

AN ECONOMIC ANALYSIS OF RETAIL PHARMACEUTICAL MARKET IN
NIGERIA: TOWARDS ACCESS EXPANSION AND POLICY

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A thesis submitted in partial fulfilment of the requirements for the degree of Doctor
of Philosophy

Institute for International Health and Development

QUEEN MARGARET UNIVERSITY, EDINBURGH

2014

DEDICATION

To Aondokator, Yohane and Yuana, you seeded the inspiration.

ABSTRACT

Rural areas in much of sub-Saharan Africa access needed health care from untrained and often poorly regulated drug vendor shops with concerns over the quality of products and services provided and their public health implications. The thesis undertook to understand market relationships in a rural retail drug market in the light of the structure-conduct-performance paradigm and isolate opportunities for potential policy interventions for improved access to quality and safer medicines.

Data was collected from a sample of patent medicine vendors and drug purchasers in Katsina-Ala Local Government Area of Benue State, north central Nigeria, over 9 months in 2012. Information from drug vendors and drug consumers was generated through semi-structured questionnaires, in-depth interviews and systematic business transaction observations. Key state and national drug regulatory officials were also interviewed in-depth and related documentary data collected and evaluated. Data analysis focussed mainly on the relationships between market structure, provider conduct, consumer behaviour and the nature of regulation, with the aim of understanding market performance in relation to access to medicines and their rational use.

The study established that patent medicine vendors were an important source of medicines for inhabitants of the local government for ambulatory primary health care. Drug retailers were said to be a reliable source of a wide range of drugs provided at relatively more affordable prices and in a convenient way that satisfied consumer expectations. However, a number of market failures existed: low quality of treatment due to poor provider knowledge of diseases and drugs and therefore inappropriate prescription and dispensing practices. Ineffective regulation was also demonstrated by way of inappropriate and inadequate regulatory regime, occasioned by wide spread regulatory infractions.

To attain the desirable public health objective of sustained improvement in the quality of products and services obtainable at patent medicine vendor outlets, regulatory strategies must be contextually relevant, providers must be trained and offered financial and business incentives and consumers must be empowered by accessible and timely health information for informed choices against the backdrop of strengthened and better incentivized inspectorate unit in a systematically intertwined approach.

ACKNOWLEDGEMENTS

The field research component of this thesis was made possible by support from the Social Science Research Council's Next Generation Social Sciences in Africa Fellowship, with funds provided by Carnegie Corporation of New York.

I most thankfully acknowledge my supervisor Professor Barbara McPake, whose excellence in learning and wholehearted guidance has left indelible influence on my intellectual development. I thank my co-supervisor Professor Sophie Witter for her invaluable contribution in the conclusion of this thesis.

Very deep gratitude to my lifelong friend Hon. (Dr) Donald Ayargwer Tsetim and Mrs Gertrude Ayargwer for the love and warmth and providing me a home during the field work. I am extremely grateful also to my good friend Mr and Mrs Terna Segher, God used you when it mattered the most.

I'd like to thank my Auntie, Lady Lucy Ato (KSJ) for her love, understanding and the invaluable support she gave in material and psychological terms. You are truly one of the finest breed and your kind are far-between. I acknowledge Mr Hingya Biem for his generous financial assistance which hugely facilitated the completion of this work.

I specially appreciate my spiritual friend, Rev. Fr. John Ikponko, who gave financially and most importantly, supported me spiritually. Mr Bernard Makir's principled stance, understanding and goodwill were highly encouraging and are appreciated.

This project wouldn't have been a success without the hugely significant roles, steadfast love and encouragement of the Shaatsors, the Agbers, the Ikpoms and the Uyinas. Joyce Davieson and Mrs Dele Adegunloye deserve special recognition for making the years in Edinburgh home away from home. My appreciation are also due to Dr. Terver Agega, Eng. and Mrs Nongo and Alex Anderson.

The author thanks the many people who provided information and assisted with this research particularly the officials and members of the National Association of Patent

and Proprietary Medicine Vendors of Nigeria, Katsina-Ala Chapter, who graciously welcomed the author, and cooperated in the activities of the field work. Likewise the roles of Head of Department of Health, Katsina-Ala Local Government Area and Mr Abaki are recognised. Every participant in the research process is preciously acknowledged.

Finally, I have also benefited immensely from staff and colleagues at the Institute for International Health and Development, Queen Margaret University Edinburgh, who have enriched the content of this thesis in numerous ways.

ABBREVIATIONS

AHWO	African Health Workforce Observatory
CMH	Commission on Macroeconomics and Health
CPC	Consumer Protection Agency
FMOH	Federal Ministry of Health
HERFON	Health Reform Foundation of Nigeria
IFC	International Finance Corporation
ISEqH	International Society for Equity in Health
MSH	Management Sciences for Health
NAFDAC	National Agency for Food and Drug administration and Control
NAPPMED	...	National Association of Patent and Proprietary Medicine Dealers of Nigeria
NDLEA	National Drug Law Enforcement Agency
NDHS	National Demographic Health Survey
NPHCDA	...	National Primary Health Care development Agency
NSHDP	...	National Strategic Health Development Partnership
NHIS	National Health Insurance Scheme
PCN	Pharmacists Council of Nigeria
SEAM	Strategies for Enhancing Access to Medicines
SCORE	Strategic Council on Resistance in Europe
SHOPS	...	Strengthening Health Outcomes through the Private Sector
WHO	World Health Organization

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CHAPTER 1: THESIS BACKGROUND

1.1 Introduction

Health is central to human existence and a critical determinant of value of human life, as evidenced in the millennium poll in which all peoples of the world consistently ranked good health a top priority. This poll was the largest public opinion survey ever, and sought to know global hopes and expectations about the role of the United Nations in the future (UN 2000). In the same line of thought, good health is adjudged the most basic element for personal and economic development, poverty reduction and an indispensable cornerstone (with education) for human beings to develop intellectually, emotionally and physically (WHO 2000). For societies broadly, improved population health status has been shown to positively correlate with economic growth and sustainable development. It is not therefore random occurrence that most of the classical breakthroughs in economic history too, have closely followed major breakthroughs in disease control, health technological advances and improved nutrient intake (WHO 2000). In pragmatic terms, the industrial revolution in Britain and Europe in the nineteenth Century, the phenomenal growth of the Japanese economy and the meteoric rise of the Asian tigers in the twentieth Century, all exemplify the instrumental role of improved population health to sustainable social and economic development.

Ill-health on the other hand imposes considerable costs on individuals and societies: it narrows annual incomes of societies, diminishes life-time incomes of individuals and households and jeopardizes the prospects of economic growth and development (CMH 2001). These losses are particularly large in low income countries (who harbour over 25% of the global burden of disease), and contribute substantially to erosion of GNPs annually (CMH 2001). The psychological impacts of ill-health, mortality and morbidity are less understood, but certainly contribute quite considerably to the overall losses.

Ill health does not only impose financial and psychological impacts, it breeds social instability. Poor health status of peoples has been identified as a key predictor of

state failure through civil wars, military coups or other means (CMH 2001). Conflicts reciprocally impose deleterious consequences on health by causing premature deaths and lifelong disabilities through disruption of economic and social infrastructure deployed to meet health needs, and the forced diversion of economic resources preferentially to defence instead of health (MacQueen and Santa-Barbara 2000; Wossen 2011). Disease agents are invested with borderless potentials: they permeate social class boundaries and diffuse national and continental borders without let.

Therefore, disease control efforts now occupy top priority in all societies and world leaders have in diverse ways and at different times acknowledged this interdependence in various declarative instruments. One such declaration is the recent Millennium Development Goals (UN 2000; WHO 2010a). The initiative encapsulated an unprecedented commitment by heads of governments to comprehensively address peace, security, development, human rights and fundamental freedoms the world over (UN 2000). While focusing on poverty reduction generally, the Millennium Development Goals (MDGs) embed a series of health goals. These are MDG4, which seeks a reduction of under-five mortality by two-thirds of 1990 level by 2015; MDG5, targeting a three-fourths reduction in maternal mortality levels of 1990 by 2015 and MDG6, which purposes to halting and begin reversing the rising prevalence of HIV/AIDS, tuberculosis and other major disease no later than 2015.

Evaluating progress made towards achieving the MDGs following a decade of implementation, world leaders unanimously expressed lack of satisfactory progress (UNDP 2011; WHO 2010a). They noted that majority of goals will not be met by 2015 and that progress was unevenly distributed across countries and regions. The meeting especially observed that slow progress had been made towards some goals and indeed a few goals were on a regressive trajectory particularly in sub-Saharan Africa (Congressional Research Services 2010; WHO 2010a). More recently, the UNDP (2013), has also reported progress in all health care dimensions of the MDGs, noting however insufficient gains in some other areas mostly in Africa. Two themes

dominated these related analyses, the notions of health systems weakness and constrained access to health care services.

All countries at all levels of development are striving towards universal health care coverage as an end (Atun et al. 2013; Evans et al. 2012; McKee et al. 2013; Palmer 2014; WHO 2011), with varying degrees of successes. Sub-Saharan Africa, which harbours about 25% of the world's disease burden, is estimated to achieve only 5-10% health care services coverage (WHO 2010b). This low population coverage of essential health care services also reflects Africa's score card when viewed through the MDG benchmarks. This state of affairs has been attributed to health systems weakness of the component countries (WHO 2010b). In particular, Nigeria, Africa's most populous and one of the most influential member country, continues to bear a heavy disease burden and serves a typical illustration.

Assessing Nigeria's health metrics against the MDGs benchmark one notes that the country has generally not made significant progress (FMOH 2013; WHO 2010a). Nigeria has under 5 mortality rate of 201 per 1000 live births, which exceeds for example, the African average of 145/1000 live births (AWFO 2008; World Bank 2012). This level is even higher than its own score on the same variable of 189 per 1000 live birth in 2003 (WHO 2006b; WHO 2010a). The country has in real terms regressed on this target. Maternal mortality has not changed from its year 2000 value of 800 per 100,000 live births (UNDP 2013). That nothing has changed on this indicator despite the over ten years of implementation means that more has to be done in relation to MDG5. This also puts the country in the league of countries in the world with the largest number of maternal deaths, second only to India globally (UNFPA 2011). Appraisal of progress on MDG6 reveals that the prevalence of HIV among adults age 15-49 is 3.7%, down from a level of 5.4% in 2000 (World Bank 2012; WHO 2006b). However, less than 20% of infected patients are able to access antiretroviral medicines. In addition, tuberculosis has remained prevalent at 546 cases per 100,000 of the population compared to 491 per 100,000 population in 2000 (AHWO 2008; WHO 2010a). The country has not made clear progress with the non-health related MGDs either. Taking MDG1, which seeks to eradicate poverty and hunger for example, Nigeria is categorised among countries that have made

insufficient-progress on the continent. The indicator for this goal reveals that 28.7% of her under-five population are moderately to severely malnourished (WHO 2010a). This value does not significantly deviate from year 2000 level of 29% (WHO 2006b), and 26.7%, reported by the World Bank (2012) for 2008.

This evidence supports the conclusions that Nigeria is not making a steady progress towards meeting the MDGs, which portends severe implications for its population health status by 2015. The irony of this low health sector score card is the rapid economic development that has occurred in the country over the same period examined. Economic development and by extension wealth, is the singular most important influence in health care provisioning (Musgrave et al. 2002). Since the 1980s, oil production has grown in leaps and bounds and has attained commanding heights in Nigeria's economic arena. To date oil sales account for more than two-thirds of the gross domestic product and the resultant high profits provide over 80% of government's total revenues (AHWO 2008). Similarly, the period 1999-2003, saw the government vigorously implement a policy of privatization of public enterprises, targeted at helping to create an enabling economic investment climate and yielding additional revenues for provision of social services (Zayyad 2007). This policy direction has led to improved performance of the domestic economy, as reflected in the steady rise in GDP from a level of 2.7% in 1999 to 5.3% currently and its subsequent re-classification as lower middle income country (World Bank 2013). Impact of this enhanced economic performance of the economy on health expenditure saw a nominally increased sectoral budgetary allocation, which marginally increased the health budget as percentage of national budget. Practically, this has seen the health budget increase from 3.2% to 4.1% of national budget in 2003 and 2010 respectively (FMOH 2011). There is however, no empirical evidence to conclude that this additional budgetary allocation has impacted positively on the health status of Nigerians. Admittedly, the government had implicitly underscored this position, but stressing that the key obstacle to improved health outcomes in the country remains a weak health system incapable of sustaining adequate access to needed health care services for all Nigerians (FMOH 2011). Understanding the dynamic undercurrents that have shaped the country's health landscape as profiled requires a detailed description of Nigeria, its population health status and the health

system development, from earliest available records to date and is undertaken in section 1.2 below.

1.2 Nigeria: Background information

Nigeria is located between longitudes 40° and 140° north of the equator and latitude 30° and 140° east of the Greenwich meridian. It is bounded in the north by Niger and Chad Republics, and sits on about 800 kilometre stretch of the Atlantic Ocean in the south. The Republics of Cameroun and Benin defines its eastern and western frontiers respectively. The country has an area of 923,768 square kilometres and a population of 140, 431, 790 million, projected to reach the 240 million mark by 2015, at current growth rate of 3%. About 70% of this population is rural and 30% urban (National Population Commission 2006).



Fig 1: Nigerian map showing key towns and international boundaries. Source: Google Maps.

Nigeria is endowed with vast natural and human resources which have remained largely untapped. The major revenue earner is crude oil export, though about 70% of its population are rural farmers. The discovery of commercially viable deposits of

crude oil in 1970 marked a watershed in the economic life of the country, which ranks as the world's sixth largest producer and to date it has raked about \$340 billion in revenues (McKinsey 2010). This unique resource endowment has naturally conferred on Nigeria, a dominant advantage over and above its West African league of countries, accounting for over 50% share of the West African economy (Club du Sahel 2001), yet poverty still plagues about 50% of the population (World Bank 2013).

Similarly, these vast natural resource endowments have also not translated into a commensurate improvement in the health levels of the larger population. The country's health care system remains weak and incapable of providing needed services (FMOH 2011; WHO 2008). This weakness has persisted despite five attempts to reform and realign the national health system towards enhanced productivity (Asuzu 2004). The health terrain is characterised by a heavy and increasing disease burden (old, new and re-emerging), and ill health remains widespread. The country has total health expenditure per capita of US\$80 (World Bank 2013), which makes it one of the lowest in the world and over 95% of private health care purchasing is out-of-pocket type (World Bank 2013; WHO 2010c). This form of health care purchasing is known to impose catastrophic consequences on households. It is also unfair, inequitable and exclusive (World Bank 2006; WHO 2010b). In this challenging circumstance, the poor and vulnerable have fared worse, bearing disproportionately high burden of the costs of health care (WHO 2010b). They thus have become the least healthy, with the most need, yet least able to access health services (O'Donnell 2007; WHO 2001; Castro-Leal et al. 2000; Filmer 2004). The gap between public supply of health services and the population's needs for health care has resulted in a highly pluralistic health system, with private and non-governmental organisations filling up the health services demand lacunae (Bloom et al. 2008; Bustreo 2003; Smith et al. 2004; Federal Government of Nigeria 2007a).

Private health markets are a rising phenomenon in Nigeria (and across most of Africa) and are widely used even by the poor (Arnab et al. 2008). The private sector provides 80% of health care services in Nigeria (Federal Government of Nigeria 2007a). The most basic unit (micro-anatomy) of the private health sector is

represented by individual medicine sellers and a particularly important pharmaceutical entrepreneur in this respect is the retail drug vendor, popularly referred to as patent medicine vendor who own and run static drug shops on profit basis. These small non-prescription drug merchants have become important primary sources of most health care services in rural and even urban areas in Nigeria (Oladejo et al. 2005; Salako et al. 2001). This general picture does not however account for how or why the health sector in Nigeria has developed in this way. Understanding these evolutionary trends in a clearer and systematic way mandates a historical analysis of the national health system development, which follows in the subsequent section.

1.3 History of the Nigerian Health Sector

This section undertakes a detailed historical review of development of the national health system in Nigeria. The period is chronologically divided into two distinct but naturally overlapping eras of colonial times and independence and self-determination. Broad overviews of the relevant social, political and economic influences that combined to shape the health landscape of the country are highlighted, while key issues are explored in-depth.

1.3.1 Pre-independence era

This era spans the period beginning from the informal pre-colonial slave trading along the coastal areas (about middle of the nineteenth century), to independence in 1960.

Available documents argue that the arrival of Western type health care in Nigeria paralleled the advent of the slave trade in the 19th century (Schram 1971). European slave masters included health personnel on board slave ships, who provided health care for their staff on board. The ship doctors offered exclusive services to expatriate ship staff and valuable commercial slaves held in transit fortresses along the Nigerian coast. The indigenous populations inhabiting these coastal areas were not allowed access to this orthodox health care.

The end of slave trade witnessed a burst of interest and influx of European religious missions and trading organizations into the coastal fringes of Nigeria. While the latter traded along the coastal areas, the missionaries ventured deeper into the hinterlands and along with proselytizing, built hospitals, clinics and dispensaries in their host communities. However, it was the pecuniary activities of European traders that caught the attention and interest of the Government in London, culminating in the establishment of formal colonial administration in Nigeria in 1861. With the unfolding of these events, came the formal commencement of a western-type health care system development in Nigeria: Missioners on one side and the Colonialists on the other. Colonial efforts to provide health care began in the coastal areas and specifically, the administrative epicentres of Lagos and Calabar. Access to the health services provided by the colonialists were for many years restricted to Europeans, and later expanded to incorporate African staff of European organizations, which contrasted the community focussed efforts of the Missionaries.

Comparatively, both the missionaries and the colonial administration had conceptualized similar health services development strategy in colonial Nigeria: health care services following institutional interests of religious conversion and government respectively, but the latter being community focussed. Since the only possible portal into the country then was the sea, the coastal regions of Nigeria were first beneficiaries of this new health care paradigm.

To provide needed health care services on a sustainable basis, both the missionaries and the colonial government required well trained workforce for the facilities that were being developed. Therefore, medically qualified mission staff members recruited and trained local people to run their health facilities and later went further to build several hospitals and institutions to formally train low skilled health related manpower, like nurses and paramedical personnel as health attendants, community health inspectors, laboratory staff and pharmacy assistants.

The British colonial government which ventured into health care services in the twilight years of the 19th century moved quite quickly in the early period of the administration to construct specialist health institutions to train its health manpower requirement. In the initial time however, it recruited and trained specialised cadres of

health personnel overseas to render services at its health institutions, which were located exclusively in cities. To meet the continuously growing manpower needs, training institutions (including teaching hospitals) were established to produce sufficient levels of the health workforce spectrum. A landmark addition to the evolving health system was the creation of the Ministry of Health in 1946, with the mandate to coordinate national health services throughout the country. The creation of the ministry was a fall out of the first colonial development plan of the 1940s. The national health system at this time had a unitary command structure, but by the 1950s, it was reformed and decentralized to allow regional governments to run independent health services (Asuzu 2004). This remained the structure of the Nigerian health system up until independence on October 1, 1960.

Though the just over one hundred year period reviewed (1850s-1960) is sparsely documented, it is discernible that both the missionaries and the colonial government played complementary roles in establishing the initial health system, comprising a mix of public and private (non-governmental) elements. The public system was unitary at onset, but later decentralized to regional governments and located preferentially in major cities and the scope of services was narrow, mostly curative. The missionary health facilities and services were spatially closer to the people than those of the colonial government's. Consequently, at independence, Nigeria inherited a national health system that was largely technocentric, urbanized and subsidiarized to the political economy of the colonial administration. The thesis will proceed to evaluate the subsequent development of this health system in post-colonial, independent Nigeria.

1.3.2 Post-independence health system development

Independence ushered in the imperatives of rapid social, political and economic development of the newly independent state. The paramount preoccupation of the nascent government therefore, was the articulation of a comprehensive growth and developmental ideology, capable of meeting the collective aspirations of all Nigerians. Beginning from 1962, the country formulated and implemented four yearly developmental plans (Anyanwu et al. 1997; Asuzu 2004), and by 1990, Nigeria had implemented four national development plans. Thereafter, the country

adopted a two yearly rolling plan, ending in 1999. It has run a yearly fiscal policy regime since then. These plans failed to capture health system development encapsulated as distinctively cohesive agendas and hence acknowledgement of the central role of health in the economic development of the state. Few national health initiatives were formulated and implemented during this period and health care organization and management continued in the relics of the Western model of health care, anchored on costly technology approach and urbanized (Shcram 1971). Nigeria has maintained this pattern of public health system development into the present despite several reforms to create a more inclusive and effective health care system (Asuzu 2004 WHO 2008). The thesis will proceed to examine the administrative structure of the system, health laws and policies and conclude with a review of the health sector reforms, to better understand current health system weaknesses and to provide rationale and justification for this study.

1.4 Administrative structure of Nigerian health system

The Nigerian health system is pluralistic and organized along public and private pathways. Public health administration in Nigeria is undertaken by all tiers of governance; Federal, State and Local Governments. The constitutional and functional relationship between these tiers of government is implicit, but the federal government is responsible for overall national health policy formulation and provision of tertiary health services, state governments provide secondary care while local governments are saddled with the important task of delivering primary health care services (Federal Government of Nigeria 2007b; HERFON 2006).

The private health sector is equally pluralistic, with non-governmental not- for- profit and for- profit private providers all actively engaged in health care delivery (Bloom et al 2008; Bustreo 2003; Smith et al. 2004). Collectively, the private sector provides about 80 % of health services (HERFON 2006).

There exists an overarching national council on health care whose task is to streamline the activities of all actors in health and optimally channel their efforts to avoid duplication of interventions and waste of scarce health system resources.

Despite the establishment of this central coordinating mechanism, intra-sectoral collaboration and linkages have remained weak (Arah 2002; Asuzu 2004).

1.4.1 Health laws and policies in Nigeria

Despite the plural nature of the Nigerian health system, there has been no clear delineation of roles or responsibilities explicitly articulated in any of its three constitutions since independence. The 1999 constitution is the currently operational version, and is in the process of a second amendment. Hopes have been expressed that the on-going amendment would incorporate the National Health bill pending presidential assent (Erinosho 2012). The bill addresses a range of health issues not covered in previous constitutions. Otherwise, in all versions of the constitution, health is always embedded within the ‘concurrent list’, implying that all three tiers of government be involved in health care planning and implementation, without specifying definite roles for each. Not placing particular levels of health care firmly under the responsibility of a particular arm of government has often resulted in redundancy, duplication and wastage of scarce health resources (Magnussen et al. 2004). Exploiting the current constitutional flaws, the political leadership at all levels have often opted to fund and provide the politically more attractive higher level care, to the detriment of basic and essential primary health care delivered closest to the point of need

Primary Health Care (PHC) formally commenced in Nigeria in 1986 as a comprehensive strategy to addressing the most basic health challenges of the country, particularly in rural areas. The implementation was underpinned by the tenets of the WHO model of primary health care (WHO 1978) and the implementation was highly successful in the early part, achieving up to 80% intended immunization coverage of under- 5s by 1990 for example, a feat yet to be surpassed to date (Pate 2010). However, this initial success was punctuated and the momentum to sustain it deflated in the mid-1990s, when international donor organizations, as key financiers of the policy-trust withdrew from the country due to the dictatorial posture of then military head of state, General Sani Abacha. At the advent of the current democratic dispensation on 29th May 1999, primary health care in Nigeria was riddled with a range of challenges bordering on inadequate funding at one

extreme, to weak health information management system at the other. In between the spectrum lay poor and inadequate state of physical infrastructures, frequent stock-outs of essential drugs and critical human resources shortages. This mix of limitations resulted in a situation of low to out-right non-utilization of primary health care facilities across the country, with most points of this level of care moribund (Asuzu 2007; Omoleke 2005). It has been decried that the current democratic governance seem to be doing little in the way of halting or reversing the decay, as resources meant for primary health services at local government areas continue to be misappropriated in other ways by officials at both state and local government levels (Asuzu 2007). However, the primary health care paradigm has remained the bedrock of virtually all health policy frameworks since then and in the present.

1.4.2 Health sector reforms

Health sector reform is a fundamental and sustained process of change in health policies led by government, focusing on the building blocks of the system and aimed at improving its workings and performance (WHO 1995). This should create new systems that offer accessible quality health care services equitably through cost-effective approaches to achieve maximum population health outcomes.

The period from 1960 to 1985 produced four national development plans, each embedding a national health development policy. Although these policies were intended to position the health system for improved performance, they were premised on the thinking that massive investments in curative services and physician training were a most viable approach for achieving improved population health levels. For example, the 1975-1980 development plan captured this philosophy quite aptly in this manner, "...a shortage of doctors continues to be a major problem. While the target set by the World Health Organization (WHO) for this part of the world is a doctor/population ratio of 1:10,000, the current stock of doctors in the country has not significantly increased beyond the ratio of 1:22,000 recorded in 1972. To achieve the WHO target, we need more than double the present number of doctors by 1980." The same document goes further "..., steps will be taken in the plan period to undertaken accelerated expansion of medical colleges and the associated facilities for clinical training."

This plan appears to over stress improving numerical strength of physicians and high level infrastructure development rather than a holistic national health system development that also incorporated primary and preventive health care. It would also appear naive to realistically attain the WHO's physician density level referred to, within the ambit of the plan period, given that physician training requires longer years of education.

The fourth development plan of 1980-1985 differed from its predecessors and marked a watershed in the history of Nigerian health system development. The plan articulated for the first time, a framework for comprehensive health care services, embedding health promoting, preventive, restorative and rehabilitative strategies. The initiative was bound-up in the concept of Basic Health Service Scheme (BHSS), and sought to provide comprehensive health centres, primary health centres and health clinics at the community level. The functional relationship between these facilities was supervisory and complementary at the same time. The comprehensive health centres were meant to oversee and support the primary health centres, which in turn provided support to the health clinics. Promising as it looked, the programme was prematurely truncated by the military coup of 31st December 1983, toppling the elected government that proposed it.

The military administration of General Ibrahim Babangida (1984-1993) was the first to pragmatically demonstrate commitment towards a comprehensive primary health care delivery system. The administration crafted the fifth national health policy based on the principle of primary health care, incorporating explicit strategies that presented realistic scope for full integration and universal coverage of rural communities within the framework of the public health system. Adapted from the WHO template of Primary Health care services in 1988 (FMOH 1988), the model was seen as an attractive alternative approach to the delivery of public health care in ways that engendered equity in access to quality and affordable health services. Primary Health Care (PHC) emphasizes prevention and management of health problems in their natural social settings, in ways that meet people's basic health care needs through comprehensive community based strategies rather than disease focused approaches (WHO 1978). It also envisions the deployment of clear strategies

that would respond equitably and effectively to basic health demands of people, while concurrently addressing social, economic and political causes of ill health. Underpinning the model is universal access, needs based service coverage and health inequity mitigation. Primary health care also stresses health promotion, disease control, community participation, self-reliance and partnerships (Tarimo and Webster, 1994). Even though the Nigerian model contained all these appealing elements, the policy failed to make the much desired difference in health status of rural citizens it primarily targeted. It suffered a major drawback reflected in the non-mobilisation of the dominant private health sector which had been growing in size and mix over this historical period. This included the faith based organisations (Christian and Muslims), private organizations (profit and not-for-profit), and private individuals, including patent medicine vendors who from available data, could have been on the scene of health service provision as early as 1936 (PCN 2008) in its design and implementation (FMOH 2004).

The lessons from the implementation of the fifth national health policy provided the appropriate experience for the sixth plan, with a focus on strengthening and repositioning the system for effective, efficient and equitable health care services provisioning (FMOH 2004). This revision of the national health policy in 2004 was rigorous and enriched by fresh perspectives from the important but previously neglected non-public actors. The generative process involved series of review meetings from 1995 to 1997 and the production of a final policy document, which was endorsed by government in 2004. A National Strategic Health Development plan (NSHDP) 2010-2015 detailing implementation guidance was also developed thereof to harmonize and align the activities of all implementing partners in order to achieve the overarching policy objectives of universal coverage with quality and affordable health care services (FMOH 2010). Though this policy was adopted in 2004, the operational framework was only designed 6 years later in 2010 and after a year's experience with it; the conclusion is that "Health indicators remain below acceptable levels at national and sub-national levels" (FMOH 2011). Although the review period might have been too soon to make any valid inferences, the conclusion of health system weakness as undermining government's ability to attain targets was plausible given the historical deficits in the system the thesis has aptly demonstrated.

The review further recommended improved harnessing of all health care resources at the disposal of government (public and private) to improve health care access for all, especially for people in underserved area.

