to offer services at significantly lower prices so as to ensure the sustainability of the supply model.

2.4 Gap in research

The previous section has highlighted gaps in drug distribution strategies. From the discussion, it is clear that two main factors are instrumental to decisions on the mode of drug distribution and the effectiveness of the approaches from stakeholder perspectives – the legislative environment, and the consolidation of distribution functions (Walter, Dragosits & Said, 2012; NPSA, 2011; Kumar et al., 2014; European Association of Pharmaceutical Full-line Wholesalers, 2009). It is these two factors that the current study seeks to shed light on. Slomiany et al. (2017) further highlight the importance of addressing stakeholder requirements in an integrative manner when assessing value-based models to be incorporated in drug development and distribution; these sentiments are shared by McCabe et al., (2009) and Miller (2011). Viewing this assertions in light of Kumar *et al.*, (2014) observation of a peculiar environment in developing countries as regards regulatory environment and stakeholders, it is apparent that specific studies aimed at addressing the needs of developing nations should be considered. The current study addresses this main gap. As an example, the lack of organizations performing the function of GIRP in Africa as in Europe, the implications of shifting to direct delivery from manufacturers may not come with the loss of support services as the services are currently not in place in most markets. This underscores the value of assessing the current distribution models, their merits and demerits, and unexploited opportunities, especially in emerging markets like Kenya. This study seeks to contribute towards filling that knowledge gap. Finally, according to Selvaraj (2019) in a quantitative study of the pharmaceutical industry in Africa posits that Kenya houses the fastest growing pharmaceutical sector in East Africa; conversely, Subramanian et al., (2017) points out the cancer treatment costs remain hinderingly high for patients in the country. It is thus apparent that there is a gap between production and service provision as pertains to treatment of cancer in Kenya.

2.5 Analytical Framework

The analytical framework adopted for the study thus interrelates the four contracts in such a manner that regulatory environment, effectiveness of model, and stakeholder interest act as prerequisites to pricing of oncology medication. Figure 2.1 provides a representation of the interrelationship between the constructs.

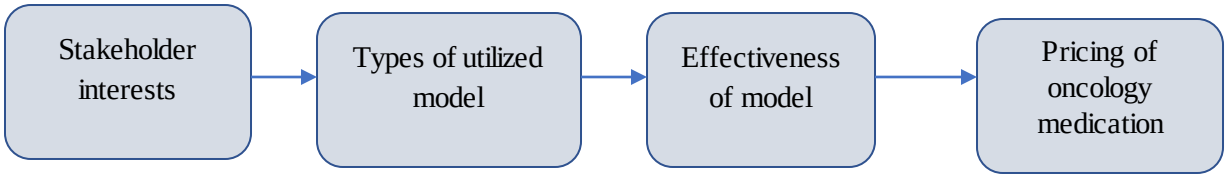

Figure 2.1 Analytical framework

2.6 Operationalization of variables

The various aspects of the variables to be considered in the study are derived from literature as highlighted in the foregoing section. Table 4.3 provides a summary of the factors considered in operationalizing the variables under consideration.

Table 2.1 Operationalization of variables.

Variable type	Variables	Measurement	Source
	Pricing of oncology medication - Actual price of medicines - Relative affordability of medicines	Qualitative (interview responses)	(Subramanian et al., 2017)
	Type of utilized model - Short-line wholesaling, - Direct sales from manufacturers, - Reduced Wholesale Arrangements (RWA) - Direct to Pharmacy (DTP) arrangements	Qualitative (interview responses)	Walter, Dragosits and Said (2012)
	Effectiveness of model - Minimization of expenditure - Timely delivery of medication - Addressing of stakeholder concerns -	Qualitative (interview response)	Lee and Hunt (2012)
	Stakeholder contribution - Payers - Patients - Pharmacies - Advocacy groups - Physicians - Government agencies & regulators	Qualitative (interview responses)	Kumar et al., (2014)

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter discussed the proposed approach to addressing the research questions. Sections touch on the proposed research design, target population, sampling approach, data collection tools, analysis approach, approaches to ensuring quality of research and ethical considerations.

3.2 Research Design

Saunders, Lewis and Thornhill (2009) highlighted three main research designs – exploratory, descriptive, and causal design. Focusing on exploratory design, the authors highlight the approach is taken when the researcher in question wishes to gain deeper understanding of the entails of a phenomenon. This study sought to give information on drug distribution models in Kenya in relation to oncology medicines. Given the nascency of the topic and an overall shortage of studies on the topic, an exploratory qualitative approach was deemed to be appropriate. The study sought to explore drug distribution concepts and propose how they can be synthesized to develop a pragmatic drug distribution model for the Kenyan oncology medicines market.

Qualitative data collection approaches were employed. The data collected, in accordance with the research objectives, will pertain to the current models applied in the market, the effectiveness of the models, and possible approaches to be considered in constructing a more efficacious drug distribution model that takes into account the peculiarities of the Kenyan context.

3.3 Target Population

The study focused on pharmaceutical companies operating in Kenya and involved in the distribution of oncology medication, including Roche, Astra Zeneca, KEMSA, MEDS, Texas Medical Center and Kenyatta National Hospital. For the companies the drug distribution manager, product manager and medical science liaison were considered whereas for MEDS and KEMSA, distribution managers were considered. For Texas medical center, the medical director were considered and for Kenyatta medical center, the HOD oncology were considered.

3.4 Sampling

A purposive sampling approach was taken to reach experts involved in distribution of oncology medication in Kenya. According to Etikan, Musa and Alkassim (2016), purposive sampling allows for the selection of respondents that suit the purpose of the study on account of their peculiar understanding of the topic under study. Mason (2010) in an evaluation of PhD studies employing the use of qualitative approaches to data collection posits that the mean sample size was 31 respondents. The author posits that responses over the 31 mark were likely to result in saturation of views thus proving additional data redundant. In line with this observation, the researcher will collect 31 interviews from the population and in accordance with the sampling approach applied for the study – purposive sampling. In the study saturation was achieved after collection of 18 responses. The responses will be sourced equally from the three groups – pharmaceutical companies (11 responses), regulators (10 responses) and hospitals (10 responses). Each interview will be recorded and subsequently transcribed to yield the desired data to be analyzed in keeping with the study objectives.

3.5 Data collection

The exploratory nature of the current study necessitated the collection of data through a guided yet unrestricted manner. The study employed a qualitative approach, with data collected primarily through in-depth interviews. An interview topic guide was developed to guide the discussions. The topic guide was guided by the research objectives, with the first main section addressing the current state of affairs regarding drug distribution models, the second addressing the perceived effectiveness of the systems, and the final section exploring effective approaches to structuring of drug distribution models suited for the Kenyan context. Respondents were required to engage in a 30-minute interview session whereby questions guided by the prompt were presented. All the interviews were recorded using a professional voice recorder. These will subsequently be transcribed and analyzed as stipulated in the subsequent section. Manufacturers were coded Mnf, distributors D, physicians P and Government entities Gvt. No distinct classification by sub-sector of participation was evidenced

3.6 Analysis approach

The primary analysis approach to be employed in the study was content analysis. Neuendorf (2001) posits that content analysis of qualitative data through a thematic exploration technique allows for the exposition of linkages between observations thus providing for deeper understanding of phenomenon under assessment. The approach is taken by McCabe et al., (2009) in assessing 15 interviews in their study on market and patient access it new oncology products in Europe. Nvivo software was applied to the analysis of data. The purpose of the software was to ensure objectivity in the theme exploration approach and to further allow for the use of powerful data exploration techniques in the bid to unearth themes from the transcribed interviews (Bazeley & Jackson, 2013).

3.7 Research Validity

Kothari posits that validity indicates the degree to which an instrument measures what it is supposed to measure; the accuracy, soundness and effectiveness with which an instrument measures what it is intended to measure (Kothari, 2004). Internal validity entails the agreeability of the queries with the constructs under evaluation whereas external validity speaks to the generalizability of findings (Kothari, 2004). To ensure internal validity, a pilot study was conducted with respondents asked to comment on the understandability of questions and their suitability apropos research constructs. To ensure external validity, the researcher focused on respondents that have experience of drug distribution in Kenya hence insights drawn from such respondents were of pertinence not only to Novartis but to companies operation in the region i.e Roche, Astrazeneca, KEMSA, MEDS.

3.8 Reliability

Kothari (2004) highlights that reliability is a measure of the degree to which a research instrument yields consistent results after repeated trials. Reliable results were primarily be ensured by the following of statistically sound approaches in the collection and analysis of data (Saunders, Lewis, Thornhill, 2009). The centering of subject-matter experts working at Novartis thus served to ensure that the expert responses are reliable through a comparative and summative approach to theme exposition. The use of NVivo in analysis and further consultations with the supervisor allowed for

objectivity in the data analysis process. It is thus apparent that the results to be obtained were, as a function of the stipulated precautions, adequately reliable.

3.9 Ethical Considerations

Ethical considerations are put in place to ensure the integrity of the research endeavor and the protection of the participants involved (Saunders, Lewis, Thornhill, 2009). Primary data were collected in the current study hence it was necessary to ensure that the participants involved are not negatively impacted by the conducting of the study. All data collected for the study were anonymized and held in confidence throughout the duration of the study. Measures were also put in place to ensure that the data is collected confidentially by arranging for offsite meetings with the study respondents.

CHAPTER FOUR

ANALYSIS AND PRESENTATION OF FINDINGS

4.1 Introduction

The purpose of this chapter is to demonstrate how the study objectives were addressed through analysis of collected data. The chapter is divided into three main section – response rate, descriptive statistics, and findings on objectives.

4.2 Response rate

According to Dilley's (2000), a qualitative study should feature at least 20 respondents although the main aim is to achieve saturation of ideas. A total of 18 respondents were reached with the shortfall, to reaching 20 respondents, resulting from hesitance to meet due to possible Covid-19 transition; the researcher however attained saturation as evidenced by repetitive ideas from subsequent respondents leading up to the 18th respondent. Respondents who decline participation via face-to-face meeting with necessary safety protocols were invited to participate through Zoom and Microsoft Teams calls. Saturation of ideas was however apparent after assessment of findings from the eleventh interview. The number of responses was thus deemed sufficient, on account of expertise of the respondents, for the purposes of addressing the objectives of the study.

4.3 Descriptive statistics

This section provides basis demographic information on the respondents. Respondents were grouped by gender (male/female) and by sub-sector of operation in the industry, with the categories being manufacturers, distributors, pharmacists, regulators and physicians. The implications of the demographic characteristics are discussed. Table 4.1 provides a summary of findings on the general characteristics of the respondents.

Table 4.1 General Characteristics of Respondents

File	Gender	Sub-sector
Interviewee 1	Male	Agency
Interviewee 2	Female	Manufacturing
Interviewee 3	Female	Manufacturing
Interviewee 4	Male	Manufacturing
Interviewee 5	Male	Manufacturing
Interviewee 6	Male	Physician
Interviewee 7	Male	Manufacturing
Interviewee 8	Female	Physician
Interviewee 9	Male	Manufacturing
Interviewee 10	Female	Physician
Interviewee 11	Male	Manufacturing
Interviewee 12	Male	Agency
Interviewee 13	Male	Manufacturing
Interviewee 14	Male	Manufacturing
Interviewee 15	Male	Physician
Interviewee 16	Male	Distributor
Interviewee 17	Female	Physician
Interviewee 18	Male	Agency

Majority of respondents were male. Coding of each document in the process of theme extraction resulted in 35 coding frames. The researcher, through the use of a matrix coding query sough to assess whether gender played a role in the emergence of themes. The codes did not show segregation by gender therefore indicating that the factor did not necessarily influence the responses observed. It was thus inferred that gender did not present as a significant influencer of responses put forward by various respondents. A word similarity assessment was conducted to assess the relationship between the data collected from different participants of the oncology distribution channel. The analysis was conducted on the basis of Pearson's correlation with data deriving from world density scores for the various files. Manufacturers were coded Mnf, distributors D, physicians P and Government entities Gvt. No distinct classification by sub-sector

of participation was evidenced. This is highlighted in figure 4.1. The inference therefore was that the sub-sector of participation did not have a general impact on the responses put forward by the various respondents.

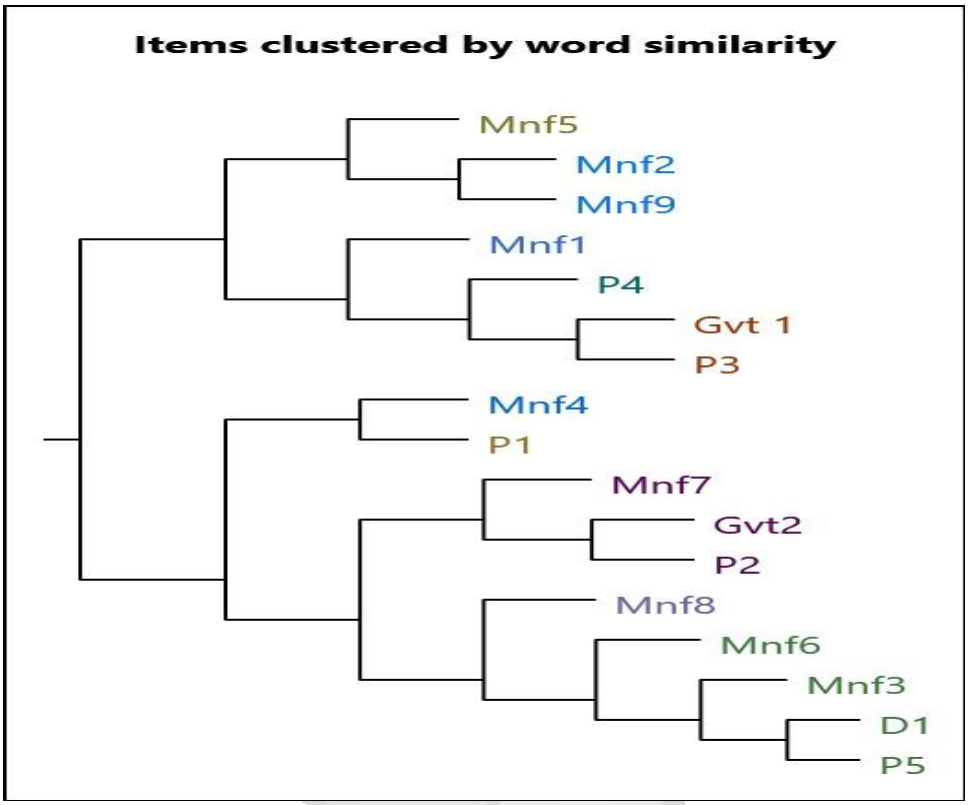

Figure 4.1 Items clustered by word similarity

4.4 Findings on objectives

This section provides a presentation of the findings following analysis of data on each of the objectives of the study.

4.4.1 Objective 1: Existing oncology drug distribution models applied in Kenyan pharmaceutical industry

Four main models were presented to the respondents as the extant-literature-derived main models – Short-line wholesaling model involving supplying a specific set of drugs to wholesalers who then distribute the market; direct sales from manufacturers is a model in which the manufacturer, although employing intermediaries in distribution of medication, maintains ownership of the drug up until sale to retailers; reduced wholesale arrangements involves the organization working with a select number of wholesalers to distribute the drug; and the final, direct to pharmacy whereby the manufacturer assumes all distribution roles, culminating in delivery to the final retail pharmacy.

Reduced wholesale agreements were the most prevalent in the distribution chain whereas direct from manufacturer options were the least utilized. Figure 4.2 provides a graphical representation of the most dominant approaches utilized by the various respondents.