Non state actors have been highly active in health and health care delivery in Nigeria right from the beginning of orthodox medicine in Nigeria as evidenced, although not optimally exploited by government. The missionaries were first to establish health clinics and dispensaries, before government responded to the challenge of health care provisioning and to date the private sector still looms large in the health arena (SHOPS Project 2012). It provides about 70% of health services and accounts for 65% of total health expenditures, much of which is out-of-pocket expenses (NDHS 2008; NHA 2003-2005; World Bank 2013). The dominant role of the private sector in health is further underscored by the pattern of health care utilization, as about 40% of individuals in the poorest wealth quintile purchase health care from private for-profit providers (Arnab et al. 2008). Private health facilities cluster preponderantly in southern Nigeria relative to the north (Dutta 2009), and cover the gamut of tertiary, secondary and primary health care facilities, as well as pharmacies, patent medicine vendors, itinerant drug sellers and traditional practitioners. Also, the private-for-profit facilities tend to locate in urban areas, where the willingness to pay for services is higher, even though 50% of the rural populace also use for-profit-private health facilities routinely (IFC 2008). The preference of facility based private health care providers to locate in urban centres has often left a rural gap which is readily filled by the smaller health entrepreneurs comprising patent and proprietary medicine vendors, itinerant drug sellers and traditional practitioners, however, the former appear more significant.

1.4.3 The private health sector in Nigeria

Even though the private health sector represented by the Christian missionaries were the first to introduce allopathic style health care delivery in Nigeria way back in the mid-19th Century, it has enjoyed limited research. This has been attributed to rapid growth of public provision and the perception by policy makers of private actors as competitors rather than partners (Ogunbekun et al. 1999). Whilst public provision grew with expanding colonial activities, private institutional health services

maintained their dominance of the health care terrain up to independence in 1960. The public provision of health care grew even more rapidly in post independent Nigeria following the aggressive developmental drive of the new administration. Expectedly, greater public focus was paid to the evolving state, while the private health sector became ignored by the research community. Public health care development post-independence was not accorded its deserved importance and as such, public supply of health services never grew sufficiently to match demand for health services at any time during this time period. Then, the economic downturn and the structural adjustment programme of the mid 80s with its associated squeeze on public spending offered scope for another surge of activity of the private health actors on the health terrain and has remained critically important to this point. This development resulted in meteoric rise of the private health sector, with health care resources increasingly going to private health markets amidst deteriorating public supply. The private health sector in Nigeria which was uniquely institutional and faith based has gradually become pluralistic with private individuals and non-faith based organizations competing in the market and offering the whole range of possible health care services. The individual component ranged from full-fledged hospitals with ownership cutting across organizations, group practice and individuals to small entrepreneurial outlets exemplified by the patent medicine vendors

1.4.4 Patent medicine vendors and their regulation

Patent and Proprietary Medicine Vendors (more commonly referred to as patent medicine vendors) are non-pharmacists individuals licensed by Pharmacy Council of Nigeria to stock and sell simple over-the-counter medicines. They constitute an important component at the retail level of drug distribution chain in Nigeria, which also include pharmacists, general goods shops and itinerant vendors.

Patent medicine vending is wide spread in Nigeria, legalized by the Pharmacy Board since the Poisons and Pharmacy Ordinance of 1936, to bridge the pharmacy human resource gap then, and has persisted to the present (PCN 2008). The regulation of the practice of patent medicine vending is undertaken jointly by the Pharmacy Council of Nigeria of Nigeria (PCN) and the National Agency for Food and Drug Administration and Control (NAFDAC). NAFDAC regulates the drug supply chain

from point of manufacture or importation to the last point where it reaches the final consumer. Its mandate is to ensure the quality and safety of pharmaceutical products in transit through the entire distribution channels. The Pharmacy Council is concerned principally with the practice of pharmacy in all its ramifications, which includes patent medicine vending under its purview. For patent medicine vendors, the Council sets practice standards, licensing requirements, inspection, supervision and enforcement of sanctions which are detailed out in a practice guideline (appendix 1). This group of small pharmaceutical entrepreneurs are intended to leverage access to basic medicines in rural and underserved areas. Their scope of practice is however constrained to non-prescription drugs only (over-the-counter) and has simple key licensing requirements in ability to read and write English language, a minimum age of 21 years and clean, well ventilated business premises (PCN 2003). The drug stock restriction is displayed below.

Patent medicine vendors have been shown to act as important sources of a wide range of health care services for both urban and rural areas in Nigeria (Oladepo et al. 2007; Salako et al. 2001; Brieger 2002), and act as first point of consultation for an array of common diseases and services, such as fevers, diarrhoeas, acute respiratory diseases (pneumonias), oral contraceptive devices and condoms (Dutta et al. 2009; Oladepo et al. 2007; Oye-Adeniran et al. 2005; Omotade et al. 2000; Salako et al. 2001). Particularly in the treatment of malaria, medicine vendors provide the vast majority (70%) of case management in Nigeria (ACTwatch 2013). In rural areas especially, consumers rely largely on the established network of patent medicine vendors for access to needed medicaments (Oladapo et al. 2007). However, despite their rising profile and seeming importance, the market is said to be poorly regulated and fraught with unethical practices and regulatory infringements (Adiku 1996, Alubo 2001).

Table 1.1: Official list of drugs for patent medicine vendors

1. Analgesics and Antipyretics	17. Disinfectants
2. Antacids	18. Wound dressings
3. Antidiarrhoeal drugs	19. Dusting powder
4. Antidotes	20. Fungicides
5. Anti-infective drugs	21. Inhalers
6. Antipyretics	22. Keratoplastic drugs
7. Antiseptic (throat) preparations	23. Keratolytic drugs
8. Anthelmintics	24. Minerals and vitamins
9. Antimalarials	25. Mouth washes
10. Antiseptic and Disinfectant solutions antidotes	26. Non-specific (General)
11. Anti-anaemia drugs	27. Nutritional drugs
12. Anti pruritic and astringent drugs	28. Pediculicides
13. Cold relief preparations	29. Purgative drugs
14. Contraceptives inhalers	30. Rubefacients and
15. Antiseptic soaps	31. Scabicides
16. Cough relief preparations preparations	32. Throat antiseptic
17. Dermatological(anti-infective) drugs	

Source: Pharmacist Council of Nigeria (2003)

The thesis now examines the structural composition of the Nigerian health system in comparison to the World Health Organization's model for building, strengthening and sustenance of a robust health system (WHO 2007), so as to more clearly understand the inherent functional weaknesses in the system and isolate areas for potential policy interventions. The recipe presents a menu of six critical components of a health system which enables it to provide needed services, allows universal access to services and guarantees universal coverage of health care benefits as stipulated in the PHC Charter.

1.5 Nigerian Health System Assessment

The WHO's framework for evaluating a health system's capacity to provide universal health coverage for the population balances a mix of health financing, leadership, health workforce and leadership and governance. Others are health information system, medical products and service delivery. These are analysed succinctly below.

1.5.1 Health care financing in Nigeria

Funding mechanisms are a good starting point of inquiry into a health system analysis: it provides insights to the relative size of the system and the role of government and therefore type of system, whether public or private (Blank and Burau 2007). Health financing is also a key determinant of access to care. Health financing function of a health system aims to collect funds to purchase health care. It also aims to provide financial risk protection and delivery of services fairly and equitably on a sustainable basis (WHO 2000). Sources of health care financing in Nigeria include government (including social health insurance), households, firms, private health insurance and international donor agencies.

Government funding of the health system in Nigeria has been grossly inadequate, for example health has consistently received just about 5% of the national budget, which represents a far departure from the 15% level agreed upon by African heads of states in the Abuja declaration (FMOH 2000; WHO 2007). This level of health expenditures are relatively low compared with other African countries, for example, Tanzania, Malawi or South Africa who spend 6.8, 7.2 and 7.5 of their GDPs on

health (Soyibo 2005). A disaggregation of total health expenditure pattern shows that the public health component is 36.7%, while 63.3% is funded privately (World Bank 2013). Intra-sectoral budgetary expenditure analysis reveals that about 70% of the budget is expended on personnel costs and just 30% is spent on provision of health care services. 70% of the health care services budget is allocated to secondary and tertiary level health services, leaving primary health care with just 30%, even though tertiary facilities cover less than 25% of the health problems of Nigerians (Anyene 2012). Therefore, the opportunity for significant contribution to population health outcomes derivable from the proven primary health care approaches that yield greater public health outcomes is perpetually lost. Furthermore, an important determinant of health care access and health outcomes is the payment mechanism for services. The consensus is that price barrier lowers access and prepayment mechanisms improve health care access. About 70% of health service purchases in Nigeria are paid for by individuals in households, and this mode of payment for health has catastrophic impact on health care consumers (WHO 2012).

The potential for financial protection for households offered through health insurance schemes is vitally important in determining health care access and appears grossly under-exploited in Nigeria. Private health insurance provides less than one percent coverage of the population and the national health insurance scheme was only recently launched in 2005. Together, they now cover about 4 % of the population financially (NIHS 2010).

The decree establishing the Nigerian National Health Insurance Scheme (NHIS) was enacted in 1999 by the military government of General Abdusalami Abubakar, but launched by President Olusegun Obasanjo in 2005, even though the idea of a public health insurance scheme for Nigeria had been muted way back in 1962 (Anyene 2012). Currently, the scheme covers only Nigerians in the formal sector, and has about 4 million enrolees made up of federal civil servants and their dependants. This number of enrolments is only about 3 % of Nigerians meaning that only one in about 30 persons in the population enjoys financial coverage when seeking health care. At this slow pace of progression, it looks impossible to cover all Nigerians by 2015, as targeted in its design. Regrettably, the NHIS does not yet cover the rural areas;

neither do the private health insurance providers. Therefore, the marginal impact of the scheme to improve health care financing remains unpredictable, and with the performance of the public financing system elaborated above, this new arrangement may probably entrench further inequity in the health system.

Donor funding for health in Nigeria adds little (4%) to the overall health care expenditure, but has been on the increase since the advent of democratic governance in 1999. However, the impact of donor partner funding of health is unclear, due to fragmented coordination and implementation of programmes and interventions (National Planning Commission 2008).

1.5.2 Human resources for health in Nigeria: the health workforce.

At the heart of any health system is the stock of human capital and evidence has revealed a positive association between health worker numbers and their quality to improved health outcomes (WHO 2007; WHO 2006). Health workers function as gatekeepers in the health system and are pivotal to the efficient or wasteful deployment of health system resources. Nigeria has one of the largest human resource for health in Africa, surpassed only by South Africa and Egypt (WHO 2006), with above average scores for both physician and nurse/midwife densities for Africa (WHO 2010c). Despite the impressive statistics, its population health levels remain one of the worst in sub-Saharan Africa (Federal Republic of Nigeria 2007b). Shortages of critical health professionals, inappropriate skill mix of health teams, mal-distribution of available work force, and persistent exodus of health professionals abroad and into the private sector as well as dual practice all stubbornly plague the system (WHO 2006; FMOH 2007a). Equally linked to the human resource for health dilemma is the production of health professionals out of alignment with the health care needs of the country, and limited capacity for health policy formulation and plan implementation (FMOH 2010). According to the government of Nigeria, it has a doctor to population ration of 30 per 100,000 populations which is greater than the African average of 15 doctors per 100,000 populations and also boasts of 100 nurses per 100,000 populations, compared to the African average of 72 (Federal government of Nigeria 2007a). These densities though consistent with those from the WHO (2006; 2010c), obscure inherent severe

mal-distribution of the workforce within the system: there is one doctor to four primary health clinics, five doctors to one secondary level facility and 62 doctors per tertiary level centre. This picture depicts that in Nigeria, doctors, pharmacists, nurses and laboratory scientists are concentrated more in urban areas where secondary and tertiary care facilities are located, than in rural primary health centres (Adetokumbo 2005; WHO 2006). Mal-distribution of health personnel between the different states and regions of the country also exists. There seem to be no precise information related to the distribution of nurses and midwives and other cadres of health personnel across the range of health facilities in Nigeria.

Inappropriate mix of health personnel production is another debacle of the system, evidenced by mismatch between need and supply of different cadre of health workforce. It occurs in the form of shortages of one category of staff or a surplus production of another. Dearth of critical competence in public health and health policy compounds the Nigerian context (HERFON 2006).

The world economic recession of the 1980s and the reactive Structural Adjustment Programme (SAP) that followed resulted in massive exodus of highly skilled health professionals from Nigeria to the West and Arabia. These locations are said to offered better pay packages, improved working conditions and prospects of career development. According to the government, these dynamics further mystified Nigeria's health workforce puzzle (Federal Republic of Nigeria 2004). It is argued that the Nigerian health workforce crisis will deepen as demand for health professionals will continue to escalate, driven by demographic and epidemiological transitions, the unfinished agendas of infectious diseases, health professional migration, HIV/AIDS epidemic and the imperatives of meeting the MDGs continue to impact the system (WHO 2006).

1.5.3 Health system leadership and governance

Health system leadership and governance also called stewardship, is said to be the most complex but a central building block of an effective health system (WHO 2007). It defines the role of government in national health, specifying the relational interactions between all other entities whose activities influence health outcomes.

Functionally, this entails overseeing and directing the health system holistically by reconciling varied competing demands on limited health resources, in order to achieve public health goals.

The two key health system functions of health financing and service provision require effective oversight and underpin the role and importance of health system governance. The Federal Ministry of Health plays a leading role in the overall management of health in Nigeria. This stewardship entails an oversight role in shaping, managing, regulating and controlling the diverse health system actors highlighted earlier in the chapter. The ministry also provides policy guidelines for all actors in the health care arena. However, as argued earlier, the government has not fully exerted its stewardship role especially with regards to coordination and productive engagement with the private sector. This sector is a major source of drugs and other medical commodities in addition to the provision of health care services. This weak functional relationship with the private sector has severely constrained the overall system performance as seen in inadequate health care access and poor health outcomes of Nigerians (Erinosho 2012). Other leadership challenges corruption, poor communication and enforcement of health policies, inadequate legal and constitutional framework for key policy thrusts and lack of health governance management capacity (FMOH 2004b).

1.5.4 Health products and service delivery

Good services delivery is a desirable objective for any health system working towards universal access. Crucial to successful service delivery are the contextual configuration and content of the services, but broadly, a well-functioning health system must be characterized by a network of service delivery points, which have the following attributes; people centeredness, accessibility, comprehensiveness, continuity, coordination, accountability and efficiency (WHO 2013). Another desirable quality of successful service delivery is coherent approach where the first level of contact with the system is the driver of the entire health services delivery system (WHO 1978). For Nigeria, the primary health care facilities are much of the time comatose, or when functional, are inundated with challenges as erratic supplies and availability of drugs, tools, and health support infrastructures. Diagnostic and

investigative equipment at most facilities are out-dated and dilapidated. Logistics that get supplies of medicines, vaccines and technologies to where they are needed are poorly managed (Erinosho 2012). These have seriously eroded the trust of the public in primary health facilities and poorly utilize them.

1.5.5 Health information system

The role of accurate, up-to-date and robust information for policy and management decision making in any effective health system cannot be over stressed. Nigeria's health information system is rudimentary and poorly developed, making reliable and timely information on health determinants, health levels and health systems scarce (Federal Government of Nigeria 2010; AHWO 2008).

The chapter has chronicled the Nigerian health system beginning from the first arrival of the missionaries and colonial government in about the mid ninth century to the present. The early structure of the health system consisted essentially of curative hospitals, clinics and dispensaries located mostly in administrative cities and around mission fields. Rural coverage with public health services was poor and preventive and primary health care was ignored. The post-colonial indigenous government towed the same model of high technology, curative and urban based health system development until 1986 when the primary health care was adopted as the blueprint for health system development in Nigeria and strategy to expand coverage of the farthest communities. The post-independence health system development era was especially dotted with multiple challenges, the continuum of which encompasses inadequate financing, inadequate and inappropriate work force, weak health system leadership, poor services delivery and a rudimentary health information system. The series of military coups and accompanying frequent leadership change also adding to the list as an important factor. These collectively have severely compromised the capacity of the system to provide Nigerians with full coverage of the population with effective, safe and affordable health care products and services. These failures have leveraged the emergence and rapid growth of private health markets to bridge the demand and supply gap in public supply. Today, health markets provide about 80% of health services and 70% of payments are out of pocket, putting the private sector at the centre stage of the Nigerian health care arena. Patent medicine vending is the

smallest recognised unit of the health market in Nigeria, with extensive network of providers across the country. They are hugely popular and patronized highly in urban and rural area and in the latter in particular, they are sometimes the only source of access to essential health care services.

This review of the Nigerian health system has highlighted the inherent weakness of all its functional parts and the repeated attempts at its reformation and the intractable challenge of inadequate access to health care in Nigeria, particularly in rural areas so, the search for the right formula persists.

1.6 Statement of the Problem

Health is now viewed as a fundamental human right to existence and health care debates have become very sensitive and highly emotive issues among individuals and remain keenly contested agenda within political circles.

In Nigeria, public health care access is inadequate and complemented by private health care markets. In this pluralistic health landscape, empirical evidence show that the non-governmental players are not only producing a larger share of the overall health system output and are in fact leveraging wider access to health care by reason of their geographical spread and networks across the country, in temporal functionality and availability terms (Barnes et al. 2008; SHOPS Project 2012; Ogunbekun et al. 1999).

In particular, private-for-profit health care provisioning is wide spread and assuming increasingly important roles in the national health system. It has therefore been generally argued that for major shifts in population health gains to occur, governments must look beyond the public sector, and develop creatively functional collaborations with the private sector, which has the potential to deliver up to 70% of needed health care capacity (FMOH 2006a; Mills et al. 2002; WHO 1998). This thinking has given rise to the on-going debate on strategic partnerships with private health care providers to strengthen the national health system and improve health access for a wider population (Bloom et al. 2008; Breiger et al. 2004; Palmer et al. 2003; Centre for Global Development 2009). Patent medicine vending in particular has assumed distinctive importance in the Nigerian health market, due to their spread

to every nook and cranny of the country. They are a major and in some situations the sole source of health care for most rural and underserved communities (Duttta et al. 2009; Salako et al. 2001; Breiger 2002; Oladepo et al. 2007; Omotade et al. 2000). Despite their rising profile and seeming importance, very little is known about this group of retail medical entrepreneurs and the market they operate in (Oladepo et al 2007). A few studies and anecdotal evidence reveal deep rooted unethical practices, entrenched regulatory infringements and weak regulation and regulatory enforcement (Adikwu 1996; Alubo 2001; Breiger 2002). Widespread consumer dissatisfaction has also been reported. These studies were simple descriptions of observed phenomena which failed to explore interactions and therefore explain the main influences and their impact on observed market outcomes and their implications for health care access. The authors also failed to adopt the perspective of retailers and consumers as economic agents, facing a multiple of financial and non-financial choice sets and motivations. Therefore, the use of an economic framework to analyse this retail health market is essential for closing the knowledge gaps and gaining new useful insights into this market. Furthermore, even though regulation was described as notoriously inefficient, understanding the challenges of regulating retail drug shops was not systematically studied. This knowledge is critical if government is to design effective policies and develop actionable interventions that can expand access to effective, safe and essential medicines for patent medicine retail consumers, particularly in rural communities.

1.7 Aims and Objectives

The aim of this study therefore is to analyse and understand a segment of the retail pharmaceutical market; the patent medicine vendors, in Katsina-Ala, a rural area in north central Nigeria and make policy recommendations to improve access to effective and safe health products in the market.

Specific objectives are to:

- I. Describe and understand the organization of the pharmaceutical market which patent medicine vendors operate in.
- II. Understand the nature of competition in the market through analysis of market structure, price and non-price competitive strategies.
- III. Describe treatment seeking of drug consumers and evaluate the appropriateness of services purchased.
- IV. Identify inhibitions and facilitators to health care access and model the market.
- V. Make specific recommendations for regulatory interventions that will improve market performance and consequently, access to effective and safe services.

CHAPTER 2: REVIEW OF RELATED LITERATURE

2.1 Introduction

Peer reviewed and unpublished literature was systematically searched guided by the thesis topic defined as an economic analysis of retail pharmaceutical market in Nigeria: Towards access expansion and policy. Published literature used was obtained from data bases as Science Direct, Scopus and PubMed, applying controlled vocabulary and key terms and limiting the review to studies published in English. Standard economics, health economics and health system related books were also consulted for relevant information. No time bounds were imposed because of the need for broad search strategy adopted. Unpublished materials used came from reports and documents of reputable and popular international organizations available on World Wide Web such as World Health Organization, World Bank, USAID, PSP-one, ACTwatch and DFID. The bibliographies of selected articles were also examined for additional literature.

Key search words were “patent medicine vendors”, “retail drug stores”, “drug shops”, “pharmaceuticals”, “self-medication” and “consumer behaviour”. On completion of the search and retrieval of information sources, article titles, their abstracts, introductions and conclusions were read and relevant sources selected based on specified criteria: Studies that evaluated the characteristics, behaviours and performances/outcomes in retail drug markets in sub-Saharan Africa; articles that investigated interventions to improve performance in retail drug market. Published literature that explored informal private providers in low and middle income countries, or that reported strategies for expanding access to healthcare or essential medicines were also included in the review. Economic theories related to markets, price theory, regulation and industrial organization reviewed were culled from standard economic text books and provided the framework for data collection, analysis and discussion for the thesis.

The review of related and relevant literature was organized along key concepts and themes that directly follow from economic theories and their supporting assumptions. The concepts and themes identified were guided broadly by the topic of this thesis

and specifically by the evaluative framework, which provided the basis for variable definitions and data collection approaches, as described in Chapter 3. It focuses on the relationship between market structure, provider conduct and consumer behaviour in determining health related outcomes in the market. These three concepts formed the core of the review, with each theme giving rise to sub-themes that are further reviewed in relation to standard economic theories that have explained these phenomena. Therefore, concepts as market structure, provider conduct, market concentration types and market failures have robust economic theoretical underpinnings. These formed the starting points for the review.

Other thematic areas reviewed such as economic theories of government regulation and health care access where empirical literature presents different aspects of an issue, the divergent perspectives are compared and contrasted and the general utility of conclusions evaluated.

Overall, sources of information reviewed fall under theory or empirical literature and the degree of fit with specific concepts or themes of the research topic and conceptual framework provided the basis for organising the literature under relevant categories.

The history of voluntary exchange of goods and services between people through the market mechanism dates back many centuries, stretching from the era of trading by barter to modern use of currencies and other financial instruments as exchange media. Today, markets have been argued to provide the most efficient mechanism for allocating scarce resources, and governments throughout the world, now tend to rely on them to achieve socially desirable economic outcomes, through actions as privatization, deregulation, commercialization and re-regulation policies. Understanding the workings of markets therefore holds great potential for improving social welfare. There are two major approaches of understanding markets: descriptive approaches which provide general overviews of market organizations and the use of microeconomic theories of markets and price. These provide conceptual frameworks for analysing and explaining the dynamics of market interactions and quantifying solutions at the demand and supply interface.

The chapter is organized in three main sections: the first reviews the economic theories of markets and price and their impacts on market outcomes and also considers health care markets comparing and contrasting them with the classical free market. The second part examines the economic theory of governments and regulation, and the chapter ends with a review of the concept of health care access and provides a working definition of access for the thesis.

2.2 The Structure-Conduct-Performance (SCP) Model

The model postulates a deterministic relationship between an industry's market structure (the number of sellers and buyers, entry and exit barriers, product differentiation, vertical integration and growth rate of market demand), market conduct (advertising, research and development, pricing behaviour, plant investment, product choice, collusion, mergers and contracts), and market performance (prices, profits, efficiency, equity, product quality and technical progress and growth). It explicitly posits that the market structure under which a firm operates will determine its conduct (behaviour), and the firm behaviour will in turn influence the market performance (Clarke, 1985). Markets therefore have been traditionally classified into four broad categories (perfect competition, monopoly, monopolistic competition and oligopoly), according to the degree of competitiveness of firms in the industry, measured in terms of market Concentration and consequently market power over price. The varied forms of market concentration exhibit differentially discrete patterns of competition, ranging from the theoretically ideal least concentrated perfect competition to the most concentrated scenario of monopoly. Tucked in-between these extremes are the relatively low concentrated monopolistic competition and the high concentrated oligopoly. These intermediate forms are sometimes collectively referred to as imperfect competition and the vast majority of markets in the real world fall under this broad category (Varian 2006). This notwithstanding, it is worthwhile understanding the two extreme forms of market organizations, because they serve as useful reference frameworks within which to explore real markets in action. In reality, some industries structurally align more towards perfect competition, while others incline more towards the monopoly model, generating market outcomes predicted by the competitive and monopolistic models respectively.

A detailed review of the range of market structures found in the economic literature on industrial organization and their predicted performances are presented (Clark 1985; Martins 1999; Samuelson and Nordhaus 2001; Tirole 1985; Varian 1992; Varian 2006).

2.2.1 Market Structure

The main components of market structure are the number of firms in the market, which determines the market concentration, entry and exit barriers, product information characteristics and regulatory framework, which are reviewed further below.

2.2.1.1 Market concentration

Market concentration measures the number of firms in the market and their relative market sizes reported in terms of horizontal concentration or vertical integration (Clarke 1985). Low horizontally concentrated markets are competitive, while high concentrated markets are uncompetitive. A number of approaches have been used to measure horizontal concentration in the literature, but lots of empirical and methodological flaws have been associated with these approaches. A simple count of the number of sellers in a market place for example, fails to specify their relative market shares. Commonly used absolute measures of market concentration are the concentration ratio and the Hirschman-Herfindahl Index, both of which incorporate the number of sellers in the market and their relative market shares (Clarke 1985).

Vertical integration describes the degree to which a firm is involved in the successive stages of production and distribution of its product. Integration has been categorized as backward (upstream) or forward (downstream) integration. In the former case, the firm gets involved in the production of its raw materials and other inputs, while forward integration refers to where a firm is involved in the distribution of its finished products as well.

2.2.1.2 Market entry and exit barriers

Market entry barriers refer to any factors that allows firms in an industry to earn excess profit in perpetuity and which may disadvantage new entrants into the market. These may arise from cost advantages of incumbent firms to produce at lower average costs, significant economies of scale and product differentiation. Other barriers may include entry regulatory patents, licensures and permits (Djankov 2002). Heavy capital investment may act as an exit barrier, because of potential huge losses arising from the re-sale of plant and machinery and consequently a deterrent to entry too.

2.2.1.3 Product information characteristics

The ability of consumers to judge the quality of a product has important implications for market competition. Goods have been broadly grouped as search, experience and credence goods (Nelson 1970). Search goods have to be inspected for quality before purchase is made, while experience goods on the other hand have to be firstly purchased before quality is judged. Credence goods are products that consumers have to rely on third party information to judge their quality, in which case providers often act as experts who determine consumer need for the product. The implication of experience and credence goods for competition is that where a consumer cannot observe quality, they are less responsive to quality signals and market failure occurs.

2.2.1.4 Regulatory framework

The array of market regulatory frameworks can be vast and include entry and exit regulations, product quality specifications, pricing policies, production process standards, conduct codes, taxes, subsidies and accreditations. The impact of regulation on market competitiveness depends on market structure, provider conduct and enforcement capacity. Generally public regulation aims at improving market efficiency for maximum social benefits (consumer protection).

2.3 Provider Conduct

This represents all the activities of sellers to shape market outcomes or influence market structure, and the set of behaviours that are crucial to understanding market conduct include price fixing, product differentiation, imperfect agency, concentration enhancing practices and response to regulation. Their main features are reviewed and how they impact on competition is highlighted.

2.3.1 Price fixing

Price fixing is observed predominantly in imperfect markets, where providers have some market power and are therefore, able to set prices above their marginal costs of production. In perfect competitive markets, firms are not able to raise prices above marginal costs, because doing so results in customer losses. Strategies used to gain market power and consequently price sovereignty by providers include product differentiation, imperfect information relationships, entry barriers and collusion. Often prices are not explicitly calculated based on price elasticities of demand, but a reliance on rules of thumb, for example, mark-ups or copying the market price leader. Price sovereignty of dominant firms manifests in the form of discriminatory pricing strategy of either first, second or third degree. In first degree price discrimination, prices vary between units of output and also between individual buyers, while in second degree price discrimination, the price variation is observed only between units of the output. Third degree price discrimination occurs when the price of a product varies from one individual to another.

2.3.2 Product differentiation

This phenomenon is observed when consumers prefer one rival product over another due to their observable quality differences, ancillary services packages, or spatial segmentation. Product differentiations are product innovations that enhance a firm's competitiveness and profitability and a product can be either horizontally or vertically differentiated. In a horizontally differentiated product market, consumers' tastes determine product differences whereas in vertical differentiation, some product has more desirable qualities than others and there is general consensus among consumers concerning preference ordering. It has been argued that where quality

signals are difficult to observe, buyers may be more price sensitive and quality insensitive. Under this condition, at equilibrium, market quality of a product will be low and additional signalling by sellers may be needed to maintain quality in the market (Akerlof 1970). In professionally based markets for example, this may mean signalling via gaining additional qualifications or use of more sophisticated equipment and procedures. However, if buyers are price insensitive (for instance, insurance users), quality competition may emerge with over-investment in high technology equipment and other observable signals of quality. This has a tendency to drive up prices, against predictions of economic theory of a fall in price.

Product advertising and promotional activities as a way of product differentiation may convey information to consumers which mitigates market power arising from product differentiation attributable to information asymmetry. In some cases the information asymmetry between providers and buyers is such that the former relies wholly on the latter for their demand and consumption decisions. This nature of principal-agent relationship may be economically exploited in situations to create and maintain Supplier Induced Demand and precipitate market inefficiency (McPake and Normand 2008).