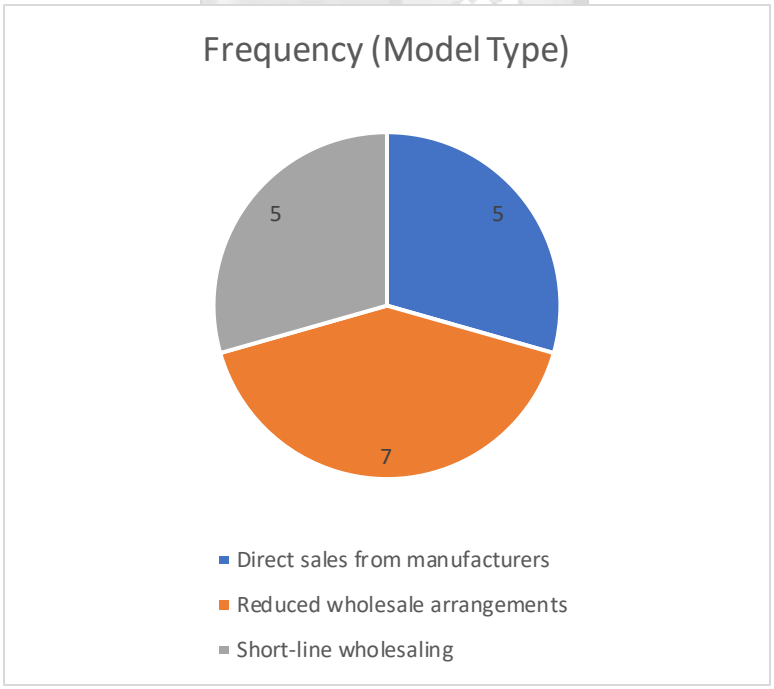

Figure 4.2 Model type frequency

Direct sales from manufacturers and short-line wholesaling were also commonly used approaches in allowing access to the drugs. The multiplicity of approaches posited by respondents pointed to market fragmentation in that the efficiencies viewed by one stakeholder were not apparent to other

stakeholders in the value chain. The biggest intermediaries involved in the distribution of medicines to both private and public facilities were KEMSA and MEDS. Five respondents pointed to the pivotal role played by KEMSA in availing medication to patients by interfacing with the manufacturing organizations; MEDS was reported as a useful avenue by one of the respondents who highlighted that the aggregative efforts of the two institutions – KEMSA and MEDS – with supplemented involvement of private players allowed for closing of the loophole in the delivery process.

> *"…the government procurement body purchases for you … so whatever facility within your locality does have the product if KEMSA is able to order it. The other option is to also focus on faith-based organizations which are also a route in which patients are able to access drugs, for example MEDS which serves the faith-based organizations; they are also another route of distribution that even that curve in terms of access for the patient. So not only are they able to go to a public facility, they are also able to go to a faith-based organization and the private channel of course still exists as well. So, all the loopholes have been covered."*
>
> *Manufacturing rep1*

This view of a far-reaching coverage of the two overarching bodies – KEMSA and MEDS – however contrasts with that put forward by a respondent perceiving the space to predominantly feature distributors.

> *"I think in my view, it's a little bit of a mixture. I see quite a lot of intermediary distributor, especially when the products are being imported, mostly because the point of importation is not for everyone. So you find that there is a manufacturer sitting outside who has an agent locally, who happens to mostly be a distributor, and that distributor then sells either directly into the hospital where the patient is being administered for the product, especially for let's say the IV ones, but they also sell now to the retailers, and in the hospital pharmacies. That's how I see the bulk of it."*
>
> *Manufacturing rep2*

Alternative methods of drug access were also reported with patient access models reported by four respondents. The aim of the programs was reported to be the circumventing of regular channels thus allowing for cheaper products to be availed to the financially marginalized individuals. Noteworthy also was Hub system intended to improve on the inefficiency of drug delivery as effected by KEMSA. The impetus behind the switch to a local delivery hub was the elimination of middle men with distributors reportedly increasing prices by at least 10% and retailers by a subsequent 15% thus rendering the final product unattainably expensive to most patients. Direct partnerships between hospitals were also reported as an existing option with the partnership entailing delivery of oncology medication from the manufacturer directly to the main cancer treatment hospital. The approach was deemed necessary following reported inefficiency by KEMSA in delivering the product to needing patients in a timely manner.

A coding of the responses by sub-sector and model type, as indicated in table 4.2 did not point to an association between participation in the industry and utilized approach of distributing oncology medication as different models were reported by participants in the same sub-sector. This finding is thus consistent with the inference of a fragmented industry. The observation was underlined by the fact that manufacturers from the same company provided different details on the approaches to distribution employed within their organization.

Table 4.2 Model type by sub-sector

Sub-sector	Model Type
Distributor	Short-line wholesaling
Government Agency	Direct sales from manufacturers
Government Agency	Reduced wholesale arrangements
Manufacturing	Direct sales from manufacturers
Manufacturing	Direct sales from manufacturers
Manufacturing	Direct sales from manufacturers
Manufacturing	Short-line wholesaling
Manufacturing	Reduced wholesale arrangements
Manufacturing	Reduced wholesale arrangements
Manufacturing	Reduced wholesale arrangements
Manufacturing	Reduced wholesale arrangements
Manufacturing	Reduced wholesale arrangements
Physician	Short-line wholesaling
Physician	Short-line wholesaling
Physician	Direct sales from manufacturers
Physician	Reduced wholesale arrangements
Physician	Short-line wholesaling

4.4.2 Objective 2: Perceived effectiveness of the models based on the experiences and opinions of oncology and pharmaceutical industry experts

The effectiveness of the models was assessed on the basis of two sub-factors – Efficiency of distribution, and relative pricing. The results on each aspect are subsequently presented.

4.4.2.1 Efficiency of distribution

A summary of findings from the respondents indicated a general sense of effectiveness of the model; figure 4.3 demonstrate this finding. This is because six respondents viewed the models

applicable to patients in their purview as effective with an additional five viewing models in effect as somewhat effective. Only five respondents viewed the models as generally ineffective.

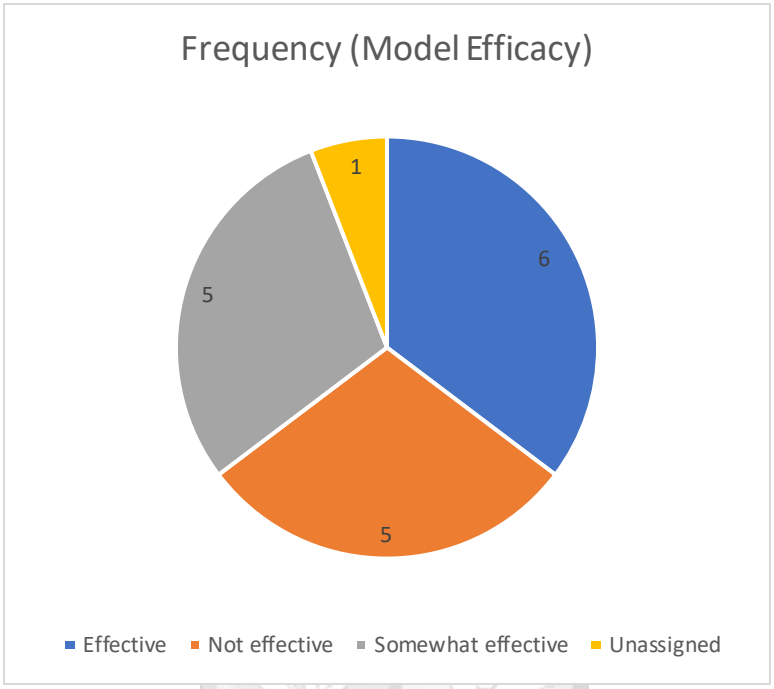

Figure 4.3 Model efficacy

An assessment of the efficacy of the extant models vis-à-vis sourcing of response indicated a general leniency, among manufactures, towards positive assessment of models in existence, regardless of the particular model (table 4.3); only one of the manufacturers viewed the model as ineffective with all others deeming the models in question as at least, somewhat effective.

Table 4.3 Model efficacy by subsector and type

Sub-sector	Model Efficacy	Model Type
Distributor	Effective	Short-line wholesaling
Government Agency	Not effective	Direct sales from manufacturers
Government Agency	Effective	Reduced wholesale arrangements
Manufacturing	Effective	Direct sales from manufacturers
Manufacturing	Unassigned	Direct sales from manufacturers
Manufacturing	Effective	Direct sales from manufacturers
Manufacturing	Effective	Short-line wholesaling
Manufacturing	Somewhat effective	Reduced wholesale arrangements
Manufacturing	Somewhat effective	Reduced wholesale arrangements
Manufacturing	Somewhat effective	Reduced wholesale arrangements
Manufacturing	Somewhat effective	Reduced wholesale arrangements
Manufacturing	Not effective	Reduced wholesale arrangements
Physician	Not effective	Short-line wholesaling
Physician	Not effective	Short-line wholesaling
Physician	Not effective	Direct sales from manufacturers
Physician	Somewhat effective	Reduced wholesale arrangements
Physician	Effective	Short-line wholesaling

Two models of distribution were apparent – the public and private route. Assessments of the two approaches appeared divergent with the public route, effected through KEMSA, generally termed less expensive but markedly inefficient in terms of product delivery. As one respondent, commenting on KEMSA's delivery, notes:

I think that now, the distribution of oncology drugs in Kenya is not well developed. And we cannot say it is that efficient in terms of delivery of these commodities to the point of use at the right time.

Regulator rep1

In further commenting on the modalities involved in purchasing through KEMSA, one respondent notes:

So KEMSA might have the drugs, KEMSA might also get stocked out. If it gets stocked out then you're allowed to purchase from prequalified suppliers but if your prequalified suppliers do not sell serve oncological products then you're in trouble because then you cannot procure any other way without getting in trouble if you're to remain within the confines of the law.

Physician 2

These views contrasted rather sternly with those of another respondent who notes:

It's quite efficient. We have not had any concerns. In the past we did when we weren't enlisted. I think we've benefited on the fact that we're on the essential medical list for the ministry of health for the oncology space. So that gives us the opportunity to get KEMSA to stock for us goods. So, in terms of footprint, our footprint is larger than your average oncology company, pharma company. Because if KEMSA is supplying your product, then it's easy to get it in whichever facility that is an oncology facility, whether it's in a peripheral or in urban areas.

Manufacturing rep 1

As another, espousing similar sentiments notes:

I think that it is okay for the number of patients that we have because the cancer burden in our country for example, is not as high as malaria, for example, or something, or infectious diseases, so currently I would say then it is meeting the needs, but we have a challenge for counties that are far.

Manufacturing rep 2

Whereas the distributor deemed the distribution mechanism to generally be ineffective, the supplier (quoted above), assumed that the product reached the intended patients as required. The contrasting views point to a lack of information-sharing and a limited span of interests – the need of the manufacturer appears to have ended with delivery of the required drug hence the approach

was deemed successful. The inefficiency in distribution was further highlighted by a respondent who notes:

... If the product is not in KEMSA, for instance, and for me this is a real case that has happened, we have liver cancer patients in Makueni and Machakos. And because their procurement policy demands that they only procure from KEMSA, then it means this patient will never be able to get the product. So KEMSA then should ensure that at least most of the essential products are available, that when counties ask for these products, the patients are able to get.

Manufacturing rep 3

The observation points to an inefficiency in distribution borne of ill-fitting legislation. Access of medication across country jurisdiction is reported to be curtailed due to the lack of decentralized cancer treatment facilities and general lead-time required to access the provided medication. Also put forward as a challenge from the manufacturer's side was the wanting listing of essential medications that could be availed to consumers through KEMSA, the largest distributor in the country. A lack of adequate forecasting provisions was cited by two respondents who mention the shortcoming as a possible hinderance to KEMSA's ability to serve its clientele. A possible explanation of the discrepancy between KEMSA's inefficiency and the perceived efficiency of manufacturing bodies is put forward by on respondent who notes:

... since oncology is a bit narrow, it offers very limited opportunity for a wide variety of competition. And so, for the person who is investing in this business will want to know if there are other competitors, are they available? If there are many competitors, then that will limit the opportunity for investment, then that will definitely reduce the efficiencies in the same.

Manufacturing rep 4

The view of efficiency as put forward by the manufacturers would thus point to assessment of performance on the basis of company as opposed to patient outcomes. Given that participating respondents generally represented major players in the pharmaceutical industry, it may be the case that the measure of success is tethered on their ability to gain listing of oncological products for access to KEMSA's purchase approval. This deduction is supported by one of the respondents who posits:

Let me give you an example of distributor X, as X, we distribute for manufacturer Y, distribute for manufacturer Z, and also, we distribute for manufacture P and for many companies. So where is the loyalty of X? It doesn't have loyalty to any particular company. So, in terms of loyalty, X doesn't have any loyalty, their interest is money.

Manufacturing rep 5

It is however noteworthy that not all respondents espoused extreme views on the efficiency of the system. The move to KEMSA as the main distributor of oncological products to the public sector was lauded on account of its move towards a positive direction in that it provides a way to reduce costs even though with limited efficiency in delivery. This sentiment was also echoed by a respondent who points to distributors as conduits of efficiency in delivery albeit with increments in cost. A go-between model levering the price efficiency of KEMSA and the delivery efficiency of distributors is proposed by one respondent.

Pricing of products

To assess the overall pricing of product respondents were required to assess product prices in Kenya as compared to those in East Africa, the United States and similar countries, and India. Respondents were also required to provide an indication of the general affordability of medicines to patients in Kenya. Table 4.4 provides a summary of the coded findings. Kenya generally fared worse than other countries in the region, better than the United States and worse than India with overall pricing generally remaining inaccessible to the public. The common sourcing of medication in the region was considered to be the main factor behind common pricing. The economic differences between the countries in questions were however deemed to impart a difference, albeit a marginal one, in cost. As one respondent notes:

...the economy is a bit stronger

compared to our partners, then everything including like let's say cost of hospitalization, the salaries that physicians earn, or the costs of commodities like foods or other support systems

within a hospital, they are a bit higher. But in terms of comparing A to A, B to B, then they are proportionately similar.

Manufacturing rep 2

Table 4.4 comparative pricing

Sub-sector	**Model Efficacy**	**Model Type**	**East Africa**	**United States**	**India**	**General price**
Government Agency	Not effective	Direct sales from manufacturers	Similar	Worse	Worse	Not affordable
Manufacturing	Effective	Direct sales from manufacturers	Unassigned	Unassigned	Unassigned	Unassigned
Manufacturing	Unassigned	Direct sales from manufacturers	Better	Worse	Worse	Somewhat affordable
Manufacturing	Effective	Direct sales from manufacturers	Similar	Similar	Worse	Not affordable
Manufacturing	Effective	Short-line wholesaling	Similar	Better	Worse	Not affordable
Physician	Not effective	Short-line wholesaling	Worse	Better	Worse	Somewhat affordable
Manufacturing	Somewhat effective	Reduced wholesale arrangements	Worse	Better	Similar	Not affordable
Physician	Not effective	Short-line wholesaling	Worse	Better	Worse	Not affordable
Manufacturing	Somewhat effective	Reduced wholesale arrangements	Similar	Better	Worse	Not affordable
Physician	Not effective	Direct sales from manufacturers	Worse	Worse	Worse	Not affordable
Manufacturing	Somewhat effective	Reduced wholesale arrangements	Not Applicable	Not Applicable	Not Applicable	Not affordable
Government Agency	Effective	Reduced wholesale arrangements	Worse	Worse	Worse	Not Applicable
Manufacturing	Somewhat effective	Reduced wholesale arrangements	Worse	Better	Worse	Not affordable

Manufacturing	Not effective	Reduced wholesale arrangements	Worse	Worse	Worse	Not affordable
Physician	Somewhat effective	Reduced wholesale arrangements	Worse	Not Applicable	Worse	Not affordable
Distributor	Effective	Short-line wholesaling	Worse	Worse	Worse	Not affordable
Physician	Effective	Short-line wholesaling	Similar	Better	Worse	Not affordable

Differences in pricing model were reported for Rwanda, Ethiopia and Tanzania with the main point of dispersion being in the common sourcing of products directly from the government to manufacturing companies in the bid to leverage economies of scale. Uganda was also reportedly in the process of adopting a similar model.

the pricing will be different in Rwanda, because they have reimbursements, almost 100% reimbursements, so you can imagine that the patients are able to get the product at a much lower price. And, quote and unquote, the reimbursement prices that were set by the Rwanda ... something, they have a lobby that sets the price.