2.3.3 Market concentration enhancing strategies

These sets of practices are aimed at increasing market concentration and market power and include such practices as mergers and acquisitions. They may also be driven by desires to reduce transaction costs, tax avoidance, guaranteeing product input supplies, securing output markets or barriers against new entrants. There can also be explicit collusion or implicit understanding between firms to limit price competition or the setting of production quotas.

2.3.4 Provider response to regulation

It has been argued that not all the time is government regulation focused on social welfare improvement as the process and implementation of rules have tended to be hijacked by private interests (Peltzman 1976). Regulation may thus work systematically to the advantage of vested interest, instead of general interest. In health markets for example, professional associations try to influence regulators to

tighten registration and licensing requirements of their professionals (Folland et al. 2010). Approaches employed to influence regulation are lobbying, campaigns, litigation or through informal interactions, and in some cases deliberate information concealing.

The interplay of structural with conduct components of the market together create the nature of competition that characterizes it and defines its social performance, and these are discussed in the subsequent section.

2.4 Types of Market Competition

The spectrum of market competition embeds perfect, monopolistic, oligopolistic and pure monopoly variants. Their distinctive features are highlighted below.

2.4.1 Perfect Competition

The perfect competitive model of market structure is an idealized construct that is rarely seen in any real world market and derives on the following assumptions:

1. Very large number of buyers and sellers in the market, so that no individual buyer or seller has dominant power over price
2. The good is homogeneous, that is all producers are producing exactly the same good to the extent that product segmentation on the basis of difference between goods is nonexistent.
3. Perfect information on all relevant market variables as prices and qualities are available to all buyers and sellers.
4. No entry or exit barriers are present. New entrants into the industry are not disadvantaged in any way, but face equivalent economic options as those already in the market.

These assumptions ensure that the market equilibrium in the short run is represented by the intersection of the demand and supply curves. Under these assumptions of perfect competition, the demand curve facing the firm is flat horizontally, that is, perfectly elastic demand, and all the firms and buyers are price takers. Also, under these set of assumptions, the demand curve of the firm, its marginal revenue, as well as the current market price all converge at a point of equality. The profit maximizing

output for a competitive firm occurs when its marginal revenue (price) equals marginal cost.

The free entry and exit assumption offers further insights into the workings of the perfectly competitive market model. Theory predicts that attractive short run profits of the market will stimulate new producers to enter the market. This will increase market supply and drive down market prices, persisting into the long run when prices would have fallen enough to eliminate all economic profits. In the competitive model therefore, the long run market equilibrium profits tend to zero, and prices will be at their lowest point. However, if economic barriers to entry exist which disadvantages new entrants into the industry, such as government regulations, licensures, patent rights, economies of scale and other restrictions, the self-adjustments in the market stated above would be impeded, and firms would earn economic profits in perpetuity. Under this situation, the market is not supported within the framework of perfect competition, even though the market prices are still determined by the forces of demand and supply. In evaluating a market structure therefore, it is important to establish the extent to which the basic assumptions of competition are satisfied.

Generally, perfect competition is canvassed as producing socially desirable market outcomes and that the more perfectly competitive an industry is the better; this is on account of its unique ability to produce socially optimal levels of outputs at minimum average costs and firms making only normal profits. This form of market organization is therefore described as economically efficient.

2.4.2 Monopoly

Monopoly describes a situation where only one firm exists in an industry. This definition though simple, the actual classification of an industry as monopoly may not always be clear, depending on how broadly or narrowly it is defined. In the textile industry for example, a firm may have monopoly in the production of a type of fabric, but does not monopolize fabric production in general. It is therefore argued that the boundaries of an industry may be arbitrary and not bring much meaning in economic analysis as the firm's market power does and considered more important in defining the concept. An industry's monopoly power is dependent on the availability

of close substitutes produced by rival industries or firms, thus, a monopoly situation can be created and sustained only where rigid entry barriers exist. Some protective instruments in a monopolist's arsenal may include economies of scale, economies of scope, product differentiation and brand loyalty, regulation and legislation. Other weapons the monopolist firm may deploy to its advantage are ownership or control over key inputs or outlets, mergers and takeovers, low cost advantage of established presence and aggressive pricing and advertising tactics.

In some cases if a monopolist's cost keeps declining up to the socially desirable output level this may create a market situation that is naturally not capable of supporting additional producers and a natural monopoly emerges. Under such scenario, theory postulates that new entrants will find the market unprofitable as the monopolist who is experiencing economies of scale can fix prices below the cost of the new entrant, thus forcing it out of the market. Similarly, a large firm producing a range of products, by sharing its strengths across its product lines, enjoys low costs and is able to make it difficult for mono-product new entrants to the market. Also, an established monopoly firm is more likely to have acquired particular competencies in production and marketing processes and may be better informed of the most efficient techniques, most reliable and cheapest sources of inputs and financing. These all add up to place the monopolist's operating cost curve much lower relative to any new entrant attempting to embark on price competition.

Other than these cost factors which sustain a monopoly structure, dominance over vital inputs, client preference for an inventor's product even when the patent right has lapsed, legal patents, ability to absorb sustained losses, massive advertising, attractive after-sale services and product innovation are non-price strategies a monopolist can apply to further amplify and consolidate the status quo.

The equilibrium price and quantity of the monopolist has implications for the individual consumer and society in general. Since there is a single firm in the market, the firm's demand curve corresponds to the industry demand curve, and theory predicts that the demand curve is relatively inelastic. This confers power on the monopolist over market price to the detriment of the consumers and is referred to as price setter. Whilst still constrained by the demand curve, the monopolist is still able

to choose what price to charge on his product and demand will respond inversely to price increases. In the short run, a monopolist maximizes supernormal profit where marginal revenue equals marginal cost, which are not competed for in the long run due to barriers to entry.

It is intuitive that the monopolist will produce different output at quite different price from the competitive firm, because they each face a distinctively different environment. However, given the assumptions of identical costs and demand curves for both monopoly and perfect competition, the latter would produce a higher level of output at a lower price at any given point. Therefore, all things being equal, perfect competition better serves the consumer than monopoly does. Under perfect competition, a firm's long run survival hinges substantially on adopting the most efficient technologies and potential innovations, while the monopoly firm is hemmed in on all sides by protective barriers and guaranteed supernormal profits in perpetuity, even if it does not use the most efficient techniques. It has been argued therefore that, the monopolist has less incentive for being efficient and it incurs a higher cost of production than the firm in a competitive environment. On the other hand, it has also been debated that monopolies may in fact achieve significant economies of scale due to their large plant size, centralized administration and elimination of redundancy that results from duplication. Furthermore, a monopoly has a greater capability to become efficient than a small firm, by investing its supernormal profits into research and development activities.

2.4.3 The Theory of contestable markets

Economists now argue that another important consideration in determining price and output behaviour in a market is not whether an industry is indeed a competitive firm or a factual monopoly, but if a real potential for competition exists (Baumol 1982). In other words, the threat of competition alone is a sufficient condition to cause a monopoly firm for instance to behave in much the same way as a competitive firm would. Embedded in the theory of contestable markets is the concept of perfectly contestable markets, representing a market situation when entry and exit costs for potential entrants are zero or when such entry may occur quite rapidly. The theory predicts that the supernormal profits of monopoly should act to attract new firms and

drive down profits, so the sheer threat of this possibility the theory argues, will compel the monopoly firm to keep prices down to just make normal profits, taking advantage of economies of scale and technical progress to be efficient. If this does not occur, potential competition will assume actual competition in the sense of entry occurring, but costless exit is a critical factor in determining firm entry in a monopolistic industry. Contestability of a market may therefore be as important as actual competition in shaping firm price and output strategy to favour consumer interest.

2.4.4 Imperfect market competition

Beyond perfect competition, the rest of market organizations can be viewed as a set of heterogeneous structures characterized by variable ability to exert market power over market prices by individual firms, differing only to what extent. In practical terms, very few markets can clearly be placed within the fringes of the perfectly competitive or monopoly models. Most markets lie between these extremes, constituting the transition zone of imperfect competition. It comprises monopolistic competition and oligopoly and their sublime variants and the key components are discussed in further details.

2.4.4.1 Monopolistic competition

Monopolistic competition is best understood as a situation where many firms are competing, but each firm employs discretionary pricing strategy, that is, each firm has some degree of market power. Monopolistic competition is located nearer the perfectly competitive end of the market structural continuum, and conceptually also, shares the assumptions of independence and free entry of firms as in the competitive model. It detracts from the perfect paradigm however, only to the extent that each firm produces an output that differs somehow from rival firms. This strategy of product differentiation leverages a particular firm to charge its unique price without losing all its clients. In this sense, it approximates monopoly behaviour. Because this market organization incorporates large numbers of firms, the firm and industry confronts a downward sloping demand curve that is relatively elastic.

In the short run, profit maximization output occurs where marginal cost equals marginal revenue, in a similar manner as obtains in any other market structure. Just as with perfect competition, monopolistically competitive firms are also able to make supernormal profits in the short term. These profits are dependent on the strength of demand for the firm's output: the further to the right the demand curve is relative to the total average cost curve of the firm, the greater are the profits. In the long run, the entry phenomena of new firms perpetually lower profits until normal profits are attained and maintained as the long run equilibrium. This is because at this point, the firm's demand curve is tangent to the lowest point of the U-shaped long run average cost curve.

The static demand and supply, equilibrium output and price analysis described above do not incorporate the full range of decision options the profit maximizing firm under monopolistic competition faces practically. It will also need to preoccupy itself with the scope of products to produce and the extent of advertising expenditure, which together form the basis of the firm's non-price competitive behaviour in the market.

The concept of non-price competition incorporates product development and advertising activities of a firm. Product development aims at creating products that will appeal to many consumers and differ from rival products, by targeting products that will have inelastic demand due to absence of close substitutes. In a service industry, product development embraces provision of services that are better and/or at least different from others and may take the form of provision of personal services, long opening hours, or stocking particular product lines. Advertising informs people of the existence and availability of a product as well as attempting to persuade them to make actual purchases of the product by stressing its specific qualities over rival products. This way, the firm intends to improve sales and make its demand curve less elastic.

The social implication of monopolistic competition is that it results in inefficient allocation of societal resources by producing less at higher cost and prices, relative to perfect competition. Firms under monopolistic competition can therefore become more efficient by moving to a lower point on their long run average cost curves. That monopolistically competitive firms can be more efficient through higher output

levels suggests they possess excess capacity. A firm in this market faces a downward sloping demand curve which can still be highly elastic because of the large number of substitutes in the market. This may benefit the consumer by presenting a wide variety of substitute products to exercise the power of choice. Supernormal profits in this market also dissipates in the long run as prices fall and firms produce at minimum efficiency scale, with associated welfare improvement.

2.4.4.2 Oligopoly

An oligopoly market structure represents a situation where there are a number of competing firms in the market, but not in large enough numbers to regard each firm as having negligible effect on price. Consequently, a few firms become dominant firms in the industry.

Under oligopoly settings, there are significant differences in the structure of industries and correspondingly there are also an array of ways in which firms may behave, for example, firms may produce almost identical products like metals, chemicals, sugar, petrol and so on, but most of the time they produce differentiated products and much of the competition then hinges on brand marketing. While there is no one grand model of oligopoly observable in much of the world, there are however remarkable commonalities. These peculiar features of oligopolies are the existence of entry barriers which vary from relatively easy to virtual impossibility and strategic firm interaction within an industry.

Strategic firm interaction under oligopoly underscores the fact that with only few firms in an industry, each firm will naturally take interest in the actions or inactions of the other firms. This means their behaviours are mutually dependent or interdependent: a change in any of the key dimensions of competition (price, product specification, and advertising) by one firm in the industry will affect sales of rival firms, who will in turn respond by modifying their strategies also. In these conditions therefore, it is difficult to predict with reasonable certainty the market performance of say a particular firm's change in price without making assumptions about the reactions of its rivals at the same time. Different assumptions will yield different strategies and this explains the lack of one grand model of oligopoly.

The key oligopolistic features of entry blockade and interdependence may guide oligopoly firms along two dichotomously antagonistic pathways of collusion or competition, subject to specific circumstances. Drawing on their interdependence, firms may club together and cooperatively act as monopolies to maximize industry profits. Alternatively, they could choose to betray each other and compete ruthlessly to gain larger share of the overall industry profits. The following section examines in detail both forms of oligopoly, firstly collusive and then non-collusive oligopolies.

I. Collusive oligopoly

Any competitive strategy embarked upon by an oligopolistic industry always drags total industry profits in the downward direction. Firms in an oligopoly environment may therefore agree on prices, market share and advertising expenditures to minimize the uncertainty they individually encounter and increase overall industry profits. Such arrangements manifest expressly as formal collusive agreements called cartels or as sublime tacit collusion. Cartel formation effectively transforms an oligopoly into a monopoly, setting price and output levels and divide the market between its members. This sort of market collusion is also called a cooperative game. In most countries, cartels have been legislated against, because they have come to be understood as not serving public interest. However the giant oil cartel, Organization of Petroleum Exporting Countries (OPEC), illustrates well the challenges of collusion and understanding why we see so little of collusion in industries where one would otherwise expect more of it.

Profit maximizing Cartel operation requires getting all members to co-operatively produce a fixed output level. Following this is getting the firms to agree on the two related issues of setting output quotas and a profit sharing algorithm. Typically, every firm desires as large a share of the revenues as possible and so there is the constant incentive for each firm to exceed its production quota. OPEC finds itself in this dilemma. OPEC does not have an effective quota enforcement mechanism in place and in particular, no way exists of stopping an erring member from dumping more than its quota into the oil market. So nearly all its members are said to cheat on quotas and almost all countries overproduce, motivated by the drive to earn more money. The outcome of these unregulated behaviours of individual countries is that

oil is over produced and prices driven downwards, well below that which the countries would have received had they stuck with their quota allotments. OPEC has experienced occasional success as a cartel, only when Saudi Arabia, the dominant country in the lot, threatens to flood the market with its excess capacity, if members continue to breach quota ceilings.

Therefore, cartels innately have mutually incompatible properties: They act co-ordinately to create monopoly profits and at the same time provide strong perverse incentives for firms to cheat, thereby eroding the effectiveness of the cartel.

Even though open collusion is unlawful in most countries of the world, firms may tacitly collude by either watching each other's prices or following in a similar way, or the firms may tacitly avoid price wars and/or aggressive retaliatory advertising. Tacit price collusion is expressed in two forms; the dominant firm price approach, where the largest firm in the industry sets its price and the remaining firms simply follow and the barometric firm price approach. In the latter case, the price leader is the firm that has had the best predictions of market conditions in the past. In practice however, any firm may take the initiative to increase its prices and the other firms who may only just be waiting for one firm to take the lead, especially where costs have risen, to act quickly by keeping theirs similar. An alternative to the price leadership approach highlighted is the tacit adoption of a simple rule of thumb that guides every firm. Under this arrangement, firms simply add a certain percentage as profit on average cost price. For example, if average costs rise by a certain per cent, prices will automatically be raised by the same per cent. The policy is particularly useful during periods of inflation, when all firms may be experiencing similar cost movements. Another approach to the use of rules of thumb is in establishing price benchmarks. When production costs increase, all firms just raise their prices to the next benchmark.

II. Non-Collusive Oligopoly

Collusions may crash sometimes because of lack of an enforcer of quotas or price agreements, or firms just choose to compete from the outset. In such case, each has to make assumptions about other firms' prices and quantities in order to make a

sensible decision of its own strategy. This interaction approximates a simultaneous game situation, where a firm takes account of its rivals' likely response while considering their own strategy. The vast range of non-collusive oligopoly models mirror the rich array of interrelationships observed under competitive oligopolies. Three best known models based on differential assumptions of rivals' decision parameters occur in economic literature and are reviewed below.

- The Cournot Model

Under the Cournot model, the simplified case of a duopoly is considered. This model permits us to capture the key characteristics of strategic firm interactions, excluding the details that complicate models with a larger number of firms. Also, the model limits its analysis to firms producing identical products as a way to avoiding the issues associated with product differentiation, thus allowing a focus purely on strategic firm interactions. The defining assumption of the model is that the rival would produce a particular quantity of output, given a stable past production history and similarly a stable market environment. Then, the strategic task for the oligopolist is the optimal choice of its own price and output in view of the forecasted output of the competitor. The Cournot equilibrium is attained where each firm finds its prediction about the other firm confirmed. The model predicts lower industry profits relative to a monopoly or cartel (because of lower prices in duopoly), but higher profits compared to perfect competition.

- The Bertrand Model

In the Cournot model described above, it is assumed that firms picked the quantities to produce and let the market to determine the prices. In the Bertrand competition model, the oligopolist fixes the price and lets the market determine the quantity to produce. It posits that an oligopolist would assume a fixed price on the part of its rival and then determine its own price and quantity. The model which also fits oligopolies with more than two firms, predicts an outcome of intense price competition between the firms until all supernormal profits are competed away. This turns out that the Bertrand equilibrium is in a way similar to the competitive equilibrium, where the price must equate marginal cost, a curious conclusion in an

oligopoly situation. The outcome of such a price competition among firms that cannot collude may thus result in much lower prices than can be obtained through any other means.

The equilibrium outcome in both the Cournot and Bertrand models is not in the best interest of the participating firms. Under each of the models, industry profits are lower than under monopoly or cartel. The equilibrium of these strategic interactions is jointly referred to as the Nash equilibrium.

- The kinked demand curve model

This theory is perhaps the most popular of all the oligopoly theories, and explains why prices remain stable even when there is no collusion between oligopolies. The theory has two asymmetrical assumptions at its roots: if one oligopolist firm cuts its price, its competitor will match the cut to stem the loss of customers to its opponent, but a price hike by one, on the contrary, fails to cause a similar response in the competing firm, which keeps its price static. On the basis of these assumptions, the theory argues that at any given point in time, attempt by one firm to raise price will induce consumers to switch patronage to the rival whose prices become relatively cheaper. This realization will cause this firm to be reluctant about a price rise. That is to say the firm faces an elastic demand curve at current price level. On the contrary, a fall in price will only cause a modest increase in sales, since the other firm will also cut its price too, and is unlikely to lose its clientele. A firm therefore, will be less inclined to lower its present price, as it encounters a relatively inelastic demand situation below the current price. Overall, each oligopolist encounters a kinked demand curve at current price and output, thus keeping price stabilized, despite incidence of considerable cost changes at any point.

The equilibrium implications of the numerous models of strategic firm interactions under oligopoly and depicted by quantity leadership (Stackelberg competition), price leadership, simultaneous quantity setting (Cournot competition), simultaneous price setting (Bertrand competition) and the collusive solution vary widely. In comparative terms, at one end, the Bertrand model predicts a perfectly competitive price outcome, with highest output and lowest price, while at the other extreme of the range

successful collusion yields the lowest industry output and the highest prices. In between this range, the Cournot and Dominant firm price leadership models predict equilibrium prices somewhat in the middle, while the kinked demand model postulates that existing prices will tend to remain rigid. These market performances suggest that a regulator's task of choosing an optimal strategy to regulate a market should reflect a fit of empirical facts to the theoretical underpinnings, not just how good a theory appears.

The large numbers of market structures and an equally expansive array of provider conduct can often lead to complex conditions that may precipitate significant market failures and providing justification for government intervention in markets. Section 2.5 therefore examines market failures in details, while the aspect of regulation is explored in-depth in section 2.6.

2.5 Market Failures

Free markets are theoretically the best ways of allocating scarce resources for society. In the real world however, markets seldom achieve this objective, and poor access to health care, environmental pollution, traffic congestion on roads, littered streets and the poor quality of products we sometimes buy exemplify cases of market failure which confront societies. These also depict situations of failure of markets to attain socially optimal allocation of economic resources in an economy and have been attributed to such influences as information asymmetry, consumption externalities, monopoly power and slow response of markets to demand and supply changes.

2.5.1 Information asymmetry

Classically, perfect competition assumes that all market actors have complete knowledge of costs and prices and quality, and consumers are best makers of their own choices. However, considerable degree of ignorance and uncertainty occur in the real world of markets and consumers are not always able to know when marginal benefits equal marginal costs in the context of their individual utility function. For many goods, consumers make purchases once or a few times in a life time and are often ignorant of their qualities until afterwards by which time it is too late.

Deliberate advertorial misinformation by producers may contribute to poor consumer judgment of the benefits of a good. Similarly, firms may be poorly informed about market opportunities, costs, prices and labour productivity among other production variables. Therefore, many microeconomic decisions are premised on expected future conditions with accompanying uncertainties, and hence the critical importance of the value of full information for rational decision making.

That firms and consumers may neither have perfect information about products nor have the capacity to judge the reliability of information they may obtain in the course of pursuing their self-interest, gives rise to the problem of dependence, which is embedded under the broader concept of the principal–agent relationship. The concept argues that people, referred to as principals, have to engage agents to carry out their wishes. It is assumed that the agent has specialist knowledge which the principal exploits to save him time and effort. The principal-agent relationship is innately ‘hazardous’ in the sense that the well informed agent may well not act in the overall best interest of the principal. To minimize this problem, the principal must devise a mechanism for monitoring the agent or the principal must attempt to modify the agent’s behaviour to serve his interest by including appropriate incentives in the agent’s contract.

Under perfect competition, principals and agents are more likely to be mutually aligned, as managers risk their jobs if they fail to manage their firms efficiently to survive in the competitive market environment. Imperfect markets (monopolies and oligopolies) which are characterized by supernormal profits provide perverse conditions where the principals and agents interest may diverge, and an appropriate incentive mechanism may serve well to bridge the gap.

2.5.2 Externalities

Externalities are costs or benefits incident on other people not directly involved in a production or consumption activity. Whenever other people are affected in a beneficial way, there are said to be positive externalities and if the impact is an adverse one, there are said to be negative externalities. So, we speak of the social cost of production of any good or service in terms of the sum of private cost faced by

firms and any externalities (positive or negative) of production. Likewise, the full benefit to society of consumption comprises the sum of the two elements of private benefit and any externalities of consumption (positive or negative). When a chemical plant dumps its waste into a river or emits noxious gases into the atmosphere, the community bears additional cost to those borne by the firm: in this case, marginal social costs exceed private marginal cost. In another way, when a forest company plants new woodland, it yields benefits not only to the company, but the community benefits through a reduction in atmospheric carbon dioxide. Under this scenario, marginal social benefit exceeds marginal private benefit. Negative externalities of consumption occur where for example people use their cars and other people suffer from their exhaust, the effects on other people of noisy radios in public places, cigarette smoke and litter. The marginal social benefit of a person consuming a good is less than the marginal private benefit enjoyed. External benefits of consumption happens in instances of rail travel for example, where marginal social benefit is greater than the marginal private benefit to the rail passenger relating to less congestion on the roads, less exhaust and fewer accidents. More examples include the beneficial effects for others of deodorants, vaccinations and attractive clothing.

The presence of external costs and benefits associated with the twin economic activities of production and consumption has profound implications for markets: where there are external benefits, too little will be produced or consumed of the good or service and on the flip side, whenever external costs occur, too much will either be produced or consumed. Either way, the market will fail and marginal social benefits will not equate to marginal social costs.

2.5.3 Monopoly power

All imperfect markets will fail to attain the state where marginal social benefits equal marginal social costs, even if externalities do not occur. This is because they do not produce at the socially optimal level so as to make supernormal profits. This weakness most characterizes monopoly and imperfect market organizations and typically generates the deadweight welfare loss phenomenon (a net loss in total surplus).

2.5.4 Slow response of markets to changes in demand and supply

The property of immobility of factors of production and therefore time lags in response to changes in demand and supply makes markets incapable of producing at socially optimal levels. Labour for instance, may be so immobile occupationally and geographically in the short run that changes in market equilibrium prices and quantities never really get to settle down before further changes in demand and supply conditions happen again. The consequence is a series of cascading changes which places the economy under constant state of disequilibrium. Firms and consumers keep adjusting in response to market signals and moving towards an elusive equilibrium point that never produces the socially optimal output in what has been referred to as the cobweb phenomenon (Rosen et al. 1994).

Market failure can be said to be an inevitable feature of all real world markets and provides the only condition under which all economists have consensus opinion for government intervention in the market, and the thesis will consider the role of regulation in correcting market failures next.

2.6 Economic Theory of Government Regulation

Regulation may be defined generally as the continuum of legislative and regulatory oversight over a system and regulatory instruments used in economic regulation have broadly been classified as market enhancing and market displacing strategies (Rice et al. 2000). There are two main theories of regulation found in economic literature: the public interest theory which argues that government actions aim at consumer protection and achieving optimal wellbeing across the population and the private interest theory (also called public choice theory), which takes the contrast path. Both are presented in their details in section 2.6.1.

2.6.1 Public Interest Theory of Regulation

Microeconomic theory prescribes justification for government intervention in markets only on account of market failure, and for the purpose of improving market performance and efficiency. Potential means of intervention include use of economic instruments such as taxes, or deploying regulatory standards and sanctions.

Assumptions that underpin this theory are; existence of market failure, regulators that have sufficient information and capacity to optimally promote public interest and regulators that are benevolent individuals pursuing public good (den Hertog 2010). This theory has been criticized because it focuses on achieving equity objectives other than economic efficiency (Joskow and Noll 1981). It has also been pointed out that when regulation is used for equity purposes, the evaluation of social efficiency is difficult because of lack of general standards of justice. This has rendered the empirical testing of public interest theory of regulation difficult, so most studies have concentrated on their effectiveness rather than their efficiency (Joskow and Noll 1981). The theory has come under criticism also for failure to specify how the various actors in the political process interact to maximize economic welfare (Posner 1974). Furthermore, it does not appear to make predictions that can be tested empirically (Stigler 1971). Hence, most mainstream economists are critical of the public interest theory of regulation (den Hertog 2010).

2.6.2 Private interest theory of regulation (Public choice theory)

Another tradition of regulation reasons that governments have political interests other than public interest to pursue, which vested private interest groups capitalize on to influence government policies in their favour (Stigler 1971). Therefore, political decisions tend to sway in relation to the electoral importance of the diverse interest groups in terms of weights of their votes and financial and non-financial contributions to the electoral process. Understanding these political behaviours in an economic perspective forms the core of economic theory of regulation (Peltzman 1989). The theory conceptualized regulation as marketable, where demand comes from interest groups to enhance their wellbeing and supply comes from the government seeking to maximize political support or other private interest. Under these assumptions, the theory argues that regulation may not necessarily arise from market failure and need to protect public interest, but as a result of the interplay of the private interests of pressure groups and government regulators, with the latter demanding and often capturing regulation from the former. Governments can restrict or ban entries, grant exemptions and subsidies, maintain price floors, or restrict use of substitutes and support for complements. Under group dynamics for regulatory

capture, the theory explains that smaller groups have comparative advantages over larger ones, because they are cheaper to organize, free-riding is minimized and from expected benefits, the average revenue per member is larger. The theory concludes therefore that regulation is not targeted at correcting market failure, but favouring firms in return for political support or other private interest of regulators.

The application of both approaches around the world is varied. A lack of consensus over explanatory dominance in practice between the two theories has been reported in economic literature (Tanguayet et al. 2004). Both theories thus enjoy widespread acceptance in the areas of industrial organization and public choice discourse and practice, and will provide a basis for evaluative insights of regulatory policies and strategies in this study.

The thesis will shift focus to a review of health care markets in the context of the generic market structures and price perspectives discussed above, highlighting their similarities and differences

2.7 Health Care Markets

The efficiency of markets in dealing with the social issues of production and consumption has been proposed by economists since the times of Adam Smith (Wells et al., 2007) and reviewed above. Health markets serve the same purpose and just as conventional markets often fail to deliver socially optimal outcomes, health care production and distribution poses particularly acute problems for the market mechanism also. Health markets display a range of peculiar distortionary properties: they are often concentrated and organized professional association regulation may bar members from engaging in competition (Arrow 1963; Detsky 1978; Feldstein 1973). In terms of differences from the competitive model of free markets, where firm owners are assumed to be profit maximizers, maximum profits may not always be the only motivation in health markets. Health care organizations for example may take up not-for-profit status and pursue improved individual health outcomes and overall social wellbeing. Also, even where profit maximization objectives are expressly specified, this may be tempered by considerations of care quality, health outcomes and professional codes of conduct. Furthermore, it has been argued that

health workers may target satisfactory levels, rather than maximum health outcomes as their objective (Palmer and Mills 2003). It has also been argued that organizations may not use market power or particular advantage to hike prices or induce demand unduly, even where the scope for such behaviour exist. In view of these arguments therefore, it is a reasonable expectation that the relationship between structure and conduct in health care markets might vary considerably from that under standard economic models. Despite these differences, the structure-conduct-performance paradigm remains a most useful approximation for the analysis and understanding of health care markets. The framework provides the basis for understanding the nature of competition in the market: the object of competition, competitive strategies and the intensity of competition and prediction of market outcomes. Understanding these relationships is to understand the means and ways of improving health market performances through regulatory instruments. A review of health care markets against the assumptions of the competitive model follows.