As another respondent notes,

For Ethiopia, for example, Ethiopia, Sudan, the government usually negotiates with the manufacturers. So, they'll just negotiate with a single manufacturer, and tell them, "We need this medicine. Can you give it to us at this cost?" And so, it won't be a free market the way we have a free market in Kenya, and people will try and compete and make profits and things like those.

I know Uganda also are trying to do something similar, and I don't know if it's gone through. But last time I spoke to them, they were telling me they want to do something similar, and they were even to discuss with the Kenyan government on whether they could do it like joint, like Kenya, Uganda, Tanzania, Rwanda, Burundi.

Manufacturing rep 4

In commenting on the model in Tanzania, a physician notes-

Tanzania's oncology care is given mostly by the government sector where majority of the patients getting treatment will be accessing a government facility and as such, the government has been able to advocate for bulk purchasing and through doing that then they've been able to drive down the cost which is unlike in Kenya and Uganda.

The general cost of the actual product was however marginally cheaper as reported by a respondent putting forward a manufacturer's perspective. As put forward:

Within East Africa or our emerging markets as we call them, the products are procured or given at almost 3% cheaper for some of them if you compare with the rest of the world, but this is for emerging markets of which east Africa as a whole fall under.

Physician 1

In summation, the general reason behind high pricing in the Kenya appears to be that manufacturing and distributor companies are allowed to operate without price restrictions in a free market marked by high demand and limited supply. The eventual effect is thus that of high margins for the first involved in delivery of the product owing to the lack of options for the affected. The inference is supported by a respondent who conceptualizes the problem as follows:

The demand for the oncology product far outweighs the supply and the demand for quality oncology products still far outweighs. It doesn't help that a lot of the new oncology products are highly specialized. So not everybody can really manufacture. So, the government should not have treated oncology the way they treat the other generic products. And that is what maybe makes it ... it becomes an expensive venture in Kenya. When they ignore it the way they ignored the other products, we don't feel the benefit of low pricing, but high pricing.

Manufacturing rep 9

In comparing the pricing apparatus implemented in the country vis-à-vis that in the US, the general observation was that whereas prices in the US were generally high, patients in the region were better position to access treatment on account of an inclusive insurance environment. Prices in

India were generally viewed as significantly lower than those in Kenya on account of economies of scale, manufacturing ability, and irreverence of patents.

4.4.3 Objective 3: A stakeholder-value-based model to support efforts towards effectively scale up drug distribution for oncology medicines in the Kenyan healthcare industry.

Findings from the forgoing discussion on objectives highlight two main aspects – inefficiency in distribution vis-à-vis a high-demand marginalized market and divergence of and fragmentation of interests among and between stakeholders in the industry. It is thus apparent that a stakeholder-value-based model to distribution is lacking. To arrive at a proposed structure, the researcher sought to benchmark the existing legal framework, to highlight stakeholder interests and to highlight ideal structuring of the distribution model as opined by the various professionals in the field. Findings on the three aspects are subsequently presented:

The existing legal framework

Four main areas of concern presented in the assessment of the current legal provisions and their impact on oncology medicine distribution – listing of essential molecules, free-drug distribution, registration requirements and duration vis the procurement act. The registration of medications is generally viewed to be lagging with regard to listing of the most updated regimen for treatment of various cancers. As one respondent reports"

... targeted therapies that we're trying to get in that have been using the rest of the world for 10-12 years, because of the hoops that have to be jumped through PPB or whatever licensing body, it takes such a long time for you to get a drug licensed in this country or registered in this country.

Physician 2

The delayed registration of products is opined to impact on the ability of manufacturing companies to channel products through KEMSA thus impeding access of essential treatment particularly to public sector patients relying on the 12 cancer treatment centers in the country.

Secondly, as opined by three respondents' access to a free market impedes provision of quality medications particularly given the free-market allowed in pricing of medications and the requirements put forward in the procurement act. As one respondent surmises,

So, if company X is able to bring Sorafenib at half a million and a company like company Y or any other can demonstrate that they bring the same Sorafenib at probably quarter the price, then Y will be given a special import license to bring that product into the country.

Manufacturer rep 5

The concern of registration was similarly put forward by respondents viewing the existing laws to generally be redundant with regard to the treatment of cancer. In particular, the feels required for registration of product and inspection were deemed hindering to innovative companies that would otherwise set up shop with the aim of providing narrow-line remedies to address specialized conditions. The abundance of intermediaries involved in distribution owing to the free access model in the country was further blamed for the limiting prices in the market. As noted by one of the respondents:

So, if for instance, you have to pay regulatory fees, somehow, they still feed into the cost for the medication. If you have to do free shipment, verification ... so the time and the money actually also has to still feed into what the patients are paying. On the other hand, the no is that there is currently no price regulation in the country. So, to that extent, then it can be free for all. So, you can have your 30% markup, I can have my 15%, there is no one to police over us and tell us, "This is the price you can pay."

Manufacturing rep 9

With regard to registration requirements, one respondent provided the following analogy:

in our country, the registration is very expensive, and then also the inspection of the plant is also

very expensive, about $4,000 per plant. Per product is about $1,000 per product per molecule. So, if it is a tablet, 2 milligrams, that is different ... let's say tablet Panadol, 200 milligrams, is different, Panadol 500 milligram is different in registration. So, it adds on to the cost of the product to the patient.

Distributor rep 1

Stakeholder interests

The researcher sought insights on the manner though which stakeholders affected and were affected by the existing distribution mechanisms employed in the market. The various stakeholders on which respondents were required to comment were as follows – payers, patients, government agencies, physicians and pharmacies. Payers were generally viewed to be at the whims of activities perpetuated in the current drug distribution model in that they were forced to purchase drugs from an inefficient system generally hampered by inefficient delivery channels and high prices. As one respondent, in a representative observation notes:

So that is one, when NHIF says that patients can only get the product from KEMSA, or from the referral hospitals or from KNH, they don't even seem to really care if the product is available. So therefore, then the patient is

really disadvantaged by some of the policies that are made by the payers.

Manufacturing rep 2

The influence of the payers to the distribution model was considered married to their ability to leverage numbers and in consultation with the purchasing agent, KEMSA, lobby the high numbers for lower costs from manufacturers and to ensure efficiency in distribution of products. As noted by one respondent in a representative remark:

So, if they really have the interest of the patient at the center of everything they do, they would ensure and demand that, for instance, if these are oncology products, that they are available in each of the referral hospitals, where these patients would be able to get. And for proper month forecasting, then it would be like reverse engineering. So, the counties would come back to NHIF

and say ... Within NHIF in Nairobi County, for instance, we have 1,000 oncology patients. And these patients have fully paid up membership. And these patients reside in x and x places. So, for instance, then KEMSA would be able to deliver the product in Bahati.

Manufacturing rep 2

Patients were the least involved in the drug distribution model with their role relegated a passive one in that they are forced to bear with the inefficiencies of the system as dictated by intermediaries prone to increasing markups. Their level of advocacy was considered paired to their ability to organize and lobby in an effective manner. As noted by one respondent as echoed by four other respondetns:

For me, the easiest way to influence that is through patient groups. I have seen that there is a lot of voice when patients come together, and they demand for their rights. So, it's grouping patients together, and only the prescribers or the oncologists in this case when we're talking about cancer, can be able to somehow help the patients get into a patient group.

Manufacturing rep 2

Physicians were generally viewed as pivotal yet inexplicably uninvolved in shaping the drug distribution models. Their advisory positions in government agencies was viewed as pivotal in informing on the most effective approaches. Evidence of the ability of the stakeholder is provided by one respondent who notes with regard to avenues of influence by physicians:

... in advocacy groups to determine how drugs can be bought, like, two years ago, we had a problem with trastuzumab. So, through patient advocacy, we changed how some of the trastuzumab is bought from KEMSA to direct purchase. So, I think that that might be one of the ways they can influence the drug distribution.

Physician 2

As another respondent puts forward with regard to the ability of physicians:

They would, for instance in KNH for instance. So KNH, I know when they really want a product in the formulary, they will go over and above to make sure that it is there. Unfortunately, unless they do this as a society ... Societies can influence.

Manufacturing rep 1

Government agencies were deemed the most pivotal to the process as they were responsible for the setting of formularies (Ministry of Health) licensing and registration of drugs (PPB) and distribution of drugs (KEMSA). The bodies were however viewed to generally effect their mandate unsatisfactorily hence resulting in the cluttered drug distribution mechanism. Pharmacies were generally viewed to be linked with hospitals with regard to influence and impact unless a direct sourcing model was involved in the particular institution. With regard to the role of government agencies, one respondent notes:

I mean, if you look at pharmaceutical PPB, of course when it comes to government procurement, because PPB is a government institution and KEMSA is a government institution as well. So, in terms of processing, it is usually very easy when government is dealing to government. Just somebody somewhere will just make a call and things will move, as compared to private. The private ones, they have to follow what we usually call … they have to follow the process, that is one and also, they have to follow the times allocated for evaluation of their queries, for evaluation of their request, you know? As compared to when a government is dealing with government. Some of these timelines are usually revised and to the government they are usually very fast.

Manufacturing rep 5

CHAPTER FIVE

DISCUSSION CONCLUSIONS RECOMMENDATIONS AND LIMITATIONS

5.1 Introduction

The purpose of this chapter is to relate study findings with those put forward in extant literature and to expound on the utility and limitations of the findings in a practical context. The chapter is, to this end, delineated into five main sections – discussion of findings, conclusion, recommendations and limitations.

5.2 Discussion of findings

This section provides an exposition of study findings in accordance with the objectives of the study and in relation to existing pertinent findings. Each of the subsequent sections assesses a specific objective thus resulting in three subsections the first addressing the existing oncology drug distribution models, the second effectiveness of the models and the third a stakeholder-value-based model for efficient drug distribution.

5.2.1 Existing oncology drug distribution models

The main aim of a drug distribution model, as highlighted by Kumar et al., (2014) is to ensure that medication to patients in a manner that is rapid, continuous, and affordable. The various drug distribution models should thus primarily address these three concerns within their markets. The three targets of drug distribution are however shaped, as stipulated by the theory of supply and demand, by the specific forces shaping the value of products and their accessibility to patients. The drug distribution models applied thus provide insights on the balance of play between supply-side and demand-side factors even though the end target of these models is to ensure access of medication to clients in a manner that is in keeping the aforementioned three principles of drug distribution.

The study findings revealed that reduced wholesale agreements were the most prevalent in the distribution chain whereas direct from manufacturer options were the least utilized. Reduced

wholesale arrangements involve the distribution of medicines through a pre-identified narrow set of distributors in the bid to leverage the efficiencies of the identified distributors. Direct sales from manufacturers involve channeling of medications from manufacturing entities straight to retailers for final consumption by patients (Walter, Dragosits and Said, 2012).

The choice of reduced wholesale agreements was informed by the interplay between interests of the two parties – the manufacture, seeking to achieve business advantage sought to leverage direct connect with manufacturers to ensure reliable availability of product at reasonable costs whereas the manufacturer, through leveraging the wholesalers grip on the markets in question, sought to find steady and ready market for produce.

Kumar et al (2014) argue that the delineation in functions involved in the distribution of medication to patients allows for optimization of the entire distribution mechanism. This proper delineation of function was lacking and particularly so with regard to the payment process following delivery of produce to the patients. The lack of a systematic payment process as would be the case with a unifying insurance body was lacking at the hospital setup whereas some patients paid for the produce through out-of-pocket approaches whereas some, the minority, paid through insurance agencies.

The payment process thus resulted in wholesalers socking only what they could sell with manufacturers providing only what they were paid for. A short-line kind of approach is thus employed by most wholesalers with the primary interests of those involved being the attainment of profit for their product. The eventual situation was thus a lack of overall efficiency in the process of making the medications accessible to needing patients. This observation was in keeping with Kumar et al.'s (2014) view that less developed healthcare systems, as is typical of the Kenyan market, are characterized by inefficient systems that result in high expenditure for patients.

5.2.2 Effectiveness of the models

An assessment of the efficacy of the extant models vis-à-vis sourcing of response indicated a general leniency, among manufactures, towards positive assessment of models in existence, regardless of the particular model. More tellingly however, was the observation that of the five responses indicating that the current distribution models were not effective, only one emanated

from a manufacturing company whereas three emanated from physicians. Given that physicians have direct access to patients are well positioned to understand the implications of the pricing mechanisms to users of the drugs, one my surmise that there is a clear disconnect between the market needs and the market solutions currently employed by the distribution companies. Further to this point is the observation that despite positive review of existing models by manufacturers, responses on the affordability of the drugs painted a picture of overwhelming unaffordability of the product. The finding thus points to a resignation, among manufacturers, that the status quo is satisfactory hence pointing to the self-serving nature of the currently proposed delivery systems. This observation makes a strong case for the need for a collaborative multi-stakeholder approach to assessment of the most efficacious approaches that can be employed to construct a more impactful drug distribution channel; this concern is addressed in the subsequent objective.

Two models of distribution were apparent – the public and private route. Assessments of the two approaches appeared divergent with the public route, effected through KEMSA, generally termed less expensive but markedly inefficient in terms of product delivery. Despite the prevalence of the reduced wholesale arrangement, direct sales from manufacturers and short-line wholesaling approaches were also reported common models. KEMSA played the biggest role in distribution of medication to facilities in the country with other players like MEDS and private wholesaling entities supplementing the process. KEMSA however appeared to contribute to inefficiencies in the distribution process by requiring public hospitals to source directly from the entity as a requirement of regulations with alternative sourcing of produce requiring authorization prior. The frequent shortages and delays in delivery thus resulted in the seeking out of the alternative delivery approaches – direct sales from manufacturers and short-line wholesaling. It was thus apparent that strengthening of the single-sourcing approach through KEMSA would allow for increased preference of the reduced wholesale armament with further optimization of the system through collaboration with such pertinent entities as NHIF possibly resulting in the crafting of a GRIPS-like entity within the region.

Walter, Dragosits and Said (2012) argue that the most important factor in crafting an effective medicine distribution channel is to ensure a streamlining of the various functions involved in the distribution process. The current situation in the local market, as evidenced by the preference of a reduced wholesaler arrangement model is that no single entity has been able to orchestrate the

various functions involved in availing medication of to needing patients. This preference of different wholesalers by different manufacturers thus contributes to a fragmentation of the market – a fragmentation that has direct implications on the prices assigned to the various drugs in the market (Kanavos, Schurer & Vogler, 2011).

5.2.3 A stakeholder-value-based model for efficient drug distribution

5.2.3.1 Proposed structuring of the distribution model

The relationship between the various players in the industry is captured in a item cluster computed by word density (figure 4.4). The relationships thus indicate a divergence of interest between three groups – Government agencies, patients and payers, and pharmacies and physicians.

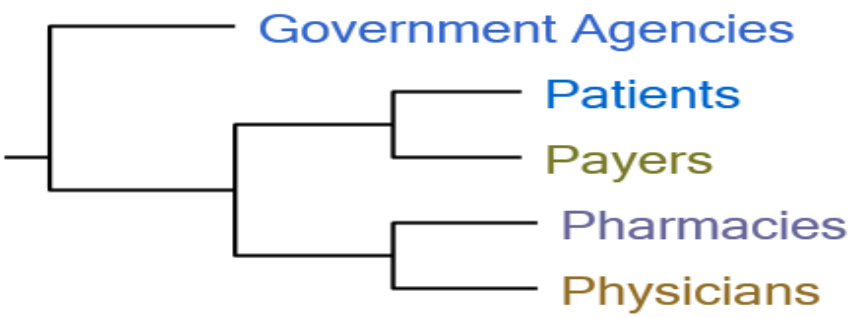

Figure 5.1 Stakeholder clustering by word density

The generally inferences, as put forward with supporting evidence from previous sections, is that the interests of the various stakeholders are generally fragmented. An ideal model would therefore begin by addressing the stakeholder interests in the bid to structure laws in regulations that address these interests preferably with the patient's concerns at the root of all laws but with sufficient consideration of the priorities of other stakeholders. To assess the emergent themes put forward

by the various stakeholders, a word-density search was performed with the aim of gauging convergence in focus between the stakeholders. Figure 4.5 provides the findings.