The consumer sovereignty conditions of efficiency which require that patients be fully aware of cost and benefits of health care purchased, bear all the costs and receive all benefits exclusively and maximize their utility in the process are non-existent in many cases. Often, patients are neither sure of the benefits of available treatment options, nor certain if cure of a medical condition was the result of a particular medical intervention or some other extraneous factor. Health care consumers rely on health care providers to guide them in making decisions about their health care needs. Health care providers by doubling as suppliers may not act in the best interest of patients. In this sense, health markets do not respond to demand, but rather create their own demand (Detsky 1978; McPake and Normand 2008).

The notion that patients bear all their health care cost does not hold true, as health insurance schemes provide financial cover for health care consumption. Similarly, health care consumers do not always incur health care benefits in that cure of say an infectious disease conveys benefits to the wider community. The condition that people exercise choice over their preferred treatment is also disputed, as instances when patients are incapable of self-choice abound in most of medicine, for instance unconscious patients, or anxiety associated with ill-health may sometimes negate

rational thinking and choice. These arguments would suggest quite significant limitations on patient sovereignty under health care markets. Furthermore, while health and health care may not be public goods, public health services possess non-rivalry and non-excludability properties. For example the consumption of a unit of medication leaves one unit less of medication for others to consume, but malarial control through fumigating a pond of water to rid it of mosquitoes, benefits every member of the community equally.

Health markets also manifest monopoly behaviours. In some disease conditions no real alternative to orthodox medical treatments are known, for example, the condition appendicitis is treatable only by surgical intervention. Also, health professional licensing, and pharmaceutical patents constitute entry barriers in health care markets. Health care providers are however not usually considered natural monopolies, except in a rural practice where travel to alternative health service centres may be prohibitive: such a local facility effectively becomes a monopoly supplier in the locality. The existence of professional bodies in health would suggest collusive practices such as price fixing, restricting output of new graduates and negotiating higher salaries for health workers than there would be under perfect competition. Scarcity of hospitals in rural areas might have implications for services to be artificially priced very high (except perhaps if providers are not-for-profit organizations). Some health professional cadre has acquired monopoly powers of practice, as for example, in some countries only medical doctors are legally permitted to recommend the use of prescription-only drugs.

Health care production and consumption activities generate a number of externalities. When a patient is cured of a disease, he derives benefit which is not confined to the individual alone, as the entire community benefits by way of risk reduction occasioned by the cure. In addition, relatives and friends also benefit by the ill being fit again and where productively employed, work disruption is reversed. On the contrary, many other production and consumption activities may impose external health costs. An example is the consumption of cigarettes, which has been positively shown to harm health of non-smokers by way of passive and involuntary inhalation

of cigarette smoke, while smokers consider only their own benefits and costs in making their consumption decisions.

Information asymmetries exist to a very large extent in health care markets. Health insurance markets often provide a sub-optimal level of insurance for the twin malaise of moral hazard and adverse selection. In the former, the insured who has knowledge of his true state of health before buying an insurance policy, thereafter, behaves in a way that disadvantages the insurer. People who are insured sometimes see it as an incentive to behave recklessly in the exercise of their health choices and cause the insurer to suffer financial losses. The case of adverse selection on the other hand, is where the better informed exploits this advantage at the transaction stage of an insurance process. The general tendency in health insurance practice therefore, is for individuals who believe they are low risk to be less likely to subscribe to insurance than high risk people, so that high risk cases predominantly select themselves to be insured (Feldstein 1973). Health insurance markets generally, because of the strong profit motives, may employ favourable patient selection approaches also: healthier enrollees by insurance firms and healthier patients by providers. This will erode the cross subsidization tenet of insurance: from the wealthier to the poor, and from the healthier to the sick (Rice et al. 2000).

In general, people place high value on their health and are willing to pay a lot for health treatments, rather than foregoing critical health care. Also, the majority of people believe that everyone should have access to basic health care, irrespective of ability to pay. Thus, other than individual factors causing market failure, collective provisioning of medical care is justified by society's definition of what is just and fair in a free social structure and not guaranteed under free market may also explain health market failure (Gubb and Meller-Herbert 2009).

Analysis of the case for government intervention in health markets is rooted in the seminal work of Kenneth Arrow (1963), who recognized uncertainty in disease incidence and treatment outcomes as well as informational asymmetries between patients and physicians. Arrow subsequently argued that without a non-market input, competitive equilibria may never be reached in health care markets and recommended government regulation, medical liability, taxation and medical ethical

codes as best strategies to fill the gap (Arrow 1972; Jacobson 2001; Rice et al. 2000). Therefore, health care regulation is becoming increasingly an important tool for most health care systems funded from general taxation (Saltman 2012). In most countries an array of regulatory bodies exist, applying a wide range of regulations to the extent that health care has been described as over-regulated (Blank and Bureau 2006; Curtis and Schulman 2006; Field 2008). For the drug market in particular, government regulation is wide spread aimed at ensuring quality, safety and affordability of drugs for consumers through strategies such as drug registration and patents, product differentiation and entry barriers that may confer market power on some competitors over others. In Africa, government regulation of pharmaceutical market has however failed to guarantee these (Ensor and Weinzierl 2007; Goodman et al. 2007a, Goodman et al. 2007b)

2.7.1 Pharmaceutical markets

A large body of literature exists on pharmaceutical markets in high-income countries, but research on this topic in sub-Saharan Africa is limited. In the West, analyses have focused on such issues as patent protection for pharmaceutical innovations, the role of generic drugs, drug prescription re-imburement by insurance companies and the regulation of the pharmaceutical industry (Ferrandiz 1999; Maynard and Bloor 2003; Walley and Mrazek 2004; Scott-Motton 2000). Studies from Africa mostly concentrate on the problems of availability of quality drugs, their costs, and practices of retail pharmaceutical outlets (Breiger et al. 2004; Goel et al. 1996; Goodman et al. 2007; Kamat and Nyato 2010; Nakanda et al. 2002; Smith et al. 2009; van der Geest and Whyte 1988). Like markets in general but mirroring health care markets in particular, pharmaceutical markets are not perfectly competitive, with products that are close substitutes of one another abounding. Demand is said to be generally inelastic and the market is highly regulated (Curtis and Schulman 2006; Maynard and Bloor 2003; Mossialos et al. 2004). The market structure consists of the big drug development companies, generic producers, wholesale outlet chains and the retail outlets (Scott-Morton 2000). The market performance is as predicted by the imperfectly competitive model. Regulatory enforcement is observed to be weak and demand and supply approaches are recommended as best strategies to improve

market performances (Goodman et al. 2007; Ensor and Weinzierl 2007; Kumaranayake 2000). Furthermore, retail prices have been found to be high and determined largely by local margins than by cost of drugs (Russo and McPake 2009).

2.7.1.1 Drug retail markets in Africa

This section of the literature review undertakes a description of retail drug shops in Africa, guided by the research conceptual framework of Structure-Conduct-Performance Paradigm. No particular study addressing this phenomenon specifically was identified in economic literature, however, the related phenomenon of general retailing of goods and commodities in Africa based on industrial theoretical underpinnings has been studied. Publications were included if they provided information on retail drug market structure, provider characteristics and operations and price mark-ups. All studies included in this review relied on qualitative methods of structured or semi-structured interviews, key informant interviews and documentary reviews for data generation. Fafchamps (1994), in a study of industrial structure and microenterprises in Africa, observed that Sub-Saharan Africa is characterized by a high proportion of people that are self-employed in their own small businesses driven by entrepreneurial incentives. He also reported that these microentrepreneurs are so numerous and easily evade government regulation. In another study characterise African commodity and product markets, Jerome and Ogunkola (2000), noted that retailing is highly diverse and dynamic, changing considerably in response to social, economic, political and environmental factors. The authors also showed that entry barriers into retail markets are few with minimal technical constraints. They further identified weak infrastructural support for this market in terms of transportation, communication and access to finance as constraints to their optimal performance in what otherwise is a near-perfectly competitive market model

Both studies are conceptually similar to this study, though focused on general retailing of non-health care products and commodities. Nonetheless, they provide a good starting point to understanding retail drug shops.

Drug retailing shops have been argued to play important roles in the supply of pharmaceutical products and services in most of sub-Saharan Africa (Patouillard et al. 2010; Valimba et al. 2014). This importance is reflected both in their market share and population coverage of essential medicines: for example, the retail sector of private healthcare market accounted for about 45% of all household care seeking for malaria in south eastern Nigeria (Onwujekwe et al. 2008), whilst in Tanzania about 40% of all antimalarial drugs sold in three districts were purchased from retail outlets (Goodman et al. 2009). In particular, patent medicine vendors alone accounted for 70% of all antimalarials distributed in Nigeria (ACTwatch 2013). These studies provided some insight into structure of malarial market in Africa, however, they did not systematically investigate the markets based on any theoretical conceptualization. Therefore, these findings provide partial insights into the complex interrelationships of the market structure.

Other studies have attempted to characterise the range of retailing entities operating in these markets and include pharmacies, static drug shops general shops, itinerant sellers and periodic market vendors, who vary substantially in their attributes. Retail providers may thus be pharmacists, persons with health related qualifications, trained drug dispensers or even illiterate as reported by Goodman and colleagues (2007b). Pharmacies operated by trained pharmacists are said to be scarce all over Africa, are permitted to stock the entire stock of drugs available in a country and cluster in cities (Adikwu 1996; Tavrow et al. 2003). General shop vendors sell few over the counter drugs along with other consumer goods and are especially important source of drugs in remote rural communities. Itinerant vendors are a common phenomenon in West Africa, but rarely observed in Eastern and Southern Africa. Specialized drug shops are by and large the most important entity of the retail drug merchandise particularly in East and West Africa and vary widely in their characteristics and framing. For example in Nigeria, they are called patent medicine vendors, chemists in Ghana and duka la dawa baridi (now referred to as ADDOs) in Tanzania (Adikwu 1996; Valimba et al. 2014). Specialist drug shops may be locate in both urban and rural areas and are operated by anyone who can read and write in English at a minimum, however, some expertise may be required in some settings, particularly in eastern

Africa. They are allowed to retail over-the-counter drugs and limited number of prescription drugs.

While these studies set out to either characterise retail drug sellers in malaria markets or evaluate interventions to improve their practices, the authors did not relate particular characteristics with particular provider behaviours, neither were interventions evaluated in the long run, which limits the reliability of conclusions.

Providers' conduct in relation to price mark-ups in retail markets are said to be high and vary widely across outlet type, location and product characteristics (Goodman et al. 2009). Mark-ups have been reported to vary from 3% to 566% for pharmacies, 29% to 669% in drug shops and oscillate between 100% and 233% in general shops (Clinton Foundation 2008). The study also reported higher mark-ups in rural compared to urban areas, when products are generics rather than branded and where tablets were loose relative to blistered. These studies however, failed to explore factors that influence pricing decisions in these markets. Furthermore, Fafchamps (1994) concluded that consumers in the general retail market respond more to price changes than quality indicators, because of generally low income levels. The studies failed to explore the cost structures of sellers and factors that influence pricing behaviour of retailer.

The market performance has been reflected in a number of concerns bordering on low qualifications of providers who seldom have pharmacy education, most having some health related background at best and incapable of matching specific disease with it appropriate medication (Abuya et al. 2007; Marsh et al. 1999; Nshakira et al. 2002). Also decried has been the stocking of counterfeit/sub-standard drugs or beyond allowed remits.

In sum, the review has presented the literature on structure, conduct and performance of retail drug shops in sub-Saharan Africa. Although the studies did not set out to explore these markets based on any economic theoretical framework, they nonetheless have provided useful insights of structure, conduct and performance elements in the retail drug shop market across much of Africa: a plural structure,

high price mark-ups and low market outcomes. This warrants a case for government intervention, which is examined in the following section.

2.7.1.2 Drug retailing and drug shop regulation in sub-Saharan Africa

Drug retailing is wide spread and a rapidly growing phenomenon and drug sellers are becoming important actors in the health care arena of low-income countries. They engage in activities such as procurement, storage and distribution of drugs, particularly at community and rural levels (Breiger et al. 2004; Goel et al. 1996; Goodman et al. 2007a; Hughes et al. 2013; Kamat and Nyato 2010; Smith et al. 2009; van der Geest and Whyte. 1988; WHO 2007). The appeal of their geographic access has ignited recent efforts to use them to expand access to essential health services and strengthen health system performance through such initiatives as the Affordable Medicines Facility for malaria and performance targeted interventions (Smith et al. 2009; Wafula and Goodman 2010). Drug shops are popular and highly patronized among citizens in most African countries because they are said to offer easy access to drugs in a quick and convenient way, ensure drug availability, provide quality of services (no opportunity cost of waiting and convenient hours of opening), are cheaper, drug quantity options in purchasing and sometimes flexible payment terms (Goodman et al. 2007b; Igun 1987; Kamat and Nichter 1998). They are reported to offer therapies for diverse disease conditions as malaria, URTIs, STIs and high blood pressure (Chuc et al. 2001; Hetzel et al. 2007; Oparaet al. 2006). Almost any kind of drug may be purchased over the counter, which portends significant implications for rational use of pharmaceuticals (Kamat and Nichter 1998). This irrational use poses danger of for example antibiotics resistance; drug induced allergic reactions and drug side-effects (WHO 2000). Also, widely reported regulatory infringement and weak regulatory enforcement have been reported (Kamat and Nyato 2010; Mackintosh and Tibandebage 2002; Wafula et al. 2012). For these reasons therefore, retail drug sellers now occupy a prominent position in health policy discourse in sub-Saharan Africa and also one of important regulatory interest

2.8 Rationale for Regulating Drug Shops

Consumers are willing to spend on drugs because of the potential of drugs to save lives, restore health, prevent diseases and halt epidemics. To accomplish these goals however, drugs must be effective, safe, of good quality and appropriately used, otherwise, drugs are poisonous. This provides the rationale for the regulation of the development, production, and final distribution to end users in accordance with prescribed standards (Ratanawijitrasin and Wondemagegnehu 2002). Problems related to drug efficacy and safety generally include the use of drugs contaminated with toxic substances or other impurities, drugs with dubious or unverified efficacy claims and medicines with unknown adverse reactions, with substandard preparations and counterfeit products completing the list. Besides their dangers to health and lives of consumers, ineffective and unsafe drugs are a waste of money, particularly in resource poor settings. It has been argued that it is possible to solve these problems sustainably through an effective drug regulatory system. In sub-Saharan Africa however, effective regulation of drugs is particularly weak, especially of drugs shops in remote areas (Ensor and Weinzierl 2007; Goodman et al. 2007; Wafula et al. 2013). Regulatory approaches deployed in regulating drug shop retailers have included standard setting restrictions, provider training and education and consumer information strategies, and their successes have been limited in improving market performance (Kamat and Nyato 2010; Kumaranayake et al. 2000). In summary, the evidence base on drug shop regulation in sub-Saharan Africa has revealed a public interest perspective in conception, but enforcement processes are weak and tend to be captured by private interests (Blevins 1995; Graddy 1991; Wafula et al. 2013).

Markets in general and their associated failures have been reviewed. Health care markets in particular have been examined in-depth and their unique distinctiveness which contrasts them from conventional markets highlighted. The review will now define the concept of access to health care and lay a framework for understanding health market interactions in the light of their implications for access to quality health care and improved population health outcomes.

2.9 The Concept of Health Care Access

Inadequate access to health care remains a major challenge for public health systems in most low and middle income countries, attributable to factors as inherent weakness in health systems, underutilization of effective health care interventions and inappropriate public health policy and planning (Khan and Bhardwa 1994; WHO, 1999). An amalgam of these is what has been aptly described as the access problem (O'Donnell 2007). Despite sustained research activities on this topic, no consensus seems to exist regarding the definition of the concept or its measurement. Implications for this is failure of health systems and health policy makers to attain effective health sector reforms that maximize population health outcomes (Goddard and Smith 2001; Gulliford et al. 2002; McIntyre et al. 2007; O'Donnell 2007; Oliver and Mossialos 2005). This section attempts to formulate an operationally useful definition of the concept of access and develop a comprehensive framework for the understanding and measurement of barriers to health system access.

A range of definitions of the concept of access to health care exist in the literature, yet, the meaning remains elusive (Chuma et al. 2010; Khan and Bhardwa 1994, McIntyre et al. 2007; O'Donnell 2007). The fuzziness around the explicit meaning and hence a uniform interpretation of access has been linked to the multidisciplinary diversity of the individual authors in the field, which varies across sociologists, anthropologists, psychologists, epidemiologists, health economists and other disciplines. Also contributing to the ambiguity is the regular transformations in our demographic, social, technological and geographical landscape of health care delivery. This has often meant frequent shifts in focus on specific dimensions of access (Khan and Bhardwa 1994). The lack of clarity and consensus on the meaning of access, the authors argue has hampered the work of health policy makers and impaired meaningful health care reforms, especially in low income countries. For the purpose of this thesis, it is imperative to review some of these definitions and pin down observable and measureable indices.

Parker (1974) defined access as, “the ability to reach, obtain or afford entrance to services.” This definition is not lucid because the term ability connotes barriers that an individual must overcome to access services, which were not specified. Access to

health care has also been conceptualized in terms of production and consumption related barriers encountered in a bid to obtain needed health care services (Lewis 1977). Even though Lewis alluded to barriers in his discourse, he too failed to capture them systematically. Elsewhere, Donabedian (1972) and Penchansky (1977) argued that how well the health system and the population in need of services fitted together was the core of access concept. In other words, the authors thought compatibility of demand and supply sides was crucial for access to be achieved. Understood from this perspective, the concept implies an interaction between the characteristics of potential users of the system and the health system, but they too did not comprehensively define the dimensions of that must match for effective access. Aday, Andersen and Fleming (1980), looked at access to include the variables which describe “the potential and actual entry of a given population group to the health care delivery system.” By their dichotomy of potential and actual entry, they argued that systems and population characteristics defined potential access, while utilization and satisfaction determined the dimensions of actual access. Access defined in terms of either ability to obtain needed services or understood from potential and actual entry into a health care system is not directly expressible in measurable terms, and therein lies the weakness of these definitions.

Others have interpreted the meaning of access as an entirely supply phenomenon related to availability of services, also referred to as spatial accessibility in the literature (Goddard and Smith 2001; Guaghardo 2004; Perry and Gesler 2000; Rosero-Bixby 2004). However, simply situating a service in an area of need does not translate to improved access, as individuals in need may not be able to afford the service or find it culturally unacceptable to use. Another school of thought argues for a demand approach in defining access (Falkingham 2004). Affordability is generally considered to be positively correlated with income or ownership of the means to pay for provider services at the point of delivery. Also, affordability on its own is not sufficient dimension that will ensure that people will use services (Birch and Anderson 2005). Therefore, a group has further defined access to mean the use of health services (Wang and Luo 2005). Equating access with utilization of services has inherent problems of variations in use by individuals with the same or different levels of needs and therefore, measurement of access (Finkelstein 2001; Goddard and

Smith 2001; Vilhjalmsson 2005; Waters 2000). Different levels of use of health service may also represent different attitudes, beliefs or preferences, and not just ability to pay (McIntyre et al, 2007). The concept of cost has also featured in the explanatory models of access. Cost is commonly taken to encompass price at the point of delivery and additional costs of seeking care, waiting for services and other costs associated with obtaining services. For example, Goddard and Smith (2001) have highlighted quality of care and information as supply factors contributing to health care costs. This broadening of the definition of cost has been said to incorporate the notion of shadow price (Katz and Hofer 1994; Mooney 1991). The expression of access in terms of shadow price for services provides a platform to further define access in terms of opportunities forgone by using a service (Le Grand 1991). Implicit in this framework is the notion of opportunity sets individuals face in health care utilization, is a synthesis of supply side and demand side influences (availability and affordability respectively) with other dimensions of access, not generally given consideration in the access literature. Factors like culture may have profound roles in determining access. For example, medical examination of female clients at a service by male doctors may not be allowed, therefore, availability and affordability of such services will still impose a significantly unacceptable opportunity cost on potential female users. Birch and Abelson (1993) and Grytten et al. (1995) seem to concur with the LeGrand's paradigm, by adopting opportunity cost as the meaning of access. The dilemma however, of this framework, is the inherent difficulty of empirical measurements.

A regular theme across the plethora of definitions is the common recognition of access as an eclectic variable, determined by a multitude of dimensions. The common access dimensions variously identified were availability, affordability, accessibility and acceptability. Penchansky and Thomas (1981) were first credited with articulating all four dimensions in their definition of the concept, and included a fifth of accommodation. Recently however, McIntyre and colleagues (2007) have streamlined Penchansky and Thomas' model by combining the accessibility, availability and accommodation dimensions in to a more comprehensive definition of availability. Their framework explores access based on availability, affordability and acceptability, evaluating the characteristics of the health system in tandem with

attributes of individuals, households or communities within each dimension, and ultimately isolating the root causes of deficient access in an area. Their availability component addresses issues of appropriately locating health services in the right places, and at the right time. It also explores factors like relationships between the spatial distribution of health care services and service users, temporal fit between service providers and service users, as well as the interrelatedness between the type, range, quality and quantity of services and range of health needs of the population being served. The affordability dimension focuses on the compatibility between the full costs of services (that is opportunity cost) to users and their ability to pay, against the background of specific household circumstances or experiences for example, sources of income and their regularity, socioeconomic status and insurance coverage. Affordability also looks at forms of payments that are acceptable to the provider like cash, credit, reimbursement or in-kind payments. The acceptability criterion describes the attitudes of providers and those of consumers towards one another and how these interact. In this framework, the provider's attitude to the consumer relates to variables such as age, gender, ethnicity, cultural beliefs and socioeconomic status. In contrast, the consumer's attitudes relates to the provider's qualifications, competence and service organization. Furthermore, these attitudinal interactions are modulated by beliefs and perceptions. Central to the framework is the cross-cutting role of information. Information is considered a core element to all three dimensions of the concept and a crucially important precondition for promoting appropriate interactions between the health system and the individuals, households and entire communities. It empowers health care consumers to make informed service utilization choices. The thesis argues that, whilst the analyses of most authors reviewed on the concept were incomplete and not systematized, McIntyre and colleagues have proposed a framework that is comprehensive and integrative, giving clear identification of quantifiable determinants underlying each access dimension. For these advantages therefore, the thesis will adopt this framework to explore access in this study.

Access to health and health care is very sensitive to people and societies, particularly who gets what, when, how and where? These seek to address the concerns of

equitable access to health services. The tenets of health care equity are discussed below.

2.9.1 Health inequality and health equity

Health and health care access discourse is incomplete without a perspective on the issues of health inequality and health equity. A brief discussion of the main issues and how they relate to public health policy is next undertaken to conclude this review.

Health outcomes of mortality and morbidity are not evenly distributed across socioeconomic gradients in all societies. The likelihood of a new-born dying before his or her fifth birthday is disproportionately higher for the poor than their counterparts born to parents in richer social classes (Evans et al, 2001). For example, studies in some European countries have shown that individuals in poorer socioeconomic groups are likely to die 5 to 10 years earlier than individuals in wealthier groups (Whitehead2000). Similarly, children in the poorest households in Ghana, have being shown to experience about 50% increase in the risk of death, relative to the least poor households (Gwatkin 2000). These differences in health and health outcomes between groups within populations underpin the concept of health inequalities, as aptly captured in the definition of the concept.

Margaret Whitehead (1992), concisely defined health inequalities as differences in health that “are not only unnecessary and avoidable, in addition, are considered unfair and unjust.” Implicit in this definition are the notion of subset difference that adversely affects disadvantaged groups within a nation. In another definition of health equity, the International Society for Equity in Health (ISEqH) (WHO 2005) puts it as “the absence of systematic and potentially remediable differences in one or more aspects of health across populations or population subgroups defined socially, economically, demographically or geographically.” This definition is attractive because of the emphasis on the important concept that differences relevant to equity are systematic as against being random or sporadic. Most other commentators have also viewed these differences as constrained, rather than a matter of choice and have

referred to them as inequities instead of inequalities (Wagstaff and van Doorslaer 2000).

The second issue is that of health equity or equity in health. Again, Whitehead (1992) defined health care equity as “equal access to available care for equal need, equal utilization for equal need, and equal quality of care for all.” Mooney (1983; 1987) distinguished two components of health care equity; horizontal equity and vertical equity. Horizontal equity referred to equal treatment for equal need, and vertical equity referred to different treatment for different need. Other commentators on the other hand have constructed health equity in terms of equal utilization, equal access, distribution according to need and equal health outcomes (Culyer and Wagstaff 1993). The consensus among these authors is that these observed socioeconomic related health inequalities arise from material inequality and behavioural differences

2.9.2 Equity implications in health policy

Equitable access to health care has recently gained eminence as a public health policy (resource allocation) objective the world over, with a purpose of universal health coverage at its basis (Cookson et al. 2009). Equity considerations address the question of fair or just distribution of health and health care in the population. However, two questions of what exactly is a fair distribution or what makes a health system fair arises. Several ideological approaches (theories of social justice) to incorporating health equity into public health interventions have being proposed Utilitarianism, Rawlsianism and Liberalism, but none commands general acceptance (Folland et al. 2010). However, whatever ethical theory of equity a society adopts, end-stage equity (equality of health) appears impracticable; rather process equity seems a more pragmatic goal of health systems to attain. Process equity in public health care may be seen as equal treatment of people with equal need (horizontal equity) or people with different need health needs are treated differently (vertical equity).

It has been observed that health equity is a key health policy consideration globally, and valuing society’s overall health care output is best not expressed solely as a

function of per capita health share (efficiency), but also as its distribution across the social gradient in the population (Cookson et al. 2009). Economic evaluation of public health interventions has however continued to tilt heavily towards efficiency quantifying; a trend arguably linked with the development of standardized measurement tools for efficiency such as the QALY (Williams and Cookson 2006). Health equity studies on the contrary are still at the developmental stages. Controversies still rage about what equity objective to set and methodologies of developing equity weights have not being laid to rest (Williams 2005). Notwithstanding these limitations, equity concerns are being increasingly incorporated into public health decision processes, though in less explicit ways.

To put the arguments so far in perspective, health inequalities do not mean a generic difference in health of individuals, but a systematic difference in the health of disadvantaged social groups in the society that could be possibly reversed by public policy. Health equity or equity in health on the contrary means the pursuit of policies targeted at the elimination of health inequalities. A clear understanding of these issues is of crucial practical importance for the purpose of health care resource allocation decisions to improve health care access (Braveman 2006).

CHAPTER 3: METHODOLOGY

3.1 Study Design

The purpose of this thesis is to explore the interactions between health market structure, provider conduct and consumer demand, all superintended by regulation and understand how these influences shape competition and determine patent medicine vendor market outcome in terms of access to quality and safe essential medicines and services in a rural setting. The study adopted an exploratory descriptive approach, employing the economic analytic framework of the Structure-Conduct – Performance paradigm to critically investigate the research market.

In generating qualitative data for this thesis, the author was constantly mindful of the influence of the researcher at every step of the research process. For example, this researcher's medical background might be assumed to affect choice of what to investigate, the angle of investigation, the methods adjudged most appropriate for this purpose and findings considered most adequate (Malterud 2001). Therefore due diligence was observed to maintain objectivity all along the research process. However, the researcher's medical knowledge was brought to bear on technical issues to gain clearer perspectives from research participants. The researcher was aware of the deep rooted mistrust of patent medicine vendors for formal health workers (seen as competitors); he therefore introduced himself in a more neutral fashion as a researcher, in order to avoid creating barriers to open communication and engender more trust. Data interpretation was guided by economic theory, empirical literature and research questions and objectives.

3.2 The structure-conduct-performance paradigm (SCPP) framework

To undertake to answer the research questions and ultimately attain the specific research objectives, the researcher drew substantially on insights from neoclassical economic theory of industrial organization, narrowing down particularly on the structure-conduct-performance paradigm (Clarke 1985). The framework offers useful

analytical concepts and provides tools for exploring and understanding this market and has been used in the analysis of a health market for fever in a low income setting (Goodman 2004a). In its most basic form, the model argues that market structure determines provider conduct, which in turn determines the various aspects of market performance. However, it has been argued that the relationship is not a simplistic unidirectional one as structure and conduct can be reciprocally constituted (Martins 1994; Tirole 1988). In other words, the simple linear causality assumed is not always the case in reality; rather a more complex interaction exists. The interactive model further extends the argument by adding that strategic conduct of firms does reversibly determine structure also. In this model, market structure consists of relatively stable factors that influence rivalry between buyers and sellers in the market environment and include variables as numbers of buyers and sellers, barriers to entry, product information, vertical and horizontal integrations, diversification and supporting regulatory framework. Market conduct of firms refers to provider behaviours and includes advertising, pricing, product choices (their quantity and differentiation), collusion, and research and development activities. Performance of the market is assessed in terms of social welfare or efficiency gains. This research proceeded by redefining market performance in terms of access to quality and safe essential health care products and services, and hypothesized that the interaction of market structure, provider conduct, and consumer demand, moderated by government regulation will determine the nature of access to health care services in the researched market. This conceptual framework is illustrated below.