Figure 5.2 World Cloud

Findings thus indicate the pivotal role played by patients as viewed by all stakeholders in the industry. The proposed model is thus as depicted in figure 4.6. The ministry plays the role of creation of regulations following consultations with all stakeholders in the industry. This includes

decisions on essential medicines as informed by stakeholders. The laws are then effected by PPB and KEMSA with PPB responsible for registration and licensing and KEMSA sourcing of produce from manufacturers. The four agencies are involved in constant exchange of information regarding new remedies and formularies. KEMSA then distributes products to private and public facilities in a pull model dictated by information exchange with the NHIF. The NHIF by leveraging industry information decides on premiums and compensation plans in collaboration with the four aforementioned bodies and as advices by patients and patient advocacy groups. The process then delivery of produce to patients through public and private facilities.

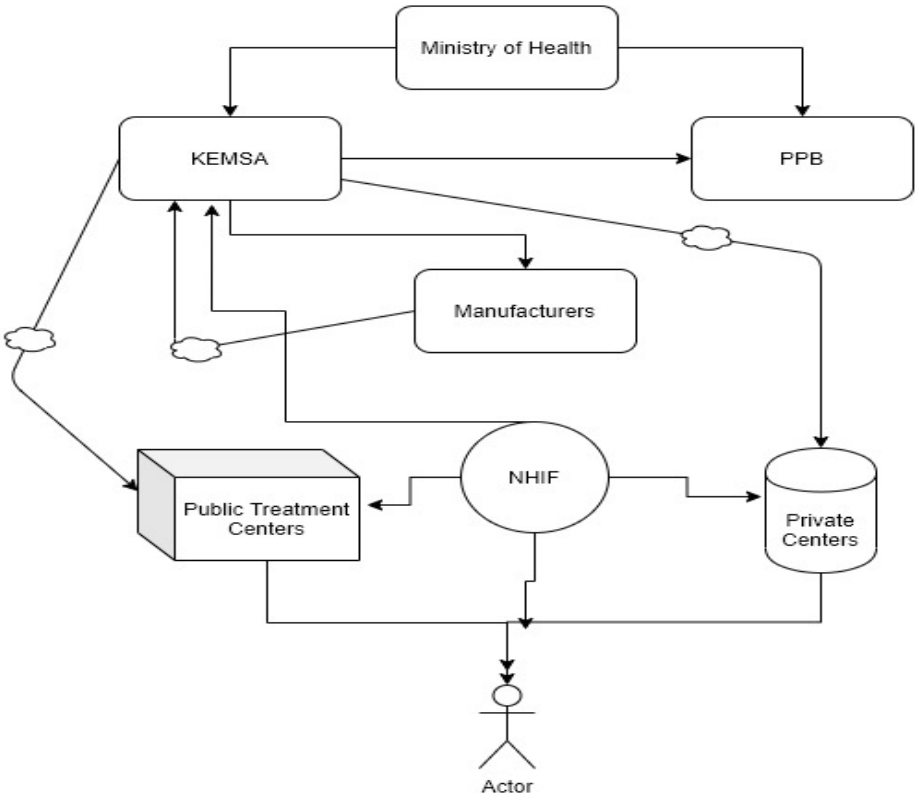

Figure 5.3 Emergent framework

As is evident from the forgoing discussion there is a clear inefficiency in distribution models; an inefficiency with sharply contrasts with the high-demand of the marginalized market. The inefficiency is apparent in all three of the characterizing factors of an efficacious drug distribution model – rapidity, continuity and affordability (Kumar et al., 2014). Moreover, also apparent is the divergence of and fragmentation of interests among and between stakeholders in the industry. listing of essential molecules, free-drug distribution, registration requirements and duration vis-à-vis the procurement act. The registration of medications is generally viewed to be lagging with regard to listing of the most updated regimen for treatment of various cancers. The overall effect of the challenges of the system was most apparent for payers and subsequently for patients. Payers were generally viewed to be at the whims of activities perpetuated in the current drug distribution model in that they were forced to purchase drugs from an inefficient system generally hampered by inefficient delivery channels and high prices – prices that are then transferred to patients in the event that the payer is an intermediary e.g. a hospital or an insurance agency.

Meijboom and Obel (2007) in assessing ideal pricing for manufacturing companies involved in global distribution of products opines that the ideal structuring results in the recouping of expenditure incurred in high-tax areas through offsetting losses by gains in low-tax areas. Findings from the current study indicate that the practice is already in effect among manufacturing firms the aim of the programs reported to be the circumventing of regular channels thus allowing for cheaper products to be availed to the financially marginalized individuals. The approach was however deemed less effective than a far-reaching GRIPS-like model that would leverage the economies of scale and single sourcing ability of such an entity to make the case for cheaper medication for patients in the region.

As alluded to in the foregoing discussion on manufacture interest in the space, current models primarily seem to meet the needs of the manufacturer while seldom addressing those of other players in the industry, most notably, of the patients after whom the system should be crafted. The shortfall in the current distribution models stem primarily from the inefficiencies introduced by a

lack of clear demarcation of player and roles involved in the distribution function and the lack of a single-unifying entity charged with the role of orchestrating the various functions of service provisioning in the oncology drug distribution space. KEMSA emerges as the currently best-positioned entity in the bid go achieve a GRIPS-like approach to service deliver.

5.3 Conclusion

In summarizing the inferences emanating from analysis of the data in line with the study objectives it is apparent that the three models in use are reduced wholesaler arrangements, direct sales from manufacturers, and short-line wholesaling; this finding addresses the first objective of the study. With regard to the second addressing the efficacy of the current models, it is apparent that there is a disconnect between stakeholders whereby manufacturers deem the systems more favorably than other stakeholders in the industry. However, assessing solely on account of the rapidity of delivery, continuity of supply and pricing of product, the systems can soundly, on the broader-scale, the consider ineffective. Finally, with regard to the final objective, assessing the structuring of a stakeholder-value-based model for effectively scaling up delivery, it is apparent that the current approaches are insufficient vis-à-vis the intended aim of deliver of produce without debilitating financial consequences to patients.

5.4 Recommendations

The main recommendation forthcoming from the study is that there need be a consideration of a unifying drug distribution model that has its roots founded in policies and that is championed by government. The study thus primarily provides evidence form the need to reconsider current policies and to construct new policies that address the need for a single-source-based market distribution model. To manufacturers, the researcher recommends reconsideration of the metrics used in assessment of the efficiency of their current framework; it is apparent that there is a disconnect between their conceptualization of what constitutes efficiency and that needs of the market. Thirdly, to all stakeholders in the industry, the researcher recommends dialogue and collaboration in the bid to find more effective ways to service the populace and the contemplation of the plight of the populace as the central driving force for drug distribution models.

To academicians and possibly policy makers, the researcher proposes a more efficacious structuring of the drug distribution model, tailored to the Kenyan context – a model crafted through the leveraging of insights from the foregoing discussion. Findings indicate the pivotal role played by patients as viewed by all stakeholders in the industry. The proposed model is thus as depicted in figure 4.6. The ministry plays the role of creation of regulations following consultations with all stakeholders in the industry. This includes decisions on essential medicines as informed by stakeholders. The laws are then effected by PPB and KEMSA with PPB responsible for registration and licensing and KEMSA sourcing of produce from manufacturers. The four agencies are involved in constant exchange of information regarding new remedies and formularies. KEMSA then distributes products to private and public facilities in a pull model dictated by information exchange with the NHIF. The NHIF by leveraging industry information decides on premiums and compensation plans in collaboration with the four aforementioned bodies and as advices by patients and patient advocacy groups. The system then facilitates delivery of produce to patients through public and private facilities.

5.5 Limitations

Two main challenges present as limitations to the current study – limitation in generalizability of findings and possible underrepresentation of stakeholders in the industry. With regard to the first, the researcher employed a qualitative approach centering on the insights of market experts and practitioners; these were engaged through interviews. Statistical limitations of the study design limit the scope of the findings in that though useful in expounding on the entails of drug distribution in the region, the findings cannot, with statistical validity, be generalized to the entire population. Similar studies crafted after a quantitative approach should be considered in future research. Secondly, the restrictions of the Covid 19 lockdown prevented the researcher from reaching as many respondents as earlier intended. The researcher was, in particular, unable to reach patient representative groups hence inferences were made form the views of other stakeholders in the industry. Subsequent studies in similar areas of study should thus consider a broader respondent representation in constitution of datasets.

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APPENDIX I: INFORMATION SHEET

2.1: Why is this study being carried out?

This study is being carried out to assess the entails of drug distribution models particular to cancer medication disseminating in Kenya. The researcher wishes to gain insights on the dynamics around selection and efficiency of models so as to infer the ideal structuring of a pricing model applicable to the Kenyan context.

2.2: Do I have to take part?

No. Taking part in this study is entirely optional and the decision rests only with you. If you decide to take part, you were interviewed to get information cancer drug pricing models in Kenya. If you are not able to answer all the questions successfully the first time, you may be asked to sit through another informational session after which you may be asked to answer the questions a second time. You are free to decline to take part in the study from this study at any time without giving any reasons.

2.3: Who is eligible to take part in this study?

- Novartis, Roche, Astrazeneca, KEMSA, MEDS ,Cancer centre heads (KNH, Texas Cancer Centre) staff with experience in drug distribution apparatus.

2.4: Who is not eligible to take part in this study?

- Patients.

2.5: What will taking part in this study involve for me?

You were approached and requested to take part in the study. If you are satisfied that you fully understand the goals behind this study, you were asked to sign the informed consent form (this form) and then taken through an interview.

2.6: Are there any risks or dangers in taking part in this study?

There are no risks in taking part in this study. All the information you provide were treated as confidential and will not be used in any way without your express permission.

2.7: Are there any benefits of taking part in this study?

The information were used provide theoretical understanding of the machinations of drug distribution models. The information resulting from the study is thus of value to individuals seeking to understand the pricing mechanisms associated with drug distribution models.

2.8: What will happen to me if I refuse to take part in this study?

Participation in this study is entirely voluntary. Even if you decide to take part at first but later change your mind, you are free to withdraw at any time without explanation.

2.9: Who will have access to my information during this research?

All research records were stored in securely locked cabinets. That information may be transcribed into our database, but this were sufficiently encrypted and password protected. Only the people who are closely concerned with this study will have access to your information. All your information were kept confidential.

2.10: Who can I contact in case I have further questions?

You can contact me, Romeo Olwal, at SBS, 0725803156.

I, _____, have had the study explained to me. I have understood all that I have read and have had explained to me and had my questions answered satisfactorily. I understand that I can change my mind at any stage.

Please tick the boxes that apply to you;

Participation in the research study

I AGREE to take part in this research

I DO NOT AGREE to take part in this research

Storage of information on the completed questionnaire

I AGREE to have my completed interview stored for future data analysis

I DO NOT AGREE to have my interview stored for future data analysis

Participant's Signature: Date:

_____ _____/_____/_____

DD / MM / YEAR

Participant's Name: **Time: _____/_____**

_____

(Please print name) ***HR / MN***

I, _____ (Name of person taking consent) certify that I have followed the SOP for this study and have explained the study information to the study participant named above, and that she has understood the nature and the purpose of the study and consents to the participation in the study. She has been given opportunity to ask questions which have been answered satisfactorily.

Investigator's Signature: **Date:**

_____ _____/_____/_____

DD / MM / YEAR

Investigator's Name: **Time: _____/_____**

_____

(Please print name) ***HR / MN***

APPENDIX II: INTERVIEW PROMPT

This interview prompt contains questions relating to the drug distribution models employed in dissemination of cancer medication in Kenya.

MODEL SELECTION

Models utilized in distribution of cancer medicines

Four pricing models typify the distribution of medication:

Short-line wholesaling – Organization supplies a specific set of drugs to wholesalers.

Direct sales from manufacturers – The manufacturer although employing intermediaries in distribution of medication, maintains ownership of the drug up until sale to retailers.

Reduced wholesale arrangements – The organization works with a select number of wholesalers to distribute the drug.

Direct to pharmacy – The manufacturer assumes all distribution roles culminating in delivery to the final retail pharmacy.

If any, which of these four models typifies the distribution of oncology medication in Kenya?

If your company employs a different approach to the distribution of medication, kindly elaborate on the entails of the approach.

EFFECTIVENESS OF DISTRIBUTION MODEL

Kindly comment on the effectiveness of your current distribution model as pertains to the distribution of oncology medicine

Kindly describe an ideal distribution model in light of the UHC goal of ensuring minimization of expenditure for patients.

STAKEHOLDER INTEREST AND IMPACT

How are payers, e.g. directly or through insurance agencies or donor services, affected by the selection of drug distribution models?

How do payers, if at all, influence the efficiency of drug distribution models? Kindly elaborate on your answer.

How are patients affected by the selection of drug distribution models? Kindly elaborate on your answer.

How do patients, if at all, influence the efficiency of drug distribution models? Kindly elaborate on your answer.

How are pharmacies affected by the selection of drug distribution models? Kindly elaborate on your answer.

How do pharmacies, if at all, influence the efficiency of drug distribution models? Kindly elaborate on your answer.

How are government agencies affected by the selection of drug distribution models? Kindly elaborate on your answer.

How do government agencies, if at all, influence the efficiency of drug distribution models? Kindly elaborate on your answer.

Does the current regulatory environment of the pharmaceutical industry impact on the pricing of oncology medication? Kindly expound on your answer.

Kindly comment on the implementation of laws within the pharmaceutical industry of Kenya with respect to the pricing models applicable to oncology medication.

The underlying assertion of the UHC goals is that all individuals should have access to medical care without debilitating financial consequences. With respect to this assertion, how does the current regulatory environment impact the availability of oncology medication?

How are physicians affected by the selection of drug distribution models? Kindly elaborate on your answer.

How do physicians, if at all, influence the efficiency of drug distribution models? Kindly elaborate on your answer.

PRICING OF MEDICINES

Is the pricing of oncology medications in Kenya similar to that in other countries in the region? If there is a difference, kindly elaborate on possible reasons behind your observation.

Is the pricing of oncology medications in Kenya similar to that in such industrialized nations as the United States? If there is a difference, kindly elaborate on possible reasons responsible for the difference.

Is the pricing of oncology medications in Kenya similar to that in such developing nations as India? If there is a difference, kindly elaborate on possible reasons responsible for the difference.

How would you categorize the general affordability of oncology medication to the populace of Kenya? Kindly expound on your answer and reasons for your answer.

Thank you for taking part in this study.

APPENDIX III: ETHICAL APPROVAL

Strathmore UNIVERSITY

31st March 2020

Mr Olwal, Romeo
olwal.romeo@strathmore.edu

Dear Mr Olwal,

RE: Assessment of Effectiveness of Existing Oncology Medicines Market Access Strategies and Proposed Expansion Model for The Kenyan Market

This is to inform you that SU-IERC has reviewed and **approved** your above research proposal. Your application approval number is **SU-IERC0706/20.** The approval period is **31st March 2020 to 30th March 2021.**

This approval is subject to compliance with the following requirements:

i. Only approved documents including (informed consents, study instruments, MTA) will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by SU-IERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to SU-IERC within 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to SU-IERC within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to SU-IERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

for: Dr Virginia Gichuru,
Secretary; SU-IERC

STRATHMORE UNIVERSITY INSTITUTIONAL ETHICS REVIEW COMMITTEE (SU-IERC)
31 MAR 2020
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NAIROBI - KENYA

Cc: Prof Fred Were,
Chairperson; SU-IERC

APPENDIX IV: NACOSTI PERMIT

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **970595**

Date of Issue: **09/April/2020**

RESEARCH LICENSE

This is to Certify that Mr.. ROMEO OLWAL of Strathmore University, has been licensed to conduct research in Nairobi on the topic: ASSESSMENT OF EFFECTIVENESS OF EXISTING ONCOLOGY MEDICINES MARKET ACCESS STRATEGIES AND PROPOSED EXPANSION MODEL FOR THE KENYAN MARKET for the period ending : 09/April/2021.

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