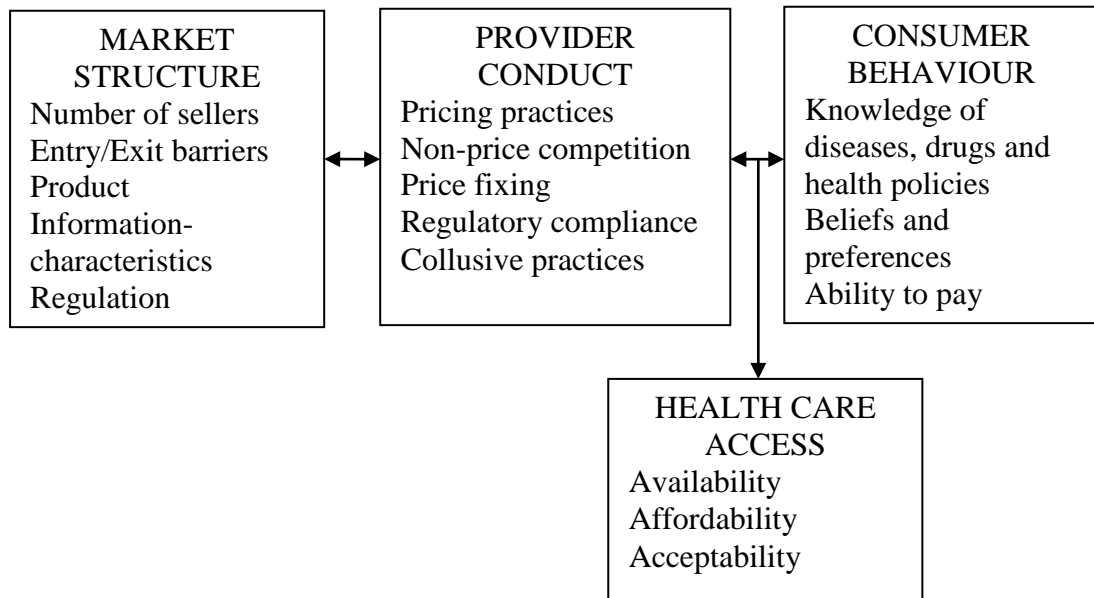


Figure 3.1: Structure-Conduct-Performance framework: Adapted from Goodman (2004a).

Guided by this evaluative framework, detailed variables representing each market component were explored and measured as depicted in Table 3.1 below. The rationale to use a single measurement instrument to collect data or to triangulate methods was determined by the objective or subjective characteristic of a variable. For example, the set of variables that make up the concept of demographic data are fairly stable and a single measurement approach was deemed sufficient for gaining credible data. Knowledge and practices as individual characteristics however, vary widely from one person to another and even in the same individual in different contexts, hence, data falling in these categories were triangulated in order to ensure rigorous data generation to support robust analysis.

Consumer demographic characteristics could best be elicited from consumers themselves from questionnaires, whereas variables as search strategy, choice of provider and knowledge of diseases and drugs are deemed to be most comprehensively obtainable through the combination of questionnaires, interviews and observation of behaviours.

Conduct variables comprising knowledge of diseases, rational drug use and competitive strategies are to be obtained through multiple channels, considering that providers acting strategically to maximize profits may not completely divulge information they have about the market at one particular moment, using a single instrument.

Market structural factor of seller concentration require facility count and relevant data will best be generated through observation of shop outlets. Other structural determinants of market structure like products and services differentiation will be studied via interviews, questionnaires and observational approaches to understand their role in the market, while information on regulation will be obtained from interviews, questionnaires, observations and review of secondary data.

In sum, the fit of variables to the data collection instruments was determined by the order of phenomena they represented and are summarised in Table 3.1 below.

Table 3.1: Research variables and corresponding measurement instruments

Variables	Data collection instruments
Consumer Behaviour	
Demographic information(population distribution by age, sex, socioeconomic status)	Questionnaires,
Attitudes Search strategy and choice of provider	Questionnaires, Interviews, Observations
User information about disease prevalence	Questionnaires, Interviews, Observations
User information about pharmaceutical products	Questionnaires, Interviews, Observations
Provider Conduct	
Knowledge about common diseases treatment	Questionnaires, Interviews, Observations
Knowledge about pharmaceutical products	Questionnaires, Interviews, Observations
Understanding of users' preferences	Questionnaires, Interviews, Observations
Competitive strategy (pricing, payments & dispensing practices)	Questionnaires, Interviews, Observations
Market structure	
Market Concentration (Seller concentration)	Observations
Products and services	Observations, interviews, questionnaires
Barriers to entry/exit	Questionnaires, Interviews, Observations, Secondary data
Relevant regulations	Questionnaires, Interviews, Secondary data

Specific applications of data collecting instruments in respect of each market component are undertaken in section 3.3.

3.3 Methods of Data Collection:

To ensure content validity of the research findings of the study, justification arose for the use of a range of data collecting instruments to triangulate information and ensure content validity of the study results (McPake et al. 1999; Goodman 2004a). To achieve the research objectives, sequential triangulation of information via semi-structured questionnaires, semi-structured interviews, observations of seller-buyer interactions, and secondary documentary reviews were employed to obtain cross-sectional data from sampled populations. The flexible, semi-structuring of data collecting instruments was preferred because of the scope it allowed for the in-depth exploration of new insights and leads that emerged during the research process.

3.3.1 Questionnaire design

Questionnaires were used to collect primary self-reported data from providers and consumers, and the design was guided by literature review of previous quantitative and qualitative work in the study area and in relation to the research question and study objectives (Conteh and Hanson 2003; Goodman 2004b). A set of questionnaires were developed for providers and clients respectively. Both questionnaires took the semi-structured format, consequent upon the realization that the data sought consisted of a mix of subjective and objective realities.

The semi-structured exit questionnaires for the consumers covered demographic data, socio-economic status characteristics, knowledge, beliefs, attitudes and preferences on diseases and providers, as well as perceptions of the appropriateness of drugs obtained, based on reported symptoms. Similarly, the provider questionnaire also sought information on a wide range of issues reflecting individual provider characteristics, outlet operations, competitive strategies and knowledge of government regulations and their implementation. These instruments were drafted in English, but were translated into local languages guided by the principle of complete equivalence, for non-English speaking participants. These instruments generated the

data used for quantitative exploration and the full complements of the questionnaires are attached as appendices 2 and 3.

3.3.2 Qualitative interviews

Several studies have demonstrated the value of qualitative methods in understanding the interactions of providers and consumers in retail drug markets (Adome et al. 1996; Brieger et al. 2004; Coast et al. 2004; Hughes et al. 2013; Igun 1987; Kamat and Nyato 2010). The study therefore, used in-depth semi-structured interviews to collect a rich amount of data, the flexibility of the method allowing a free rein of inquiry in particular cases yet, retaining comparability of topics covered during each interview.

Again, a review of the literature provided key ideas that informed the lines of thought explored against the economic framework of structure-conduct-performance and the current conceptualization of health care access. The initial domains related to supply side variables including provider perspectives of their roles, skills, knowledge and performance, regulatory framework, enforcement and compliance, and future business expectations. Additional issues and themes identified during data collection provided new avenues that were further explored in subsequent interviews. These specifically were relationships with formal pharmacies and the supervisory agencies, especially the Pharmacy Council of Nigeria and the National Agency for Food and Drug Administration and Control, and business problems and challenges. Demand side variables investigated during interviews were consumer perceptions and expectations of drug shop retailers and perceptions of the roles and expectations from government, as well as their knowledge of health issues. Although these key areas formed the basis of the interview guide, useful insights arising during the interview process were further examined in detail.

Interviews of key regulatory officials explored mainly, the role of the patent medicine vendors, regulatory framework and implementation, challenges of regulating pharmacy practice in general and then patent medicine vendors in particular and the future of this pharmaceutical entrepreneurs in Nigeria.

All interviews were conducted in English by the researcher and recorded with a digital recorder, between the usual business operating hours of 8 am and 10 pm. Interviews lasted between one to two hours, and at the end of each interview, notes were made of observations made about the interviewee's attitudes and non-verbal languages and clearer ways of asking questions in future interviews highlighted. Also, informal analysis began with the writing of post interview memos. All three interview guides are included in the thesis as appendices 4, 5 and 6.

3.3.3 Provider-consumer interaction observations

Observational studies consisted of on-the-spot assessment and documentation of actual processes of market interactions between drug vendors and clients, undertaken in purposively selected (highly patronized) drug shops, and on a systematically selected sample of drug buyers, recruiting every n^{th} customer until the required sample size of ten was attained. This activity was assumed to attain some degree of unobtrusiveness because it was timed at the end of other research activities when the researcher had become well known to the retailers and his presence regarded as normal. The activity entailed documenting detailed descriptions of interaction episodes, specifying the nature of interactions as whether the consumer consulted, demanded a medicine or presented a prescription and what the provider did or failed to do. The exercise was check-listed and supplemented with additional notes made of relevant observations. To maintain an atmosphere of unobtrusiveness, the researcher adopted the attitude of social engagement with providers alternating with moments of simulated reading, so that even when the researcher had to scribble down pieces of information in the course of provider-client interaction, the former did not see it as unusual. The variables observed on medicine vendors were whether there was questioning related to illness symptoms, duration of ill-health or drug history; physical examination of clients and final actions taken, such as sale of medication, written or verbal advice on how medications were to be used, wound dressing, administration of injections, referral or health education talks. Social closeness of actors, client satisfaction and the practice setting were also documented. Finally, the duration of the transaction was noted. Both observational check-lists for the provider and consumer interactions form appendix 7 of the thesis.

3.3.4 Secondary data collection

Secondary sources of information collected for this study related to background information from relevant documents like relevant health policy documents, programme intervention reports, evaluation reports of essential drug management programmes and government health reports. A search for these documents was undertaken in relevant ministries and extra-ministerial departments, professional organizations, bilateral and multilateral agencies (Conteh and Hanson 2003; McCombie 2002). These data were identified and retrieved from diverse places as the Federal Ministry of Health (FMoH), World Health Organization (WHO), World Bank, Health Reform Foundation of Nigeria (HERFON), Pharmaceutical Council of Nigeria (PCN), National Agency for Food and Drug Administration and Control (NAFDAC), Consumer Protection Council (CPC) and PATHS 2 Nigeria.

3.3.5 Sampling techniques and administration of research instruments

The need to collect data that was representative and therefore useful for policy recommendation made it mandatory that standard data collection approaches and instruments be deployed. These are described in the section that follows.

3.3.6 Provider questionnaires, interviews and observations

Providers were sampled using a stratified random sampling approach, according to their geographical spread as documented from the outlet census above. Using the numeric coding of each drug outlet referred above for each NAPPMED district, the codes were placed in a cap, thoroughly mixed and samples picked without replacement to make the required sample size in each case. Therefore, in Katsina-Ala district, 18 outlet shops were sampled out of 56, 4 out of 12 shops sampled at Gbor, and 4, 2 and 2 sampled respectively at Tor Donga, Abaji and Sai districts, to make a sample size of 30 outlets. The outlet questionnaires were then administered to their owners to fill out. The questionnaires were left with the shop owners and later collected when fully completed. From this random sample of 30 outlets, another sample of 10 providers who were judged to be the most enthusiastic about the study was later picked conveniently for in-depth interviews and assumed unobtrusive observations, having become very familiar with the providers over the course of the research. This pattern of approach was intended to facilitate the development of a cordial relationship with the providers and it was believed this intention was achieved to the extent that the researcher's presence came to be seen as quite ordinary.

In addition, six key informants drawn from state level NAPPMED executive, state and federal levels regulatory officials and policy official at Federal Ministry of Health were purposefully selected for in-depth interviews.

3.4 Methods of Data Analysis

The general approach adopted in data analysis was one of thorough familiarization with the data, content analysis and generation of a coding framework and data interpretation, all in relation to the research question and study objectives. Content analysis of nominal data from semi-structured interviews was undertaken to structure and categorize the information gathered. The interview data were transcribed and the transcription notes reviewed for accuracy by comparison with two reviewers. The contents were then re-read systematically and coded line by line into structured categories manually, using a two level coding approach. First, an apriori set of codes was generated from the conceptual framework of the research before the data was collected. For example, broad categorical codes as consumer behavior, market structure and provider conduct derived from theoretical framework, from which several narrower apriori sub-codes such as entry barriers, exit potential, linkages and regulation were framed, as reflected in Table 3.1. In the careful reading and analysis of data, new ideas, relationships and meanings emerged through inductive reasoning process, which gave rise to a multitude of emergent codes, some of which included ideas as motivation, professional expert, first aid provider and social embeddedness. The full complement of emergent themes is discussed in Chapters 5 through 7. The fit of these structuring codes to the data and purpose of the study was ensured via constant comparison of newly coded texts with previous similar codes. The approach allowed for consistency of coding and guided data interpretations and visualization of patterns.

Quantitative data were double-checked and entered into Microsoft Excel version 2010 and imported into SPSS version 19.0. Descriptive statistical analysis was performed on demographic data, and relationships between variables explored through cross tabulations. Observational field notes were coded by type of behaviour, and frequency counts derived. Key findings were isolated and summarized data described and displayed as charts, figures and tables to aid visualization of relationships between variables. Drawing on insights from the structure-conduct-

performance theoretical framework, market concentration was studied based on the number of patent medicine vendors in the market and entry conditions explored through entry requirements, ease of exiting, wholesale market structure, vertical and horizontal linkages and tie-ins. Strategies of non-price and price competitions formed the items of data collection for provider conduct while consumer behavior was looked at from knowledge of disease and drugs, search strategies and rationale for the choice of providers. The final determinant of market performance in the form of regulation was evaluated by looking at policies, their implementation and enforcement approaches.

3.5 Study Limitations:

The sensitive nature of much of the information that was sought by the study made it likely that some of the research methods would not accurately measure all the target variables. Semi-structured interviews though allowing for in-depth exploration of issues may have been biased by social appropriateness of responses and sometimes hazy recall. Observational studies are subject to the Hawthorne effect, and data from documentary sources may be fraught with errors, such as missing parts or biased reporting. The study design had been guided in recognition of these limitations, hence triangulation of data collection methods used for some variables. The small size of the area studied relative to the vastness of Nigeria imposes severe limitations to the generalizability of the findings, but the rigorous random techniques adopted will minimize errors or biases, and enhance the credibility of the evidence generated.

3.6 Ethical Issues

Ethical clearance to undertake this study was obtained from the Ethical Committee of Queen Margaret University, Edinburgh in October 2011. Further ethical clearance from the Benue State Ministry of Health, Makurdi, Nigeria, was granted for this study in November 2011.

All participants in the study were firstly fully informed of the purpose of the research and the educational institution involved. Their expected nature of participation was clearly explained and they were then given opportunity to ask questions where ambiguities lingered and needed further clarifications. Due to the nature of behaviors

in informal markets of this sort and potential legal implications thereof, only oral consent was obtained in the study, as evidence has shown that private health providers feel threatened and discouraged by written consent, thereby either limiting their participation or biasing information (Goodman, 2004a). Consent was also sought for recording of qualitative interviews. Written requests to key regulatory officials were sent through land mail seeking consent, date, time and venue of interviews. Participants were well informed of their rights to refuse to answer any questions, ask any questions at any point during the study and to withdraw voluntarily from it at any time. Where a participant was keen, he or she was given the full information sheet to read, before proceeding with any activity. Anonymity of participants was ensured by treating all information obtained with strict confidence, and by transcribing the data using code numbers, storing the interview tapes and transcribed notes in locked cabinets. Also, the research laptop computer holding participants information was secured by a personal password.

3.7 Data Collection Activities

3.7.1 Study site

The study was undertaken in Katsina -Ala local government council, of Benue State, in North Central Nigeria, from January 2012 to December 2012. This Local Council is about 190 Kilometers north east of the State capital, Makurdi. The Council has a population of 248, 218 inhabitants, who are mostly rural dwellers. It is known in Nigeria for its production of yams in large commercial quantities and boasts of a robust yam market. This economic resource has served to attract a diverse mix of people (mostly Igbos, Hausas and Fulanis) from across the country to immigrate and take up businesses within its precincts. Katsina-Ala Local Government Area (LGA) is one of 23 LGAs that make up Benue State, with its administration headquarters in Katsina –Ala town. The LGA is divided into 12 political wards and has a population of 249, 219. The Tiv speaking people are the dominant indigenous group along with a minority Etulo speaking race. The main economic activity of majority of its inhabitants is small scale mixed farming. The local council has a total of 48 government health facilities, comprising a State run general hospital and 47 Local

Government primary health clinics and dispensaries. These geographical characteristics are depicted in figures 3.2 and 3.3 below.

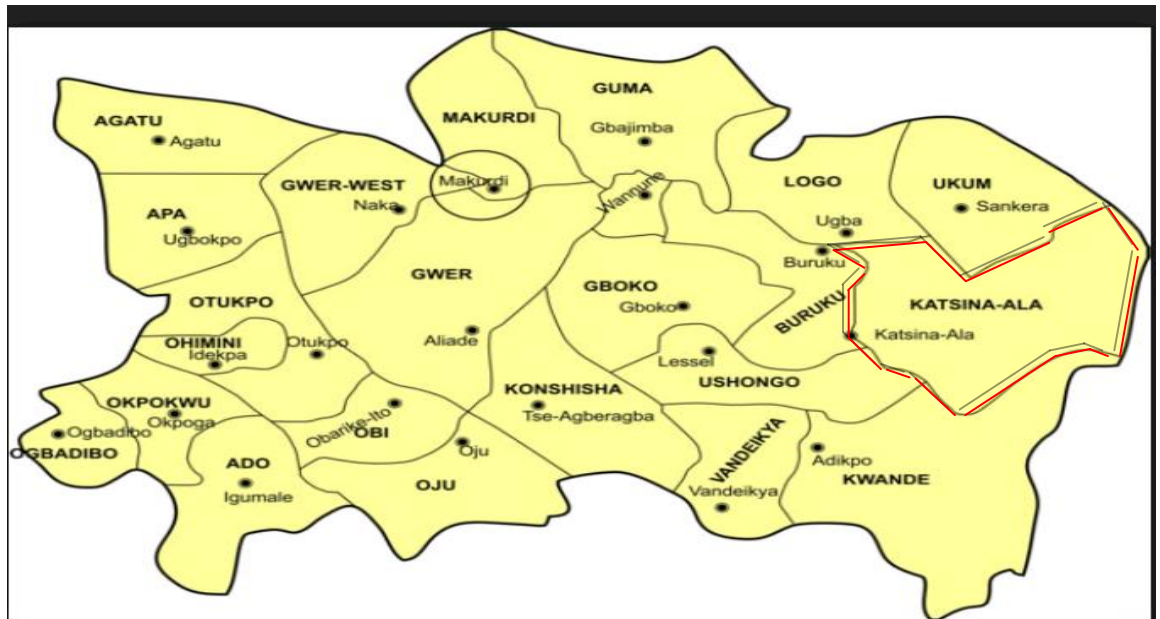


Fig 3.2 Map of Benue State showing Katsina-Ala Local Government Are (Source: Google map).

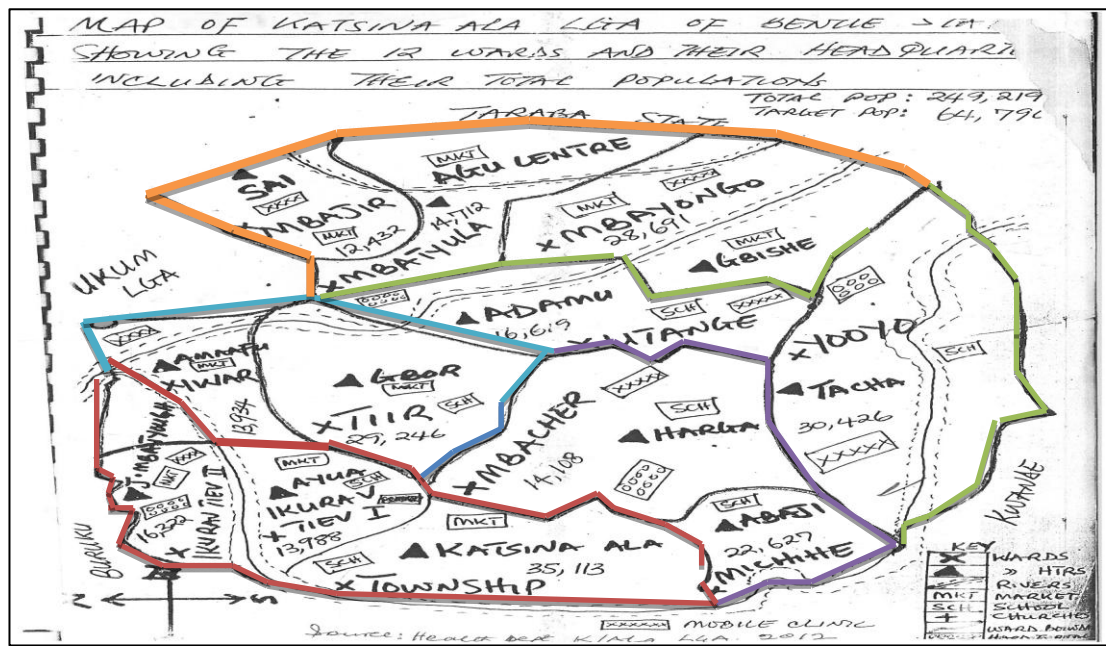


Fig 3.3 Map of Katsina-Ala showing the five NAPPMED districts and corresponding sub-markets

Source: Health Department Katsina-Ala Local Government Area, Benue State

- Katsina-Ala submarket
- Gbor submarket
- Tor Doonga submarket
- Abaji submarket
- Sai submarket

Rational for selection of study site:

The rich socio-cultural diversity described above was judged to present a perfect context for understanding cross-cultural influences on health care behaviours in patent drug markets and also gave the study a broad and in-depth coverage of the research topic. Additional consideration was the current security challenge in Nigeria and since the researcher is of Benue State extraction, this site appeared safest.

3.7.2 Preliminary activities

Prior to commencement of actual data collection activities, all the research instruments (questionnaires, interview guides and observation checklist), were pretested in a pilot study at Ikpayongo, a small community in Gwer East Local Government Area, also of Benue State. This was to establish their appropriateness to elicit research relevant data from participants and the results helped revise and shape the final research instruments. Two research assistants were recruited for this project: One had secondary school level education and her role was to help with administration of questionnaires, assisting uneducated participants to fill out their questionnaires and follow up and collect completed questionnaires from sampled drug shop owners. She had been trained in this role. The second assistant held a Masters in English Literature, and served as alternate transcriber of interview recordings.

3.7.3 Entering the field

To effectively embark on the task of collecting the appropriate data required to answer the research question and attain the research objectives, the researcher undertook advocacy and sensitization visits to the Local Government Council Authority, which serves as the principal gate keeper into the area. The researcher held two successful meetings with the Head of Health Department, who assigned the Supervising Officer for Pharmacy and Immunization as my guide during the research. The officer subsequently introduced this researcher to the President of the National Association of Proprietary and Patent Medicine Dealers (NAPPMED), Katsina-Ala chapter. NAPPMED is a nationally and legally registered umbrella body of patent medicine vendors that serves to protect principally, the business and welfare interests of its members. It is structured along national, state and local government chapters. The researcher had three meetings with the local chapter executive members before their acceptance and cooperation on the research was secured. Thereafter, the researcher attended and addressed congress meetings of all the district chapters of the association in the local government Council. At all of these meetings, the researcher introduced himself fully and the purpose and usefulness of the research were explained and this strategy was intended to enhance

the researchers acceptance in the eyes of the association members. Katsina-Ala chapter of NAPPMED is further organized into five districts associations, located in Katsina-Ala Township, Gbor, Sai, Abaji and Tor Donga. The sub-districts, their component council wards and population served are shown in Table 3.2 below.

Table 3.2: NAPPMED sub-districts, their council wards and populations

NAPPMED sub-District	Nos. Council Wards	Population Served
Abaji	2	36,735
Gbor	2	43,180
Katsina-Ala	3	65,423
Sai	3	55,835
Tor Donga	2	47,045
Total	12	248,218

During the period of interacting with the officials and members of the drug retailers, time was also taken to understand the research setting through mapping the physical, social and cultural terrain, as well as conducting a census of provider outlets and numerically coding each outlet at the same time (Conteh and Hanson 2003). These activities yielded a fertile ground for the entire research process. In all, there were 93 patent medicine vendor shops identified, 82 were registered with NAPPMED, while 11 were not registered with the association. The distribution of these retail outlets is as shown in the table3.3 below. Katsina –Ala township District had 56 outlets; Gbor District, 12; while Tor Donga, Abaji and Sai Districts had 12, 8 and 5 patent medicine outlets respectively.

Table 3.3: Distribution of Patent Medicine Vendor Shops in Katsina-Ala LGC

District	Nos. of drug shops	%	Population
Abaji	8	8.6	36,735
Gbor	12	12.9	43,180
Katsina-Ala	56	60.2	65,423
Sai	5	5.4	55835
Tor Donga	12	12.9	47,045
Total	93	100	248,218

3.7.4 Study Population

The target population for the supply side of the study market was the 93 drug shops identified through prior outlet census, while the demand side population was all individuals in all households who actively made drug purchases from the sampled patent medicine shop. However, because of time, financial and physical effort constraint, samples were drawn from these populations.

Table 3.4: Distribution of Sampled Patent Medicine Vendor Shops in Katsina-Ala

District	Nos. of drug shops	Nos. of shops sampled	% of sample
Abaji	8	2	6.7
Gbor	12	4	13.3
Katsina-Ala	56	18	60
Sai	5	2	6.7
Tor Donga	12	4	13.3
Total	93	30	100

3.7.5 Consumer exit questionnaires and interviews

30 consumers were systematically sampled to participate in the questionnaire survey at 10 purposively selected points of use. Two patent medicine vendor outlets were selected in each to the five districts of the Local Government Chapter of NAPPMED. Though Katsina-Ala district accounted for 60% of the patent drug shops in the entire Council, it serves only about a quarter of the population. Therefore population spread was given greater consideration in choosing outlets for consumer data collection. Three consumers were systematically enrolled, picking the first enrollee randomly and then the nth customer in each of the ten drug shops selected, making a total of 30 adults (>16years) who came into the drug shops to make drug purchases. The participants completed the questionnaires at the shop premises and returned them

immediately at the point of purchase. Where a participant was not literate, she/he was assisted by the researcher or the research assistant. Again at each of the 10 outlets, a consumer was conveniently picked and interviewed during the round of interviews.

3.7.6 Observation of provider-consumer interactions

In each of the five patent medicine sub-markets, two provider outlets were randomly selected for presumed unobtrusive observation of sales transactions. Overall, ten such observations were made in the entire market as spelt out in section 3.3.3 above.

A summary of all data collection activities is presented in table 3, below.

Table 3.5: Summary of research activities

S/no.	Time	Activity
	(2012)	
1.	Jan-Feb	Advocacy, familiarization and patent medicine outlet census activities
2.	Mar-Apr	Provider and consumer questionnaire administration, and data entry into Excel and importation into SPSS
3.	May-July	Provider and consumer interviews and transcription using Windows 7. Next Generation in Africa Social Science Fellowship workshop in Ghana (15-21, July)
4.	Aug-Sept	Regulatory officials interviews and transcriptions using Windows 7
5.	Oct-Nov	Unobtrusive observational studies
6.	Dec	Winding down and exiting the research field

3.8 Exiting the research field

On completion of all the data collecting activities outlined in the research design, the research was wound down with informal social visits to drug shops who participated in the study. These meetings involved general discussions and further clarifications about any particular areas of the research, usually over drinks. Photographs of some of the participants were also taken at this time. As a group, I conveyed my gratitude to the executive of NAPPMED for their cooperation during the research and assured them of access to research findings on successful completion of my PhD. In like manner, thank you visits were made to the Health Department of Katsina-Ala Local Council and the Director of Pharmaceutical Services of the Benue State Ministry of Health, where again assurances were made to disseminate the research outcomes at the end of the researcher process. Thus the fieldwork was wound down to a close.

CHAPTER 4: RETAIL MARKET STRUCTURE

4.1 Introduction

The main objective of this thesis is to evaluate the impact of the interaction of market forces of demand and supply, and their implications for access to quality and safe essential drugs in Katsina-Ala local government area. The result analysis approach adopted therefore is one of relating practice to theory, identifying areas of similarities and fit and differences between them, and exploring the latter in terms of their implications for market performance. The findings of the thesis are presented in a series of four chapters. In each result chapter, findings are presented and considered in relation to economic theory and evidence in economic literature as reviewed in Chapter 2 of the thesis.

The results have been organized based on analytical themes related to the research question and objectives. Each chapter develops from a synthesis of evidence generated from the three main data collection activities, with the intention of presenting in-depth and cohesive insights of each key thematic area. Consequently, the current chapter begins with an assessment of market structure and addresses objective 1 of the thesis, while Chapters 5 and 6 relate to objectives 2 and 3, and takes a close look at provider conduct and consumer behaviour respectively. Chapter 7 reports findings on retail drug sales regulation, a cord which cross-cuts all five research objectives, and finally, Chapter 8 discusses and concludes from the evidence from all four results chapters integrated into a synopsis of the implications for effective access policy, thereby jointly addressing objectives 4 and 5 of the study.

4.2 Market Structure

The first objective of the thesis is to understand the nature of organization of the patent medicine market in Katsina-Ala Local Government Council, serving as a first step towards determining the form of competition in the market. As a prelude to the analysis of the market structure of the researched market and to lay a firm foundation for further analysis, the thesis firstly will define the market researched. A market

traditionally, is defined along product market and in terms of the geographic market over which trade in the product occurs (Morrisey et al. 1989; Kleiner et al. 2012).

4.2.1 Definition of the market

Market definition along product and geographical lines both require the condition of substitutability in demand and supply as an underpinning principle (Morrisey et al. 1989). The product market in the study context was taken to refer to health enhancing medicinal products bought and sold from patent medicine vendor outlets, even though medicines are heterogeneous in nature. This definition is anchored on the assumption of substitution between providers and the products they sell in the market. It is pertinent to clarify that, itinerant medicine vendors and market-day drug vendors were not considered important for the purpose of the study, based on their distribution in the area and therefore not included in this definition. For instance, the researcher did not encounter a single itinerant medicine vendor all through the research period, though market day vendors were occasionally spotted. In the course of the research process, it appeared that the market day drug vendors could have been the handiwork of some actual patent medicine vendors who in addition to their static shops might have been trying to make more sales. Also, there was just one pharmacy in the entire Local Council Area, located in Katsina- Ala town, which was likewise not deemed significant in the study either. Therefore, substitutability in supply was limited to shop based patent medicine vendors. Consumers substituted between branded, branded generic and unbranded generic products, but basically the same drugs. The geographic market was delimited along the geopolitical unit of the Local government Area. This geopolitical definition of a market though simple and widely used in the literature, does not enable quantification of market concentration and market power accurately. For purposes of anti-trust policy for example, economic definitions of geographical market adopting patient flow data, price and shipment approaches are preferred and said to be more meaningful (Dalmazau-Matarrodona and Puig-Junoy 1998; Kleiner et al. 2012; Morrisey et al. 1989). These approaches employ empirical evidence on patient flow data, price and shipment patterns to establish market boundaries, even though these variables are subject to measurement errors (Morrisey et al. 1989). This researcher could not undertake to collect data on

any of these dimensions due to resource constraints hence, the recourse to the simple geopolitical delineation of the market. For the purpose of analysis of concentration in the market, consideration was given to consumers' transportation, time and distance costs, which informed further division of the monolithic geographic market into 5 sub-markets, corresponding to the 5 administrative units of the Katsina-Ala chapter of National Association of Patent and Proprietary Medicine Vendors (NAPPMED), as earlier described in Chapter 3 of the thesis. Also, this unit of analysis was supported by findings of very similar shop dimensions within a particular sub-area of the market. Observations revealed that competing drug shops were mostly located near each other, commonly in or around market squares. Stand-alone drug shops located deeper in interior villages had no competitors. In spite of these geographical delineations, in pragmatic ways, the thesis recognises that these boundaries may neither be rigid nor self-contained, with some overlap in actual consumer drug purchase behaviour across these geographically bounded sub-markets. The thesis will now estimate market concentration as prelude to defining competition in this market.

4.3 Market Concentration

Market concentration is evaluated on sub-market basis first, then overall in the Local Government Council and is considered purely as seller concentration in the market. Concentration estimation along product market is not undertaken, as this was defined in generic terms of all the pharmaceuticals sold in the geographic market and secondly, an audit of products sold was not undertaken as part of this study due to time and financial limitations. Also, gross annual turn-over of sampled retailers was not revealed by over 80% of respondents, and those responding documented questionable data compared with other evidence from interviews and observations. Not a single interviewee said he/she kept a sales record book, although the sensitivity of this information may also have accounted for this behaviour. These limitations therefore constrained the analysis.

Conventionally used measures of concentration in industrial organization literature are the concentration ratio (CR) and the Herfindahl-Hirschman Index (HHI). Both measures attempt to directly capture the number of firms or sellers and their

corresponding market shares or indirectly by market share proxies represented by sales volume or reserve capacity, as variables in the computations. The HHI is preferentially adopted by the antitrust agency in the United States for the analysis of mergers and evaluation of their potential impact on competition. For this purpose, the guideline stipulates that a market with an HHI less than 0.1 is un-concentrated, 0.1 to 0.18 is moderately concentrated while an HHI score above 0.18 is deemed as highly concentrated as defined by the US Federal Trade Commission and the Department of Justice (Gaynor and Vogt 2000).

Less frequently used measures of concentration include the Lorenz curve, Gini Coefficient, Inverse Index and Entropy, all of which also employ market share in their quantification (Encaoua and Jacquemin 1980). In this research however, it was not possible to measure market shares of the sellers, so analysis of market structure for the purposes of gaining insight into the nature of competition in the studied market will adopt simple approaches of patent medicine vendor shops per capita and the inverse Herfindahl Index, with the latter making assumption of provider outlet symmetry. This approach is considered reasonable because it was observed that most of the drug shops in a particular sub-market appeared grossly similar and any differences in shop sizes is therefore taken not to be systematic (Encaoua and Jacquemin 1980). The computation of the market concentrations indices are presented in Table 4.1 below.

Table 4.1 Measurement of market concentration in study area

District	Nos. shops	Population	Shop per pop.	HHI (1/N)
Abaji	8	36,735	1:4,591	0.125
Gbor	12	43,180	1:3,598	0.083
Katsina-Ala	56	65,423	1:1,168	0.018
Sai	5	55,835	1:11,167	0.2
Tor Donga	12	47,045	1:3,920	0.083

N = number of shops in a sub-market

Shop per capita for the entire Katsina-Ala market is 1:2,669 while the inverse HHI is 0.01

In order to interpret the findings, patent medicine shops are framed as proxy pharmacies in this rural context (since they represented the only sources of retail medicines for local consumers) and drug shop per capita determined. Drawing on WHO's recommendation of one pharmacy to 2000 population (Azhar et al. 2009), only the market in Katsina-Ala town may be said to meet this recommendation, while all others fail on this benchmark with Sai market appearing to be an outlier. The shop per capita for the patent medicine vendor market in the overall Katsina-Ala local government council is also generally above the WHO recommendation. The implication is that there are fewer sellers in the market than is required to ensure proper functioning of the market and guarantee adequate access to medicines for optimal population wellbeing. The computed Herfindahl-Hirschman indexes for the submarkets indicate that Katsina-Ala, Gbor and Tor Donga all have un-concentrated markets, although Gbor and Tor Donga are relatively closer to the moderately concentrated region. The market in Abaji is moderately concentrated and placed at the extreme end of the spectrum is the submarket in Sai, which is highly concentrated. Based on the computed HHI results, there is a tendency towards unconcentration in the market overall, because at the sub-market level, three out of

five are unconcentrated while only the Sai market is concentrated in this analysis. This is further supported by the overall inverse HHI score of 0.01. However, that the sub-markets have both concentrated and unconcentrated features coexisting in them makes a firm conclusion of the nature of competition without further consideration of the other important determinants of market competition difficult, and are undertaken in subsequent analyses.

The result also shows an increasing pattern of concentration as one move away from the local government headquarters in Katsina-Ala. For example, a movement to Gbor from the headquarters, the number of patent medicine outlets falls sharply from 56 to 12 and then further precipitously to 5 in Sai, with a corresponding increase of population per shop distribution north-wards. Going eastward out of Katsina-Ala, a similar pattern may also be observed, although less explicitly. The observed trend may be attributable to the socioeconomic advantages of Katsina-Ala as the administrative headquarters and the harbouring of a tertiary institution in its precinct, both capable of boosting economic activities in the area: a powerful incentive for sales and profit maximization. Though the researcher did not acquire data on village or ward level shop per capita distribution gradient, this evidence would have more clearly measured actual access to services at the point of need. Furthermore, the conclusion so far also recognises the artefactual nature of the terms of analysis of the geographic market, which was not established with certainty.

4.4 Entry Barriers

Evidence for entry barriers came mostly from qualitative interviews and is evaluated descriptively. The most frequently cited barriers to entry were lack of knowledge of drug use and start-up finances. When questioned about their experiences with entry into the drug retailing business, respondents held these common views:

“Patient medicine shop is not just a business you can start like the provision shop, spare parts or any other business. It is all about medical care, so we go through several training after school, we go into practical, that is where you serve for eight years and gain knowledge and master everything about first aid before starting.” (R02).

“I was trained and after training, worked under Maltina Company, after sometimes, before I decided to set up a business of my own...” (R06)

“You cannot do patent medicine business without training in the business. It is not like provision selling, where anybody can just decide today to start buying and selling and he start. You have to train for some time, in fact for many years before you can start selling medicine” (R 07)

All these quotes stress the technical nature of drugs and underscore prior knowledge of drugs as an entry barrier into the patent medicine market. Lack of start-up capital was another barrier to entering the business. Most of interviewed participants confessed they started on very small scales and scopes due to financial constraints. Some of their experiences are borne out in the statements represented below.

“Yeah, when I started this business newly, at that time, I did not have enough money to obtain drugs, sometimes I don't have the drugs so I go to my colleagues and get it for them ...” (R.05)

“Generally, my problem is finance. That is my major problem, because even if I have enough capital, this place will be full and I will not have any problem. You see all those places are vacant, no medicine, that is my major problem. (R 01)

“In this business you need plenty of money before you can start. If you no get enough money you cannot get customer.” (R 09)

The challenge of financing source as an entry barrier was also brought to the fore in questionnaire answers. 70% (21 out of 30) of respondents in provider questionnaires were not aware of any formal institutions to access loans to either start or expand their businesses. For some, shop growth depended purely on savings accruing from business turnover. It is noteworthy to observe that most patent medicine vendors had dual businesses, suggesting that perhaps, financial surpluses from one business line could be ploughed back into the other business portfolio to ensure sustainability, a circular financing mechanism, as affirmed by this interviewee:

“Because I am a farmer too, sometimes if I get profit here, I carry it for the farm, like today, I carried N 2000 for the farm, so that is how it is.” (R 03)

Another vendor said:

“Oga (Sir), you see this business need a lot of money to start, and it is not easy to raise money to enter business. If you go to the bank, they will ask you to bring C of O and how many of us fit get that? That is the problem we have with the bank.” (R 08)

Other entry barriers identified were high cost of licensing fees, taxes, regulatory requirements and unofficial payments to regulatory agents. Costs of regulatory compliance, for example premises levies and licence renewals fees were also said to exist, as well as multiple informal payments to obtain business registration approval and police officials both on high way checks and those who regularly paid predatory visits at drug shops. The research did not explore whether all providers actually paid these charges regularly, as this was not in the scope of the study. The multiplicity of factors together might have constituted considerable entry conditions into the market.

The collectivisation and coordination of sellers under the NAPPMED umbrella described in chapter 3 of the thesis, also portends important implications for entry into the market. Asked about the relationship with patent medicine vendors who were not registered with the union, a member said:

“That is the reason why we inaugurate members of task force to be moving round, to find any person who is selling without being a member of the union. When we eventually find them, we ask them to get registered, and if they fail to do so, we do ask police to go and pounce on them.” (R 09)

This statement implies subtle exercise of monopoly behaviour by NAPPMED through entry clampdown.

These entry barriers notwithstanding, the majority of providers believed entry by new entrants into the business was free. The evidence presented would support a conclusion of low entry barriers in this market very broadly.

4.4.1 Exit Potentials/Barriers

Funds management was cited as a key predictor of possible exit from the market. Most providers interviewed agreed that exit was not a common phenomenon, but identified capital erosion arising out of poor management of resources in terms of reckless expenditures, uncontrolled provision of credit sales and other high financial personal outlays as possible causes of business failures and exit from the market. Underscoring the role of credit as a possible exit factor, one interviewee put it this way:

“I still give them, but not that I need credit because in this business, if you put credit forward, the business will not move anywhere, so if people are coming and you are giving out credit, at the end, you will be at loss, some of them will come back and pay, some of them will go finally.” (R 07)

Also listed among possible determinants of exit was inability to secure loans from formal financial institutions like banks, to expand and sustain a business since demand may be weak at times:

“I don’t have much money and I don’t have collateral security to collect loan from bank.” (R 09)

Poor sales of stocked drugs were seen as another possible way of exiting the market. All sellers said unsold stocks retained over an extended length of time may lead to expiry and loss of efficacy. Stocks falling into this category are usually destroyed, with the druggist incurring capital loss thereof. Repeated losses may lead to failure and exit from the market, as one patent medicine vendor captured it:

“It depends on how your market is moving, because some of these drugs use to expire quickly, but you have short time to sell, so you have to buy small so that you sell before they get expired, because you will have to pack them and throw away if they expire and it is loss on your side.” (R 08)

In both the questionnaires and provider interviews, respondents mentioned the potential of exit by regulatory shut down, although no particular incidence was volunteered.

“They walk into our shops and be checking drugs. Even if they see any drug, like ampiclox, they will say ampiclox is not on our list of drugs to sell, they will take it and carry us to lock some times, or close your shop.” (R 07)

The ninth Interviewee also talked about regulatory closure as a result of regulatory infringement.

“Eh, even when they see something like piriton, they can decide to seal your shop and you have nowhere to go and nobody to fall back to.”

An official of NAPPMED, who doubles as a task-force member articulated their duties concerning regulation of member practices this way:

“We don’t spare any section, because when the government agencies come in, they will not spare anyone and we have to have access to them if we can’t have access, we will make you fold up, because we can’t allow you to keep on giving a bad image to the union.”

Observational evidence of entry and exit barriers might not have been robust however, but at the point of exiting the research field, all the initial 93 patent medicine vending outlets were still operational and one new patent medicine shop was observed to have come on stream in Katsina-Ala town. This indicates the existence of low entry barriers, though the duration of the study was short (9 months) to support firm conclusion. Exiting the business was said to be fairly easy and entailed either a gradual disengagement process or the bulk sell-off of stock to another vendor, with both approaches yielding minimal financial losses.

4.5 Horizontal Linkages

Provider interviews and observational studies revealed evidence of some form of horizontal linkages in this market. About 70% of interviewed providers entered the business through the apprenticeship model, where knowledge of the business is acquired through understudying an experienced provider (often a family member already in the business), over a specified tie-in period after which the intern is given start-up capital to establish his/her own drug shop. The views of two interviewees support the assertion.

“Any way, I started by serving somebody for some years and there I was taught more on drugs administration on patients.” (R01).

The second interviewee said:

“It is all about medical care, so we go through practical: that is where you serve for eight years and gain knowledge and master everything about first aid before starting. So I served my master after my secondary school, after eight years, we settled, I then opened my shop, that is how I started.” (R 02)

Such new entrant into the business is therefore likely to hold allegiance to his benefactor by taking instructions from the “Master.” As an example, one of the questionnaire respondents in this study would not complete the questionnaire until he had consulted his “Master”, who gave the go ahead. This behaviour is likely to manifest in the real market situation and influence both price and non-price decisions.

4.6 Vertical Linkages

The wholesale market may exert considerable influence on market structure and by extension concentration and competition in a market below it in the distribution chain (Brooks et al. 2008; Gaynor and Town 2012). From questionnaires answers, retailers stocked from multiple sources, with majority (53%) using pharmacies while 35% stocked through wholesalers. However, provider interviews and observations revealed that the commonest source for restocking used by patent medicine vendors was the wholesale drug market in Onitsha, located over 400 Km away, in the south

eastern state of Anambra, Nigeria. This Wholesale market also serves stockist from the rest of the country and therefore may be highly concentrated. Field observations also suggest that pharmacies might have been an alternative stocking source, but not a significant one. A few other patent retailers stocked from other patent medicine vendors occasionally. This evidence base would suggest that the concentrated nature of the wholesale market probably exerted some deterministic influence on the structure of the retail distribution chain below and it might therefore not have been coincidental that the majority of retailers at this study site originated from the eastern part of the country, even though resident in Katsina-Ala. The definite nature and impact of the relationship was however not explored further because of time and financial constraints.

Generally the study of retail market structure has limited place in historical studies on retailing and it is more restricted in the pharmacy specialty, especially in sub-Saharan Africa. The potential therefore to rigorously compare findings related to the elements of market structure in this study was severely constrained as only one study examining the structure of retail drug shops in Africa was found in prior economic literature (Goodman 2004a). However, several overlaps were discovered with other studies of the related phenomenon of retail pharmacy in the UK and the US, which will be used as points for general referencing.

Economic theory predicts that low concentration market structure will be associated with efficient market performance and welfare enhancement.

The evidence has demonstrated a mixed market structure in this market: concentration and unconcentration. The established concentrated retail structure of the market would agree with the findings of Goodman (2004a) who also concluded that the retail market for the treatment of malaria and fever in Tanzania was concentrated. Brooks, et al. (2008), also found high levels of concentration in the related retail pharmacy market in the United States and more generally, health care markets, especially its retail component tend to be highly concentrated (Gaynor and Town 2012; Nowakhtar and Widdows 1987). The study also established that the patent medicine market in this research location tended to become more concentrated the further one moved away from the administrative and economic hub of the local

government council. Doucette and colleagues (1999) had also found that U.S. counties with higher per capita incomes had more retail pharmacies per capita, while those with higher poverty rates recorded decreased pharmacy per capita. They subsequently theorized that the local pharmacy supply in an area will be related to the underlying health system and socioeconomic context in the area. The finding of new entry into the market despite the perception of established medicine vendors that entry was not easy, points to potential contestability. This pattern of contestability also occurred in the study of retail malarial treatment market in Tanzania (Goodman 2004a). Elsewhere too, the coexistence of concentration and the constant threat of potential entry by new entrants have been established (Koutsomanoli-Fillepaki and Staikouras 2003). The evidence that most of the patent medicine vendors restocked from a nationally concentrated wholesaler market had also been reported by Onwujekwe and colleagues (2004). Similarly, pharmaceutical wholesale markets have been reported to be nationally concentrated in Western economies as well (Brooks et al. 2008; Gaynor and Town 2012). Furthermore, these authors have also argued that the level of competition in the drug wholesaler market might potentially exert significant influence in the structure of the retail market distribution chain below.

The unconcentrated element in this study is compatible with the findings of Jerome and Ogunkola (2000), who reported that retail markets in Africa were in general unconcentrated.

The shop per capita and the HHI have been interpreted in this study based on notional ideals, but they fail to explicitly specify the pattern of distribution of the shops and therefore the nature of actual spatial access to these drug shops. For example, empirical evidence may show an unconcentrated market, yet shops might not have been accessible in real terms, because the shops are clustered in one part of the market as observed in this study where majority of the drug shops were cited around market squares, removed from where consumers actually work and live. This means that dwellers in distant places may still have challenges in accessing medicines when they have the need. The policy implication for understanding of access therefore is that accessibility may best be understood from the perspective of

distance to a service point rather than some quantification of a statistic and comparison to a notional ideal.

4.7 Summary and Conclusion

Leading up to this point in the analysis, the thesis has evaluated the structure of the patent medicine market for pharmaceuticals in Katsina-Ala local government area. The geographical market was analysed along geopolitical sub-markets using the administrative boundaries of NAPPMED, as introduced above. Only the sub-market in Katsina-Ala town is clearly unconcentrated via both approaches of shop per capita and the inverse Herfindahl-Hirschman Index. Whilst the markets at Gbor and Tor Donga are also unconcentrated by the Herfindahl index, they are concentrated by the shop per capita assessment scores. The sub-market at Sai is concentrated on both evaluative dimensions of market concentration used in this study. There are also findings suggestive of low entry and exit barriers, as well as elements indicative of both horizontal and vertical inter-relationships. Overall, it is difficult to firmly place this market at a specific point on the perfect competition-monopoly continuum as it is invested with both features of monopolistic and oligopolistic competitions, also meaning that it remains contestable.

In sum, the chapter has analysed the market structure of patent medicine vendor market in Kastina-Ala local council area. The evidence has demonstrated that the market is low concentrated overall and potentially contestable.

CHAPTER 5: RETAIL PROVIDER CONDUCT

5.1 Introduction

This chapter extends the exploration into the nature of competition in the researched retail drug market and complements the ideas on market structure articulated in chapter 4 in order to fully define competition. Conduct variables are examined through analysis of provider perceptions of their roles and how these perceptions are operationalized through price and non-price competitions against the backdrop of regulatory adherence. The analysis begins with reporting of the perceptions of retail drug shop providers, as this knowledge is essential for understanding what influences shape and drive behaviour of providers in the market. It is also fundamental for design of innovative strategies to align these micro-entrepreneurs with public health policy goals of improved and timely access to effective and safe remedies for basic health care needs. The chapter draws substantially on provider interviews, supplemented by observations and questionnaire responses and results are presented in four main thematic lines. Provider perception of their roles forms the core of section 5.2, while section 5.3 explores non-price competition. Sections 5.4 and 5.5 analyse provider response to regulation and price competition respectively. The chapter concludes with a discussion of the nature of competition in section 5.7. Pertinently, interpretation of findings in this chapter is facilitated by the researcher's multiple competencies in clinical medicine and pharmacology.

5.2 Provider Role Perception

The provider perception of his role provides a good entry point for understanding of motivations and actual conduct of medicine retailers in the study market. Findings in relation to this inquiry are presented and analysed.

5.2.1 Provider motivations

All patent medicine vendors stated that the motivation to join the business was driven by the pragmatic need for a profitable means of livelihood. As custodians of medicines, which are associated with cures, medicine sellers distinguished and contrasted their trade from the more regular trading in other non-medical

commodities as unique. This awareness seems to confer particular privileges such as respect from the community and the corresponding responsibility of gate keepers to curative medicines. The evidences come from notions expressed during interviews. One interviewee said:

“Unlike other business, you know people don’t just walk to chemist and say they want to buy drugs, just like they use to buy from store. Not until somebody is sick, or may be having one problem or the other before they come to the chemist.” (R 01)

In spite of profit motives of patent medicine vendors, a sense of responsibility was also seen to moderate the profit maximising entrepreneurial drives of providers, as expressed by one respondent.

“I consider my customers. Some of them may not have money, I can give them on credit, when they have they come to pay, that’s why we say that God called us to this line, it is not only to make money, but see it as a helping business.” (R 09)

This reveals that patent medicine sellers are inspired not entirely by financial considerations; they may also be driven by the desire to render services to their communities and be respected and trusted.

5.2.2 Professional experts

Patent medicine vendors saw themselves as medical experts in the various communities they were located in, and consumers were referred to as patients, customers and clients interchangeably. They described the nature of interactions with their customers variously as simple drug selling, medical and health information counselling, diagnosis and treatment or referrals. These were observed to include simple selling, consultations and treatments and occasional advice encounters, no referrals to formal facilities were observed. Their views were captured separately in the following excerpts:

“They say they are feeling like this or like that, then you have to know the problem and give them drugs. Sometimes if you are not satisfied with the explanations, you refer them to laboratory technicians, after the result is out, they will get prescription and they will come to chemist and buy the drugs.” (R 01)

“I do both by the discipline I have, and that has helped me a lot, it has also attracted people to come to me, because I will see their conditions, prescribe and dispense, where I don’t even get drugs, I recommend them to where they can easily get it and they will get it.” (R03)

Other providers also expressed their opinions of what they thought about themselves:

“First of all, we have labs, where I direct people to go run test and bring me results so when I get these results I now use these results and the prescription with me to compare with what is on the ground, and I give accurate prescription.” (R 07)

“... then we are in the interior, here illiteracy is everywhere, so we still talk to them, teach them and show them what to do and we are getting results like that.” (R 10)

“Well, as trained personnel, whenever they come, I don’t just carry drugs distributing to them or dispensing just like that. When they come, I have to find out the cause of sickness, how long the sickness has taken before the issue of prescribing, because when they come, first I investigate to find out the cause of the sickness, I use to diagnose, find out before I give drugs to them.” (R 04)

Some respondents also reported overriding clients’ demand for medicines, where professionalism and clients’ best interests were reckoned more desirable rather than profit maximization.

“When they refuse my advice, I tell them I know what I am doing, so let them abide by what I have told them. If they don’t have that money for full dose, let them go and find it before they come. Some of them will go, some will say they will go and buy in another place.” (R 09)

Although patent medicine providers viewed their role as expert custodians of medicines and customers as inadequately knowledgeable about drugs, consumer autonomy was fully recognised in purchase decisions. There was no consistently observed procedure for the sale of any drugs. Products were dispensed on request. A transaction failed to take place only in instances when the vendor had a stock out. Consumer autonomy was explicitly upheld as borne out in the following statements.

“What I meant by environment is not that here is a villager with N20 and you tell them that that N20 medicine will not help them, they will insist telling you that that is what they have and the drugs should be given to them, no matter what you say, would fall on deaf ears. As a place in the local area with people who are not well to do, like farmers etc. so even if you tell them the right thing, they will still insist on their opinion, so that is what I meant by environment, and the financial insufficiency.” (R 02)

This practice reflect the exercise of free choice by consumers and supply responding to demand, and on many occasions led to sale of under doses of medicaments and in some cases inappropriate treatments.

5.2.3 First aid providers

Most interviewees described their practice as providing first aid before full care was sought at a later time, or at a higher level of care.

“..., so I started gradually, improving up to this time, so in patent medicine business, even if someone brings N20, you can still find some medicine as first aid and give to the person.” (R 04)

“For instance in Benue State today, there are local governments that you will find less than two pharmacy shops, in these places. It is the patent medicine vendors that bring in little first aid.” (R 10)

The notion of first aider role held by patent medicine vendors in this study further supports the argument in section 5.1.1, that vendors may also value altruism other than financial incentives in making choices of their market behaviours.

5.2.4 Meeting need and complementing the public system

Patent medicine sellers identified gaps in the formal health system in terms of financial barriers and poor availability of drugs, and thus viewed their role as providing cheaper alternatives for consumers and improved proximity to products, provided at extended and flexible work hours. Patent medicine sellers felt they

played complementary role to the formal health systems by emphasizing referral of serious cases, and receiving prescriptions from them in turn.

“It is not that so, one good thing is this, the grassroots is where the population of the entire local government is based. The general hospital here is the only general hospital around this place, and it has no drugs, they are either on strike or not functional and that one alone cannot meet the needs of the entire people. So sometimes, we get the drugs to ease the pains of the masses.” (R 03)

“When you talk of the issue of malaria, you see that some of the anti-malaria, we are allowed to sell, but our license do not cover it, there is need for us to sell it, because there is no any pharmacy in local areas. I want to tell you that without patent medicine dealers in Nigeria, there is no way you can help the condition of patients in this country. Reason by yourself, in this local government area, how many of these pharmacies do we have? Can one pharmacy be able to attend to everybody in this local government area? And some local government areas do not have any pharmacy shop. It is we that are providing drugs where there is no pharmacy.” (R 02)

Whilst these drug sellers emphasised their role in complementing the public sector in attaining the overall health agenda of the country, they viewed the public regulatory body, Pharmacy Council of Nigeria (PCN), a body of mainly pharmacists as rivals and competitors in the market. Their expressed views were borne out in the following excerpts:

”... even though they are genuine and we bought them from the pharmacies, they will come and put pressure on us, because they are controlling us, so that they will make more profit. When they are selling ciproxine at N500 and we said no, ciproxine is supposed to be sold at N300, they will now bring law enforcement agency to harass us in the business, so that they can sell that ciproxine which can go for 300 naira at N500. That is what they are doing, it is not regulation.” (R 03)

“You know, in this field I earlier said that the Pharmaceutical Council of Nigeria do not allow us to fill our shops in the same way like a pharmacy. They want our shops to be maintained in a skeletal form.” (R 05)

“One of the challenges we have in expanding the scope given is the fact that some feel that they are our competitors for example the pharmacists say that this is their business. They have gone to school and spent money and when they come out someone who have not spent the time and money will come and hijack the business.” (R 10)

These expressions clearly betray the mistrust the regulatee has for the regulator and his intention. They also provide a perspective for understanding regulatory outcome in the market.

5.2.5 Practice boundaries and linkages

All medicine sellers appeared to acknowledge the limits of their competence and resource availability as reflected in their expressed willingness to refer difficult cases to hospitals and laboratory facilities, which are better staffed and equipped. Again, interviewees explicitly acknowledged their knowledge and practice limits.

“As I earlier said, we don’t just go into treatment, we provide first aid. When doctor prescribe, we can now supply the drugs. In case of malaria, if it is a high condition, we can refer you to lab and then make doctor to prescribe drug for you, after which we can now supply you the drugs. When we see that the situation is not severe, we can give you panadol to cure the temperature, before the patient go to the laboratory man. That is how sometimes we do in this environment.” (R 02)

“What am able to do I do, if the situation is not above me, like when you come with wound that is minor or say if it is the issue of minor malaria, I still handle it, but if it is a serious malaria fever, I tell you to go to the hospital because I don’t have drugs to administer and if it is the issue of surgical operation, that one, everybody knows that it is the hospital, we are not even up to the standard of clinic or dispensary, we are just patent medicine shops. We are only here to give drugs to the people to settle their problems, if it is above us, they go to the higher level.” (R 06)

The motivations for these decisions and actions may be patients' best interest and concerns for implications of poor outcomes and community perception of provider competences. Providers might have been mindful of the poor public judgement of their competence if they treated complaints that exceeded their capabilities and the associated negative impact on patronage from community members.

5.2.6 Regulation and legitimacy

All medicine sellers recognized the appropriateness of regulation over medicine distribution; "we want to avoid uncontrolled, unskilled, uncertified and unlicensed person presenting themselves as people's doctor" (R 10), but expressed frustration with current regulation, describing it as corrupt, duplicative and redundant, meant to undermine patent medicine vendors. The regimen of regulation involves the Pharmaceutical Council of Nigeria (PCN), National Agency for Food and Drug Administration and Control (NAFDAC), National Drug Law Enforcement Agency (NDLEA), and the Police Force, sometimes with no clear delineation of roles. The last was particularly described as notoriously corrupt and often extorted informal payments from patent medicine vendors. These impressions form the core of the following excerpts from provider interviews:

"Anyway, the little profit that we make, we share it with the government, because we have a union, any time we have a meeting, especially monthly, they will attend the meeting and say ministry of health says this or that, National Drugs Enforcement Agency say this or that, Pharmacist Society of Nigeria says this or that. So they will tell us to be contributing money so that they will visit them so as to avoid disturbance. ...because all those people are government agencies and even the police, we visit them, so any little money that we make is shared among them." (R 06)

"Police visit us regularly. They are regular visitors to our shop not that they will come in a harsh way, but they will just come and say hello to us at times. When they come now, we do call them our big friends, so they will say they come to say hello to us. So we do understand with them and find some pure water (informal payments)

and they will just leave. At times when they are passing, they will just enter our shops and say hello, then we understand with them.” (R 04)

This speaker is meaning paying bribes to police to avoid inspections.

Whilst conceding to regulatory infractions, most patent medicine vendors felt the bar on the scope of their practice was not realistic and gave legitimacy to their practices thus:

“Actually, what you are saying is true, eh, some of the drugs we sell, our license did not cover it, but since we are in local area, where sometimes, we only find one pharmacy or not, we do have those essential drugs, but not on our own to prescribe, but if they are prescribed through the doctor, we can now supply you the drugs. So we only supply them with drugs based on the doctor’s prescription so that is how we help the community.” (R 07)

“That is where the union come in to say that when you are practicing in this area, you don’t present yourself as a doctor or pharmacist and also why the workshops and trainings by NGOs like Society for Family Health comes in. A lot of them are sponsored by America and World Health Organization. They come to train patent medicine vendors on how to handle certain issues.” (R 02)

Community approval of their good performance was also perceived as further support for the legitimacy of the practice as one provider implied:

“yeah, they are getting back to tell me and appreciate my service,” (R09).

Furthermore, collaboration with the National Agency for Food and Drug Administration and Control was also cited as lending credence to their practices as one NAPPMED official said with excitement:

“NAFDAC applauds our actions. They gave us the standard and that is why we are working with them. Most of the time when NAFDAC comes for their random checks, they discover that the union is actually working and they commend the union on their efforts.”

Patent medicine vendors expressed satisfaction with an internal self-regulatory mechanism (Taskforce) put in place by their umbrella body: National Association of Patent and Proprietary Medicine Dealers, although questions remain about the adequacy of this process. One official of the union describing the regulatory activities of the body said:

“..., the union does not overlook these offences, but we do not invite the law enforcement agencies to such an offender.”

Pressed on why the union would not hand over offenders to be prosecuted, the official went on:

“We have a good rapport with the police and we make the police understand that we are not trying to kill these offenders or send them out of business.”

This may mean that the Task force plays the role of mere moral suasion without enforcement capacity, which members might have been aware.

5.2.7 Aspirations and expectations

All interviewees and questionnaire respondents consistently expressed the desire for enhanced knowledge, skills and practice improvement through continuing education and information dissemination from the government and its regulatory organs. However, having perceived current regulatory interventions as oppressively unfair, all desired autonomy and the establishment of a patent medicine regulating body. One described the value of practice improvement this way:

“The Government, Federal Ministry of Health and even people outside have to look at us and say these people are improving, then they stand in a better position to argue in our favour to upgrade and give us more recognition, but if they come and see bad things, then they will assume that we are killers.” (R 08)

Another captured his expectations for the vocation thus:

“Also we want the government just as they are having the School of Medicine, School of Midwives, to have a school also for patent medicine practice. When this is done, they will be able to review drugs that they are allowed to sell upward.” (R 10)

Most vendors were impassioned about autonomy and freedom to engage in the full spectrum of drug selling:

“We feel that they should allow us to be selling drugs like the pharmacy, freely, because when you go to their shops, they sell anything they want to sell but not that we are appealing to the law to sell any kind of drug that we want to sell, but just to give us our licence telling us what to sell. Without licence, we don’t have any authority to sell, but hence we don’t have that licence, police disturb us because they know that we don’t have the licence. They know that we are selling illegal, and we are doing or operating illegal because we don’t have anything to stand against them.” (R 04)

“The PCN or the Ministry of Health should allow us, we the patent medicine dealers to be practicing our business and at least give us our licence, that will enable us to be carrying out our business, because the local area where there are no pharmacy, it is this patent medicine dealers that do help people, like here in Gbor, there is no single pharmacy, and before you could find any, you must go a distance.” (R 05)

There was also unanimity about desire for improved access to financing capital to expand their businesses.

“I do not get enough money to buy drugs. That is why sometimes people come to ask me some drugs, I do not get it, so they go away.” (R 06)

“Everything that moves around us is finances; enough money makes us to move forward. So I need more aid and assistance from government.” (R 03)

Patent medicine vendor expectations include practice improvement through enhanced knowledge, regulatory autonomy and improved access to financing capital.

This section has presented the results of perceptions of patent medicine vendors in relation to their roles, customers, regulation and aspirations for the future. Patent medicine vendors see themselves to be knowledgeable enough to sell drugs and also feel their practice is legitimate. This derived from training in handling of drugs through the informal apprenticeship paradigm of working alongside other patent medicine vendors, in pharmacies or hospitals or other relevant formal health training.

The former was frequently linked with family members who owned drug shops already. Formal training was acquired at institutions as nursing schools, schools of health technology or community health extension schemes. Collaboration with formal regulatory organs of government and international NGOs was perceived as conveying legitimacy. They believed they were constrained however, technically, materially and by the complexity of clinical manifestation of diseases and desired knowledge improvement and better access to formal financing opportunities. Whilst profit maximization was the primary motivation for going into the business, this appeared to have been tempered with a realization of the sense of responsibility to society. All medicine sellers recognized the appropriateness of regulation over medicine distribution, but expressed a sense of frustration with current regulation, describing it as corrupt, duplicative and redundant, meant to undermine patent medicine vendor interests. Respondents consistently expressed the desire for progress and service improvement through continuing education and information dissemination from the government and strongly expressed the desire to see an expansion in the current number of drugs they are legally allowed to sell at the moment. Finally, patent medicine vendors perceive pharmacists as competitors and therefore to be supervised by the Pharmacists Council was unfair and desired an independent regulatory body.

The thesis will now focus to examine competition in the market, beginning firstly with non-price competition and then price based competition.

5.3 Non-price Competition

Non-price competition is interpreted as provider perception of service qualities which differentiate one provider from another and lead consumers to prefer a particular provider over other rivals (Scherer 1970). It may operate through product specific properties or through provider related unique approach brought to bear on a business practice (Dinlersoz 2004). Such provider engineered features may include both observable and unobservable product and service attributes. Empirical evidence from provider interviews and questionnaires showed that the main axes of non-price

competition were availability of drugs and their reliability, convenience, courtesy, perceived provider competence and the scope for credit. These causal mechanisms of competition are considered individually in relation to the data gathered to enable a better understanding of the nature of non-price competition in this market.

5.3.1 Availability and range of drugs

It was observed that medicine vendors stocked a wide range of different categories of drugs including antimalarials, analgesics, anti-allergics, anthelmintic, antitussives, vitamins and antibiotics. These were sold in diverse forms including oral capsules and tablets, injectables and other parenteral preparations. Some sellers additionally stocked surgical items, such as intravenous drips, sutures and hand gloves. In one particular drug shop, even the short acting surgical anaesthetic ketamine, was bought by a customer. Stocks were extensive and included innovator brands, generic brands and unbranded generics, in pre-packed and packaged forms. While almost all qualitative interviewees reported consistent drug availability as a strategy for attracting and keeping customers, only 2 of the 30 questionnaire respondents thought that consumers patronized their businesses because of reliability and range of drugs stocked. However, 92% claimed they received referral from other drug shops on account of their consistent stocking of needed drugs. The rate of outward referrals almost paralleled inward referrals with 83% of providers also indicating that they referred customers out for non-availability of drugs. During provider interviews some patent medicine vendors argued quite strongly how they often received referrals for drug purchases from formal facilities to support the claims of product availability:

“I used to buy drugs and keep in my shop so when am selling out, I will be using that money to continue buying until I make sure my shop come to a limit that will be attracted to customers.” (R04)

Poor stocking in contrast was linked to loss of customers.

“I do not get enough money to buy drugs, that is why, because, sometime people come to ask me some drugs, I do not get it, they go away, that is it.” (R 07)

These claims were empirically confirmed in Katsina-Ala town for instance, where consumers actually came into drug shops with prescriptions obtained from the general hospital in the town to make purchases. It has emerged quite clearly that adequate stocking is signal for attracting customers and conferring competitive advantage.

5.3.2 Drug quality

A typical patent medicine vending shop was a single room often poorly ventilated and partitioned in front by a counter containing drugs and also serving as a reception point. The walls held hanging shelves stacked with a variety of pharmaceutical products. Some providers went further to box-out a small cubicle within the shop for administration of injections and wound dressings. The stocking of shops also varied, with some shops impressively stocked while others displayed sparsely furnished dusty shelves. However, in particular locations, shops were fairly of regular sizes. All retailers dispensed using dispensing trays and spoons from packaged drug containers.

From qualitative interviews, it emerged that poor drug quality and inaccurate diagnosis of disease symptoms were among reasons shop owners felt could elicit aversive behaviour from consumers. This thinking was supported from questionnaire answers also, where over 90% said they believed they attracted and maintained customers based on consumer perceptions of the quality of drugs they sold. Fake drug sale by vendors was reported by providers as a common infringement in the market. However, they had no way of accurately judging genuine products from fake ones other than the reality that a product carried the drug regulatory agency's registration number printed on the packing, generally referred to as "NAFDAC number" by sellers and consumers and the public broadly. An interviewee said:

"We look out for fake drugs, which are drugs without NAFDAC number and not registered with NAFDAC, substandard drugs and expired drugs" (R 10).

The NAFDAC number inscribed on the pack of a drug serve as the most powerful indicator of product genuineness and therefore drug quality. This quality barometer

is however not reliable as shown in chapter 7 of the thesis, where the challenges of fake manufacturing concerns is discussed from regulators' perspective.

5.3.3 Provider knowledge, competence and agency role

Provider expertise will relate to level of educational attainment, years of experience in drug retailing, having a relevant health professional training and regular attendance at workshops, trainings and seminars. Of the 30 providers sampled, only two had only the legal minimum educational level of primary education, 17 (56.6%) attended secondary schools, and formed the modal class for the distribution, while the rest 11 (36.7%) indicated they have had post-secondary schooling. The distribution is shown in the pie chart below.

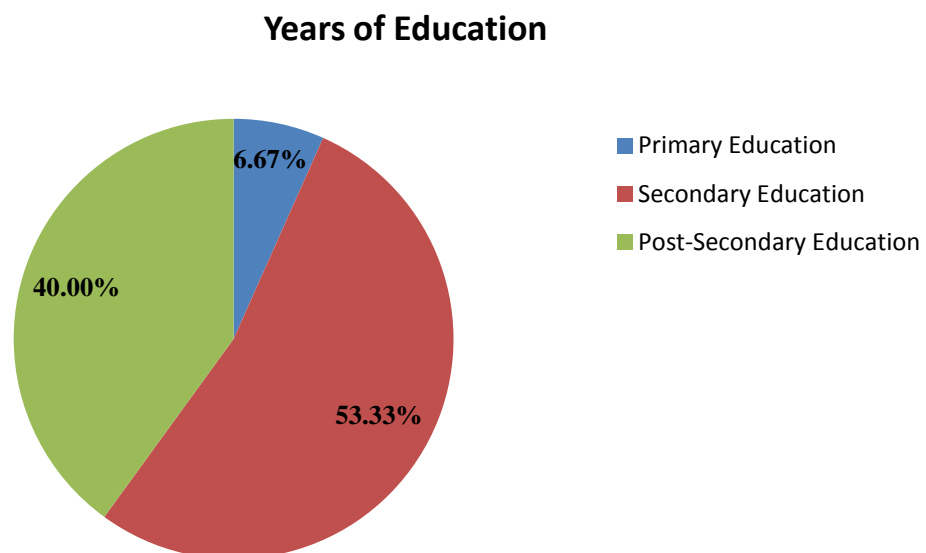


Figure 5.1: Distribution of years of education of patent medicine vendors.

Professional education is acquired in Universities and Polytechnics and the minimum entry requirement for admission into tertiary institutions in Nigeria is secondary school qualification. Therefore, this result implies that over 92% have potential for even professional training in any health related discipline.

It is interesting that the participants who indicated they had post-secondary education turned out to be vendors with a form of health related training or another and

included diverse specialties as nursing, pharmacy technology, medical laboratory and community health extension work or some relevant experience in formal health sector work. The range of health related professionals practicing as patent medicine providers is displayed in box 5.1.

Box 5.1 Health related cadres retailing as patent medicine vendors

- Staff nurses
- Pharmacy technologists
- Medical laboratory technicians
- Community health extension workers

It is possible this category of health personnel might provide an explanation for the technical practices identified by vendors as unethical at this level of health services delivery as discussed below.

Also, there was great variation in years of experience in retail drug vending of the sample, ranging from a year to thirty years. The years of experience distribution is shown by the histogram below.

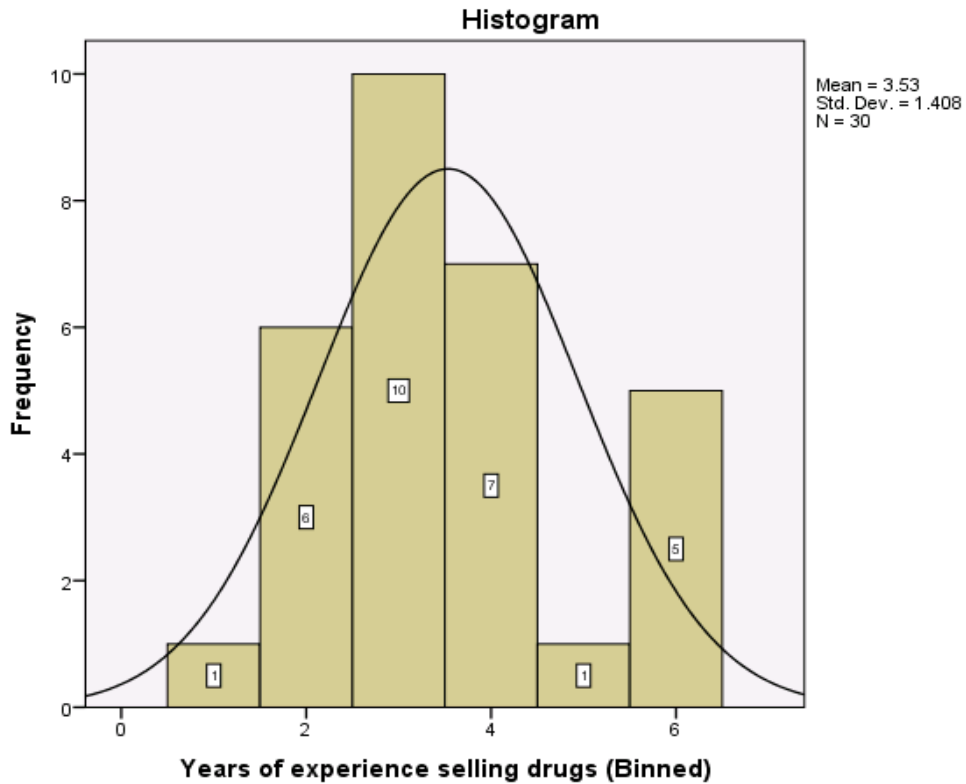


Figure 5.2: Distribution of years of experience of drug retailers.

Class 1: 1-5 years of experience in drug retailing.

Class 2: 6-10 years of experience in drug retailing.

Class 3: 11-15 years of experience in drug retailing.

Class 4: 16-20 years of experience in drug retailing.

Class 5: 21-25 years of experience in drug retailing.

Class 6: 25-30 years of experience in drug retailing.

The near symmetrical distribution of years of retailing experience may mean a market that is perhaps very dynamic in nature and therefore potentially contestable.

Only 40% of the respondents indicated they had ever attended workshops organized variously by the Pharmacy council of Nigeria (PCN), National Agency for Food and Drug Administration and Control (NAFDAC), National Drug Law Enforcement Agency (NDLEA) or Society for Family Health aimed at improving their practice.

However, all providers said their competence was what attracted customers to their shops. All providers indicated they had not received any complaints about their services as 90% claimed they were providing standard quality of care. However, just one of them said he knew he was providing good care based on positive affirmation from his customers. Whilst the vast majority were satisfied with their output, 33% admitted to knowledge of unethical practices among patent shop outlets, which included sale of fake drugs, unauthorized drugs, expired drugs, administration of injections and intravenous fluids. They also saw drug sale by some individuals as unethical, labelling such providers as untrained or quacks. The sale of unauthorized drugs and expired drugs were the most common unethical practices identified. A list of unethical practices alluded to by the sampled population of patent medicine vendors are reproduced in the box following.

Box 5.2 Unethical practices of patent medicine vendors

- Sale of unauthorized drugs
- Sale of expired drugs
- Sale of fake drugs
- Administration of injections
- Administration of intravenous fluids
- Selling by untrained individuals (referred to as quacks)

Exploring provider competence in-depth through provider interviews, interviewees argued further that their proven competence was what informed clients' decisions to consult them for diagnosis and treatment and health advice other than acting as simple salesmen. On a few occasions, drug providers were seen taking a brief

history, enquiring about the nature and duration of illness, consumer age, followed by advice of an appropriate drug and dosages clearly written out. This is how a sample of them underscored their capabilities:

“..., then I do advise them on what to do that will prevent them from being sick always. I advise them on health programmes, I tell them that this is what you will do that will help yourself or help your children, if it is diarrhea. I advise them on how to do that diarrhea will stop in their family. If it is malaria problem, I will tell them the way they will do that malaria will stop in their family. So because of that, they like coming to my shop, because they know that if they come here, they will feel like they have gone to the hospital, because what the hospital do tell them, is what I tell them when they come. So they feel if they come here I will still give them the correct treatment or the correct advice they use to get from the hospital, so for that, they feel like coming to my shop always.” (R 04)

“I can dress wound, give injection, give drugs.” (R 09)

“I fit do diagnosis and treat for the same time” (R 05)

(I can diagnose and treat patients at the same time).

Also the issue of unethical administration of injections was examined closely during provider interviews. While some providers said they did not administer injections, a few others stated they prescribed and administered injectable drugs. This sub-group included mostly providers who had health related training background and one other vendor without medical training when pressed. It was observed that most shops actually partitioned a secluded area for practical procedures like administration of injections and wound dressing. Interestingly, some medicine vendors referred to others as quack provider as one argued:

“Well, I can’t tell about other medicine dealers, because some of them are not trained, they just feel like they want to run this business and just start it so they don’t know the ethics of this business, because the profession has its own laws. So if you don’t know the ethics that means you will not be able to do fine, because there are some patent medicine dealers that do not go to school. Some of them did not finish

secondary school, they don't attend any health facility. I've not been with them, so I don't know how they treat their customers or their client, so I cannot tell much about other shops, but I must emphasize on what I do in my shop." (R 01)

However, to the patent medicine vendor who started a drug shop from the apprenticeship model, a quack meant someone who neither had a medical background nor mastered the art of drug retailing through apprenticeship.

These pieces of evidence support a conclusion that there might be high levels of unethical practices, poor quality of care and regulatory violation in this retail drug market.

Patent medicine vendor knowledge of diseases and drugs was analysed to establish the veracity of these assertions, as revealed by this encounter between the researcher and vendor 04.

Q. Do you know the Federal Government's guidelines for treating malaria?

R. I don't know.

Q. Do you treat malaria here?

R. I don't know.

Q. So you don't treat malaria?

R. They catch us for malaria treatment one certain time and they talked about chloroquine, so we stop all those things.

Q. So what do you use now?

R. I use one fansidar and camoquine, for small babies.

Q. And for adults, what do you use?

R. I don't have that one for adults I only give fansidar and camoquine.

This provider clearly lacked knowledge of the national guidelines for the treatment of malaria, one of the commonest ill health conditions of children and adults alike, requiring prompt treatment to prevent progression to the more severe form of the disease. During observations of interactions between providers and clients, it was observed that most drug retailers simply sold what customers demanded or just dispensed according to a tendered prescription of any sort. Where a customer came with complaints, vendors demonstrated limited understanding of signs and symptoms of diseases generally. Drug envelopes were not labeled with names of medications, side effects were never explained nor contra-indications for a drug sold out. Sub-doses were commonly sold as was the selling of under-dose combinations of drugs, referred to as “mixture” locally (poly-pharmacy). In some shops, children less than 16 years sold drugs independently, without an adult supervising. However, in questionnaire answers, 90% of drug shop providers indicated they were aware of the dangers of drug use and misuse.

Empirically therefore, the conclusion reached is that patent medicine vendors in this market demonstrated a low understanding of both diseases and drugs. A summary of the basic characteristics of patent medicine vendors is presented in below:

Box 5.3: Basic characteristics of patent medicine vendors

- 83% male sellers
- Modal age group is 26 – 30 years
- All have at least primary level education
- Majority (67%) have no health related training
- 77% of participants have a minimum of 10 years of retail experience
- Most (53%) are married

5.3.4 Convenience

Providers stated in qualitative interviews that people patronized them because they were located close to them, and in remote places, they were the only drug source for the communities. They also said services at drug shops were fast, devoid of the time wasting associated with government facilities. A transaction time lasted 5 minutes on the average, ranging from 3 to 8 minutes. Also listed as providing convenience to consumers was the long opening hours provided by drug shops, all of whom opened from 8.00 am to 9.00 pm, Mondays to Saturdays and for some Sundays as well. These long opening hours were said to be particularly suitable in rural settings where farmers require flexible opening hours that fit into their farm schedules: most rural people worked on farms during the day and would only want to use health care when it was convenient to them, thus ensuring minimal disruptions to their farming activities. Shop services may also have been more convenient because of proxy buying, where people bought drugs on behalf of others.

5.3.5 Credit selling

Credit selling was also cited by many patent drug shop owners as a strategy to attract and retain customers, provided the customer was regular, trustworthy and could be located in the event of default. Asked what they did when a customer could not afford the cost of medication, 46.7% of questionnaire respondents said they offered a price reduction, 27.7% sold on credit, while 10% withheld services. This is how some interviewees expressed their views about credit selling:

“Well, in any business you are doing, you cannot avoid credit. Because, some of them when they come, they claim they are the people that know me very well. So at times when they don’t have even ten kobo, they will still come, asking me to give them drugs before they will find money and come for payment. So for that, there are some people I do consider, when they come for credit. I still give them, but not that I need people buying for credit, because in this business, if you put credit forward, the business will not move anywhere, because it is a petty business.” (R 04)

“It is difficult, now that there is economic melt-down, companies no longer give drugs on credit, if they give you drugs, they collect their money, so it is difficult to sell on credit.” (R 06)

“Before I give credit to somebody, I feel because at times somebody will have a severe sickness and if you have come to me without money, for me to reject such persons becomes difficult, because I am dealing with human beings, so putting this thing at the back of my mind, I just decide to help some of them. Some of them are people that are very close to me, they know me for long and have been patronizing my shop for long, so when they come, I consider their patronage, so I decide to give out drugs to them on credit basis.” (R 09)

However, observations revealed that buying on credit may not have been common, as not a single case was witnessed during this study. This means that credit sales might not have been an important competitive strategy in pragmatic terms in this market. However, sale of incomplete dosages was rife in the market and was practiced across all providers. It is therefore more realistic to conclude that under-dosing could have been a competitive strategy, rather than credit selling where a consumer’s ability to pay was lacking. This practice may also have been a reflection of low provider and consumer knowledge of the importance of appropriate dosage buying for disease outcomes. Payment in kind was not observed and did not appear to be an important dimension of competition either.

5.3.6 Provider courtesy

All drug retailers regarded good relationships with customers as critical to enhancing patronage and were unanimous that people would only come to shops where staffs were polite and friendly. They stated that once patients had established rapport with a local shop, they tended to come back repeatedly afterwards.

“It is how I do with them, if I do them treatment, if they are well, they can go out and advertise that if you come to this person’s shop, this is how she will do me, she treat me this case and the case is over, so I will just get more people.” (R 08)

“When my customers or my client come, what I normally do is that I welcome them fine and be simple and jovial to them. So by doing these to them, being social to them, very lenient to them and operate on a very small scale, I do not charge them high.” (R 03)

Surprisingly, staff attitude was not considered an important factor for custom in questionnaires, but during observations it was noticed that providers treated customers well by being polite and giving courtesy. When there was no pressure on time, vendors would engage customers in long conversations about burning social, economic and political issues, interspersed with jokes and laughter.

This section has examined and evaluated the elements of non-price competition in detail, with the evidence suggesting reasonable levels of competition along most dimensions of non-price competition. The patent medicine vendor market improved access to drugs in the local council area, given that it had only one formal pharmacy shop and several government facilities which often had no drugs. The quality of these drugs however, could not be guaranteed. Services were provided close to consumers and at convenient hours with considerable customer autonomy to purchase any drug in whatever quantity. Products and services were traded under cordial and polite conditions. Analysis of competition on provider knowledge and competence revealed that competitors had low knowledge of disease prevalence and presentations and manifested inappropriate drug dispensing practices. There were also reported regulatory infractions on a wide scope.

Having analysed non-price behaviours of providers, the thesis will turn to provider knowledge and response to regulation. This is apt because the main axis of regulatory success hinges substantially on provider perceptions and response to this key strand of market competition.

5.4 Knowledge and Response to Regulation

All retailers agreed that sale of drugs should be regulated because of its potential harm when misapplied to humans. Responding to the research questionnaires, 80% said their business premises were formally registered with the Pharmacy Council of Nigeria, and 60% had at least one regulatory inspection in the last one year preceding

the study. Only 2 shops, representing 6.7% of the sample had not been inspected at any time in the past by any of the regulatory agencies. Regarding the level of regulation, only 6.7% of the sample expressed dissatisfaction, a majority of 83% was satisfied with the level of regulatory performance. On the contrary, provider interviews revealed that regulation was unsatisfactory with widespread regulatory infringements as earlier highlighted in the section on provider perception of the processes of regulation.

One vendor said:

“There are some drugs that really as you said, the Ministry of Health or the Pharmaceutical Counsel of Nigeria does not allow us to sell, so we sell them to people that we feel we can assist them to get those drugs and it will help them.” (R 06)

Others gave reasons for breaking the laws regulating the market in the following sequences of dialogues;

R.09 We are not supposed to give injection, but we are doing it.

Q. Why?

R.09 We are not getting too much money, but if you give injection, you will get small money, that is all, but it is not good, everybody know. Because even in the clinic, if they give injection and it develop any problem, they will answer a query, talk less of here in the chemist, that one is dangerous.

R. 10 There are some bound drugs (prescription-only), the reason why they bound (banned) them is not because when you take them, it have a health effect or toxic effect, but the reason why they do bound those drugs is because people are using it and diverting it to another thing apart from the real work of that drug to that particular sickness, so by that the Ministry of Health or the Pharmaceutical Council of Nigeria feels that if they allow this thing to open like that, it will make the drug too addicted and when you treat them, it will not work. That is the reason why some of these drugs are bound from selling, not that when you give to customers, it will

affect them or it will give a toxic effect to them. So being like that, we do sell to some of our customers that we feel it is necessary to give them.

Q. You know for instance that this ampiclox you are selling, you are not suppose to sell, because this is a patent medicine store and the law says you should not sell antibiotic, why are you selling it?

R.01 We don't know like that, I don't understand, that is why I use to sell it; even if it is dangerous for us to sell ampiclox antibiotic we can stop it. (We will stop the sale of prescription drugs)

Patent medicine vendors demonstrated good knowledge of existing regulations but also conceding to regulatory infringements at the same time for reasons clearly linked to profitability of prescription drugs and misunderstanding of the principles underpinning regulation of drug use by the public.

5.5 Price Competition

Pricing and price competition is another key dimension of provider conduct and understanding the price process is crucially important in defining the nature of competition in the market. Price is traditionally the main axis of any industrial market analysis and it is particularly important in this study given the contexts of poverty, combined with full out of pocket payments. The section proceeds to describe pricing mechanisms, sources of price variations and explores the extent of price competition.

Economic theory predicts that the degree of price competition will depend on the location of a particular market along the perfect competition–monopoly spectrum. In perfectly competitive markets, firms are not able to raise price above marginal cost and are described as price takers, while the monopolist has absolute market power over price and is a price setter. Producers in market structures in-between these extremes possess varying degrees of power over product prices, their output quantities and qualities.

Therefore, in markets characterised by strong price competition, firms will have limited scope for price setting and there will be low price mark-ups. Also, relatively stable prices are expected for a defined product.

The findings of the researched market are presented against these theoretical concepts and the thesis proceeds to establish whether medicine vendors in Katsina-Ala were price takers or price setters.

5.5.1 Price setting

Qualitative data is used to explore how drug shop retailers fixed prices and their perceptions of their price fixing behaviour. All providers questioned said the prices of drugs were determined by wholesaler drug costs, transportation costs, informal payments to regulatory agencies and the police and profit considerations: the same set of factors mentioned in survey responses. Interviewees also reported that prices of particular drugs were identical for all shops and any attempts to raise price would lead to loss of patronage to other sellers, considering that they operated in small communities and price sensitive consumers would easily detect a price differential between the same products within the market. This would indicate that patent medicine vendors perceived themselves essentially as price takers in a way, as one of the interviewees observed:

“Some of the reasons I can say is let’s take an example: somebody come to buy paracetamol syrup which is ₦ 80. If I start selling the paracetamol syrup at ₦ 100 or ₦ 120, some of them will run away from me, because they will no more buy. They will run away if I say a card of ampiclox is ₦150, when everybody know is ₦ 80 or ₦ 100. They will say it is costly, so they will run away from my shop.” (R 05)

Although drug prices were said to be uniform generally, when pressed, some confessed to allowing price concessions for the poor, particularly in emergency need for medications. Throughout the research activities, no such case was observed.

To fully gain insight into mechanisms of price setting, interviewees were asked to describe their price fixing strategies and their narratives are presented below, including one extended dialogue between the researcher and interviewee 04.

"It depends on how much we purchase, how it comes. If Onitsha is given us a pack of ampicillin or cloxacilin for N500, with the transport we have paid to bringing the drugs down here, we may now sell at say N530 that is N30 gain, and it is from this N30 gain that we settle agencies who come to check and do other things and put our association together. It is how we purchase." (R 02)

"This business, I earlier said that it is profitable because if you take just a small amount like N10, 000 if you sell finish, you will be realizing something like N15, 000 and with this, I believe this business is more profitable than other businesses. In the area of this field of medicine, there are some drugs you bought and then, even if you sell cheaper, you will be topping 10% or 50% of what you bought." (R 06)

Q. So a card of ampiclox is how much?

R.04 Is ₦ 100

Q. How much is a packet?

R. A packet is ₦ 550

Q. If you are buying, how much does a card cost you?

R. A card is ₦ 50

Q. But you sell it at ₦ 100?

R. Yes

Q. That is 100% mark up, why do you mark up so high?

R. Is it so high?

Q. You bought it at ₦ 50 and you are selling at ₦ 100, which is 100% mark up

R. Mmmm

Q. How do you decide to sell what you buy?

R. that is all over, it is everybody, not necessary only one person that is selling like that, it is all over.

Q. So all of you decide to sell like that?

R. Yes

Q. In your meeting?

R. Not in the meeting, but even if you get to Katsina-Ala or Zaki-biam, a card of ampiclox is sold at ₦100, Beecham is ₦350 and you can sell it at ₦400 or ₦450 like that. You will calculate your transport and police on the way.

Interviewees appeared to have also considered seasonal sales pattern in determining prices of medicines. One retailer said:

“Ok, in this business area or sector, there are some periods that we do get customers more than others, like during raining season around April, June and July, we use to have a lot of customers in our shop because this is time of mosquitoes, malaria outbreak, so we do experience much attendance in our shop. Around that December down to February, we do have customers too, because during that time, we expect diarrhoea problem, so from now till September to that November, we have a lot of patronage in our shop too. At the other months if they are sick, it will be difficult for them to come to clinic or to a health facility, so during that time, we don't normally have customers.” (R 04)

The dynamics of price fixing in this market is complex, but grossly the cost structure appears to be influenced by the costs of purchasing stocks from wholesalers, transportation, informal payments and profit top-ups. Although prices were said be uniform in the market, the dominant role of a price leader appeared insignificant, as there was no clear reference to any particular price setter in the study. Superficially therefore, this suggests a price taking behavior of sort. However, in a less than imperfect market structure, the implication of these fairly uniform prices might be that retailers either simply tended to copy each other or avoided potential loss of business through undercut if they raised their prices, or tacit adoption of rule of thumbs. Interviewees made definite mention of top-ups over the range of cost elements in fixing drug prices as enumerated above. Vendors consistently talked of 50% to 100% top-ups to the overall cost of a product, suggestive of collusive pricing

strategy or simply an implicit understanding among retailers. From a consumer welfare perspective and superficial evaluation of these mark-ups, they may be judged as high especially when bench-marked against international standards. The WHO for instances, recommends mark-ups of between 25-50% on retail pharmaceuticals (WHO/HAI 2011) and when further compared to other settings for instance, gross retail mark-ups have only averaged 25% for most of the 20th Century in the United States (Larson and Rosen 2002; Kaiser Family foundation 2005). On closer examination however, these recommendations did not capture the range of hidden costs retailers in this researched market may face. The retailers alleged hidden outlays, which can potentially increase operational costs of retailers and conceal true profit margins. Unofficial practices and regulatory capture in African health care markets have been widely reported, which may support the claims of these medicine vendors (McPake et al. 1999; Wafula, et al. 2013). With limited information about the cost structure and financial risks associated with transportation, storage, marketing and retailing of products, it is difficult for the researcher to determine if retailers' margins are actually excessive, even though grossly the mark-ups exceed the WHO recommendations.

From economic theory, we can predict that retail prices should be a sensitive indicator of pricing behaviour and price sustenance in this market may be understood from both the abstraction of the kinked demand model and the collusive oligopoly paradigm (Clarke 1985). The Kinked demand model argues that if providers believed that a price cut will be matched but not a price rise, then prices will remain sticky at equilibrium. This offers a lens to see why no provider might have attempted to undercut prices in the market, rather accepting the general price. Providers had actually alluded to losing customers if they tried to sell at higher prices, because other providers did not increase their prices. Another interesting dimension in understanding pricing mechanism in the market is the allusion to uniformity of prices in all sub-markets as demonstrated in the dialogue with interviewee 04 above. It is therefore quite possible that explicit or tacit collusive pricing might have been operational in the market as an alternate pricing mechanism, although this was explicitly refuted by retailers. However, the role of NAPPMED in the market broadly and therefore specifically in price fixing process cannot be ruled out. Given that the

association principally sets out to pursue best interest of its profit maximizing members, as even the disciplinary and self-regulatory task force it instituted did little to instill disciplined practice among its members. One way of achieving this pricing behavior might have been through fostering collectivization of interests and discouraging competitive individualism. This conclusion is further supported from the observation of interviewees constantly making the association a reference point for behaviour, for example the use of the personal pronoun, we instead of I during interviews was a recurring decimal.

Contradictions emerged between survey responses and interview opinions of providers. For example, outlet providers expressed satisfaction with the level of regulation and its implementation in surveys, but strongly critical of the regulatory system during interviews. This discrepant posture may be linked to initial distrust for the researcher and the purpose of the research, which became replaced with acceptance and support later in the project, when the research was more fully understood to be in no way inimical to their business interests.

5.6 Summary Findings and Discussions

Retail drug shops perceived they were highly patronized because they were close to the people provided quality and reliable drugs, the convenience of services and courtesy. Other studies have also documented similar advantages of retail drug shops in other settings (Adome et al. 1996; Brugha and Zwi 2002; Goodman et al. 2004; Hughes et al. 2012; Molyneux et al. 1999; Stenson et al. 2001; Van der Geest 1987; Williams and Jones 2004). Even though drug shop providers are unspecialized health care providers, their convenience and perceived cheapness could explain why they are accepted for perceived simple ailments that needed first aid care. They also stocked beyond their legally allowed stocking list, this tendency to stock prescription only drugs has also been widely reported in the literature (Adikwu 1996; Fassin 1988; Goodman, et al. 2007; Indalo 1997; Kumaranayake et al. 2003; Oshiname and Brieger 1992; Van der Geest 1987).

Drug shop providers viewed themselves as knowledgeable first aiders as well as complementing the public health system which is often plagued by recurring health

worker walk-outs and stock-outs. Drug stock-outs in public facilities have been reported elsewhere in Africa (Gilson et al. 1993; Gilson et al. 1995; Hughes et al 2012; Okoli 2001). Patent Medicine vendors saw themselves as providers of health care for acute ambulatory health problems; however, since interventions at this stage of a disease process also influence the probability of progression, the activities of drug shop providers is likely to have an important impact on overall disease outcomes in terms of disease morbidity, co-morbidity and mortality (Greenwood et al. 1987). The recognition of their knowledge gaps and therefore practice limit is important in designing strategies to align their practice with public health goals.

The variation in levels of education of patent medicine vendors and their equally diverse training in health related disciplines reported in this study are consistent with findings in other settings in Africa (Adikwu 1996; Brieger et al. 2004; Oshiname and Brieger 1992; Kumaranayake et al. 2003). In this particular regards, it is interesting that vendors themselves had created a dichotomy within them, with some viewing others as quacks, because of lack of health related training of the latter. The issues of poor storage of drugs, under-dosing and inappropriate drug combinations have also been found among drug shop vendors in Tanzania and Uganda (Amin et al. 2004; Goodman et al. 2004; Goodman et al. 2007a; McCombie 2002; Marsh et al. 1999; Nshakira et al. 2002).

Limited evidence on retail drug shop mark-ups were found, but high prices have been reported in private pharmacies in Kenya and Ghana (Madden 2004; WHO and HAI 2003). Russo and McPake (2010) also reported high retail mark-ups in the related phenomenon of pharmacies in urban Mozambique. It was discovered in the WHO-HAI study that drug prices were lowest in public facilities, followed by not-for-profit facilities and most expensive in the private outlets, a conclusion which will support the induction that private providers are likely to be more expensive for the same product market. The study also showed that brand premiums in African countries were high compared to generics. This means that in these settings prices were higher than the marginal cost of production and incompatible with predictions of the perfect competitive model.

5.7 Nature of Competition

From the evidence base presented so far, the patent medicine market may pass for a competitive market on face value, given that even though they sold a vastly wide range of drugs, within a drug category, these products are based on relatively fixed chemical formulations within the class and therefore, the retailers may be viewed as providing what may reasonably be termed as homogenous products. No attempts by providers to influence market structure through publicity strategies or predatory pricing techniques were observed. Drug consumers obtained drugs freely and regularly and were likely to have been well informed about prices and products indications from repeated purchasing, though they remained poorly informed about the technical issues of drugs such as dangers of injections from unqualified providers, dangers of misdiagnosis and the risks of inappropriate drug use. Thirdly, purchases were all out-of-pocket payments therefore, consumers were probably price sensitive as against the situation of insurance coverage. Consumers also had options to choose their providers and were also free to demand particular products. This constellation of features would seem to constrain the market in the perfectly competitive direction.

However, the market also approximates a few features of the oligopolistic paradigm. For example, entry barriers existed as evidenced by regulatory entry requirements and the unclear role of NAPPMED and its relationship with non-NAPPMEND drug vendors. Furthermore, it has also been demonstrated that retailers exhibited strategic pricing behaviour by taking into account the expected behaviour of their competitors, for example in the case of an upward price change. These characteristics are consistent with economic theoretic predictions for oligopolistic competition. However a potentially oligopolistic market structure does little to specify the nature of competition in the market. Pinning down precisely the nature of competition requires comparative analysis of the multitude of oligopolistic models reviewed in the economic theory of markets in Chapter 2. Particularly insightful are the models that relate to a firm's price setting behaviour.

The classical price leader-follower paradigm makes assumptions of homogenous goods, with market leader setting the price and output levels and the followers taking

these price and output decisions as given. However, it has been argued that the health care market is fragmented, and pharmaceutical markets are highly differentiated in both products and provider characteristics (Gaynor and Town 2012), making the standard leader-follower model an inappropriate approximation of the market phenomenon observed. Moreover, sales volumes across retailers were not quantified in the study and a market leader could not therefore be clearly observed. Collusive behaviour offers plausible explanation of the price sustenance in this market and provides further helpful insights in characterising the nature of competition in the market. The features conducive for the evolution of potentially successful cartel include the small number of sellers, especially when viewed at sub-market levels. Therefore members might have been able to more easily have full information about each other's prices by directly observing or eliciting such information from consumers and thus able to mitigate cheating behaviour among its members if this was a situation of explicit collusive arrangement, as exemplified the real world cartel, OPEC (Dibooglu and AlGudhea 2007). The research did not establish support of open collusion between the retailers. Tacit collusive model may better fit this market, based on the evidence presented particularly in reference to the uncertain roles of NAPPMED, the formal umbrella body of drug shop vendors, which appeared to only foster the norms of cooperation rather than articulate any systematic codes of professional conduct among its members. This sort of cooperative market behaviour among micro-enterprise owners, rather than competition, has also been documented in reviews of industrial structure and microenterprise in Africa (Fafchamps 1994; Tripp 2001).

Price sustenance behaviour in this market can also be explained from the kinked demand model, which allows visualization of how established price may resist a fall and be sustained in a stable position even where providers are confronting changing costs as discussed above.

This chapter has demonstrated a strong non-price competition, but weak price competition picture, tending towards a collusive paradigm as retailers appeared to be takers of a given price without an identifiable market leader. Prior findings in chapter 4 showed a general tendency towards un-concentration in the overall market, but a

mix picture at the sub-market level. However, with the findings of strong oligopolistic pricing behaviour among medicine vendors across drug shops in the entire local council areas in this chapter, it is difficult to conclude that one single market structure and competition model perfectly matches the analysed market. Both monopolistic and oligopolistic features coexist together in this market, only to varying degrees.

CHAPTER 6: RETAIL CONSUMER BEHAVIOUR

6.1 Introduction

The third objective of the thesis is to analyse the health seeking behaviour of consumers in the patent medicine retail market in Katsina-Ala. The conceptual framework of the thesis specified in chapter 2, predicted that the nature of competition and hence market performance is a function of the interplay between market structure, provider conduct and consumer behaviour (Martin 1994; Tirole 1988). The first two elements of the model have been analysed in the preceding two chapters and this chapter will complete the spectral analysis of market interactions by undertaking a detailed view of consumer behaviour in the researched market.

Conventionally, human behaviours are shaped by perceptions and beliefs and the value judgements made regarding phenomena. Therefore any attempt to explore behaviour in a market situation must be rooted in an understanding of the normative systems of the consumers concerned as a first step. The chapter therefore opens with a presentation of consumer perceptions of the multiple characteristics of market providers in section 6.2, to consumer health choice making behaviours and utilization experiences in sections 6.3 and 6.4 respectively. Section 6.5 evaluates consumer expectations from providers and regulators, while section 6.6 provides a synopsis of the chapter analysis. The thesis then situates these findings in the context of current economic literature in section 6.7. Section 6.8 ends the chapter with a summary of all results chapters to this point.

Following on the pattern of the analysis of provider behaviour in the preceding chapter, the current interpretation of findings regarding consumer behaviour will draw substantially on exit consumer interviews, with exit consumer questionnaire responses and research observations providing complementary evidence.

6.2 Consumer Perceptions

Providers were referred to variously as doctors, chemists, patent medicine vendors, or simply as drug sellers and generally described either as qualified or quack. They

were therefore judged to offer services of varying standards, although overall, patent medicine vendors were perceived as rendering useful services.

6.2.1 Provider role

Questioned about their perceptions of the role played by patent medicine vendors in their communities, all respondents felt that drug shop vendors played crucially important roles in their host communities. They were thought of as providing emergency services, temporary treatment before definitive treatment and they also offered affordable services:

“Well, I feel the medicine store sellers too are of help, because in emergency situations, they address immediate problems that may arise,” ... (R 04)

“These people are important because they are helpful, especially in times of difficulties, like now.” (R 06)

Other opinions expressed by interviewees further revealed the diverse roles played by patent medicine vendors.

“Actually, my husband doesn’t like the idea of going to retail shops for treatment, but since he is not around, I decided to come to the retail shop for treatment, so that the illness will subside, and whenever he returns, he will take the person to the hospital.” (R 08)

“... but I hope to go to the hospital for adequate treatment, for now, I only wants to control the situation.” (R 10)

Implicit in these perceptions of drug vendor roles are the notions of first aid, substitutability and complementarity between formal facilities and the informal drug shops and therefore, their indispensability. It also portrays patent medicine shops as places where consumers may get services in a way that best suits their actual situations and expectations.

6.2.2 Provider qualification and competence

Respondents to the exit consumer survey did not consider provider qualification as an important consideration in choosing which provider shop to buy drugs from. During interviews, even though drug shop providers were perceived as providing needful services, doubts existed about their qualifications and competences, as expressed by some interviewees. Opinions oscillated from viewing them all as non-professionals to describing some providers as quacks.

“I consider them to be non-professionals; they are just business men trying to make their own money.” (R 01)

“... personally, I don't tell them anything, because I feel they are not qualified to treat me, I buy as prescribed by health professional.” (R 10)

“,,, just take a look at this young boy selling, he came here as a little boy, who sold since then to this level, after getting independence from his Oga (Master), he was given money to operate the business and he eventually ventured into it. He is just a quack, he is not qualified in any way, That is why these pharmacists should be encouraged.” (R 09)

Other consumers however, expressed satisfaction with the performances of some patent medicine vendors, whom they associated with prior work experience with the formal health sector, as one said:

“He tries very well, because he formerly worked with a clinic and he can administer any kind of treatment apart from surgical operations.” (R 02)

“Some of them are qualified because they graduated from the required institutions, like school of health technology, some are health attendants and they own and operate shops, but some are quacks actually, these are the type that prescribe drugs or administer treatments that have side effects that kills at times. I have witnessed it.” (R 03)

“..., in most cases, people who are not qualified to operate in the system are found operating the system, they buy drugs from somewhere and set up their businesses in

a different places. There they start to administer drugs that are dangerous. I have seen a situation where drugs meant for adults alone were given to little children, this sometimes lead to something different even administering drug that have other side effects.” (R 07)

“I had never for once placed confidence in their way of treatment, that is why I always opt for hospital treatment, I still reiterate my commitment to going to the hospital, even if it means going there up to twenty times, am ready, provided I have the required money.” (R 06)

Asked to judge treatment outcomes, one consumer said:

“Sometimes, you get relief and sometimes it will re-surface or come back again, in this case you will then be referred to the hospital after they have taken our money.” (R 10)

The findings clearly demonstrate consumers’ dilemmas of and desires for quality amidst perceived low provider competence. It also implies that drug buyers may not be mere passive consumers, but may in fact consciously do their utmost to get the best quality in the market. Consumers also expressed dissatisfaction with the apprentice mode of entering patent medicine business and identified the formal sector with better quality.

6.2.3 Drug quality

In consumer questionnaire responses, participants placed high premiums on quality as an important consideration in the choice of where to make drug purchases. All sampled individuals unanimously indicated drug quality as a principal factor guiding their decision to use a drug shop. Also, during consumer interviews, interviewees raised issues around the quality of drugs bought from patent medicine vendors. Drugs consumed were sometimes said to either be ineffective or caused adverse effects. Some buyers simply described some drugs as fake.

“Yes, there was a time I bought a particular drug cimetidine when I was having a feeling of pain on my chest. When I took it, I noticed the pain was getting worse. It brought a lot of negative effects on me, so I had to drop it.” (R 01)

“Some of them sell fake drugs, such that even if you take it, it will not work.” (R 08)

Drug consumers judged drugs sold at formal pharmacies to be of better quality than drugs traded in patent medicine shops.

“Yeah, for quality, I cannot bet on that, but the quality when you buy from the pharmacy, is better than retail shops.” (R 08)

The conclusion from these consumer notions would be that consumers valued treatment outcomes highly and therefore, the quality of drugs purchased mattered much. They however are not able to know true quality.

6.2.4 Consumer knowledge of drug regulation

Consumers’ knowledge of regulations guiding the operations of patent medicine vendors and drug use varied in depth and breadth between respondents. While a few appeared fairly knowledgeable, the vast majority seem to have little to no knowledge of retail drug vending laws and drug use. A large number of drug buyers confessed to no knowledge of any laws regulating the market in any way. Evidence supporting this inference is presented below.

“I will just look around on the wall to see if there is a certificate pasted on the wall; this will clearly indicate whether the seller is a quack or qualified personnel” (R 03)

“No one has told us about laws guiding the sale of drugs. We do not know which drug to buy and which one not to buy” (R 10)

Consumer knowledge of regulations designed to ensure the availability of effective and safety drugs in the market and their safe utilization was for the most part poor among retail drug shoppers, even though the market was highly valued by consumers, as discussed in more details in section 6.5 below.

6.2.5 Perception of regulatory enforcement and compliance

With the background knowledge of poor consumer awareness of laws regulating patent medicine vendor operations, the researcher sought to explore participant

perceptions of regulatory enforcement activities and their impact on provider practice. A consumer said:

”Yes, I know of one of agency called drugs enforcement agency, but this time around, due to the corrupt nature, there are no proper regulations, when caught, they bail themselves with money. (R 03)

“I know of NAFDAC, Standard Organization of Nigeria, but sometimes they don’t reach many places, like here in Katsina-Ala you don’t feel their presence at all, they are not in existence.” (R 07)

“This is one of the reasons I have earlier emphasized, it is because of ignorance and the lack of adequate regulations or adherence to the laws that is actually perpetrating these practices” (R09)

Regarding element of compliance with regulations by patent medicine vendors, these are some consumer views:

“No matter what you tell them is your problem, they assure you of doing it, they sometimes suture, they normally go beyond their powers to even operate. Sometimes they suture even when you have a deep cut, and they will give you plenty drugs.” (R 07)

“Sometimes, they have it available in the shop, and other times, they will tell you to wait , they will get into private rooms and bring it but most at times all their drugs are mostly available.” (R 10)

“if they see that you don’t have any understanding concerning drugs, they may give you less quality and collect plenty money or give you different drug entirely, simply because you don’t have any idea, these are the practices they do, but here they are aware that I have a better understanding of knowledge about drugs, so they don’t do that to me, but they’ve been giving many people. Sometimes when people bring empty packets of drugs for easy identification, they rather give you a close substitute with the assurance that the one they’ve given you is better and preferable instead of giving you what you actually demanded for.” (R 09)

These comments reveal that consumers have low knowledge of existing patent medicine drug vending regulations and also have no clear knowledge of which regulatory organization have oversight over what and the lack of any visible regulatory activities in the area. They also lend evidence of unethical practices on the side of vendors such as sale of prescription drugs and suturing of wounds and injections.

6.3 Consumer Knowledge of Diseases and Drugs

Consumers in some instances appeared to be certain about the impressions they held about the nature of their ill health and the appropriate drugs they self-prescribed, others were hesitant. One who demanded an antibiotic, traditionally used in the treatment of microbial infection, explained to the researcher the different indications he uses the medicament in this way:

“Sometimes if I have skin infections, fever and body scratch, I take it for relief and even in operations and accidents, it helps in bringing quick healing.” (R 05)

Pressed further for the specific need on this occasion, he said “this time around, I bought it for my wife who had stop baby breast-feeding and is suffering from swollen breast. She also is having some form of skin scratches, so I bought it for her use.”

Asked again why he did not attend a formal consultation at a hospital, he responded thus: “even if I take her to the hospital, these will be the same drugs that I have bought that will be prescribed.”

To further underscore the poor knowledge of diseases and drugs by this buyer, the antibiotic was combined with a laxative used specifically for the treatment of constipation.

Questioned if he checked for the expiry date label of drug packages before making a purchase another buyer responded, “No, I feel it is not significant bothering the seller to bring the package for checking the expiration date before buying.” (R 05)

Another consumer said:

“Well, we just buy them not minding whether they’re genuine or not, but they sometimes help us. We don’t really know how to identify the drug that is genuine or not, especially here in the village, here where we do not have the experience to know that.” (R 07)

These consumer opinions portray poor knowledge of diseases and appropriate drug use: consumers seem not to bother with checking out observable signs of drug quality such as NAFDAC registration numbers or drug expiry dates. Even though drug consumers seem not to demonstrate adequate levels of knowledge concerning diseases and their appropriate medications, they knew about the potential for adverse effects posed by inappropriate drug consumption. There is also an element of experience gained through past purchases guiding repeat drug use.

“If you are taking drugs just like that, without going to the hospitals for a check-up, then it can cause adverse drug reaction.” (R 08)

One customer summed all the shortcomings of patent medicine vendor practice in comparison with formal provision in these words:

“I believe that government hospitals or hospital treatment are better than medicine stores treatment.” (R06).

In most of the provider-customer interactions observed, patent medicine vendors acted essentially as economic agents who simply responded to customer requests, rather than acting as health information resource persons.

The combination of questionable provider qualifications, poor regulatory enforcement and compliance and flawed consumer knowledge of diseases and drugs, health seeking in the researched market might have been substantially influenced by belief based on past experiences and credence status of providers and health products. The apparent failures highlighted in association with the market notwithstanding, it appeared consumers still used patent medicine vendor shops more frequently than hospitals and other better staffed facilities. The thesis next seeks to understand the factors that shaped the observed behaviour.

6.4 Consumer Utilization Behaviours

To undertake the analysis of provider utilization by consumers, the demographic characteristics of the 30 surveyed participants is presented first. 93% of drug purchasers had at least primary education, out of which 53% were schooled up to the secondary level and 33% had tertiary education. In 5 out of the ten observed transactions, drug purchases were made on demand from the consumers, in 3 cases, customers had a consultation with the druggist and in the remaining 2 cases, the clients presented a prescription request (though the sources were not verified). This dominant trend, where consumers are exerting independence in health care purchases might mean that purchases have been repeated events for uncomplicated illnesses, which patients are well informed about. The age distribution of clients demanding drugs from patent medicine shops ranged from 4 days to 72 years. Consumers posited several reasons why they resorted to utilizing patent medicine vendors. These spanned over an array of motivators: cheapness, availability of drugs, convenient opening times, easy access, provider social embeddedness and credit opportunities, perceived severity of disease and constrained utilization (default utilization).

Basic characteristics of patent medicine vendor consumers are summarised below:

Box 6.1: Basic characteristics of patent medicine vendor consumers

- Most consumers (70%) of patent outlets bought for self-consumption
- The modal age of consumers is 31 – 35 year old category
- Majority of buyers are males (73%)
- The vast majority (83%) have at least secondary school level education
- The majority (66%) of customers are self-employed

6.4.1 Affordability considerations

Relative affordability appeared to be the most frequent motivation for the use of a patent medicine vendor shop rather than a government facility or other formal provider, as expressed by interviewees.

“I am financially handicapped and maybe if I go, the charges will be too expensive to afford, and I consider the retail shop to be the immediate source of solution to my problem.” (R 03)

“Anytime that I come, I tell him the amount of money that I have and he gives me drugs.” (R 04)

“Personally, my treatments are mostly done in government hospitals, it is because of financial constraints that have made me come to a retail shop for treatment.” (R 06)

“You know all fingers are not equal, some people may not afford the money to go to the hospital, if these patent medicine shops are closed, many will have no way to get drugs, especially those who treat on credit, you can see that even the little here they find it difficult to afford, how much more will they afford that of the hospitals?.” (R 09)

Inductively, one may conclude that charges at formal health facilities provided perverse incentives for utilization of patent medicine shops. Affordability in the view of consumers was interpreted relative to outlays at a formal facility where consultation fees, laboratory charges, transport fares, all contributed to treatment costs.

6.4.2 Drug availability

Users of patent medicine vendor shops also cited drug availability and their range as another reason for patronage. One customer said:

“there have been a difference, between buying from a shop and in the hospital, and even when I go to the hospital and they prescribe drugs, they direct me to go to the retail shops to buy the drugs, so instead of going to the hospital to be directed to the shop again, I go to the shop directly and buy the drugs” (R 03)

Another buyer also said:

“The difference there is, when I go to the hospital, they always prescribe drugs for me to come to the retail shops and buy.” (R 03)

Results of exit surveys showed that 60% of respondent indicated drug availability was a reason for the use of a patent medicine vendor.

The conclusion here is that drug consumers found the patent vendors more reliable and dependable source of required medicaments than hospitals and a strong influence on their utilization.

6.4.3 Consumer convenience

A multiple of reasons for the use of medicine stores fit into to this broad group. This connects attributes such as closeness of provider to home, proxy buying, quick services and suitable opening times, as these typical responses reveal:

“I have so many children, so when they go ill, I usually consult the retailer on behalf of my ill child, and disclose the symptoms of the illness, and he administer drugs that cures the child’s health immediately” (R 02)

“The retail shops are better because they respond quickly to people’s problems, unlike the government hospitals, they don’t even have drugs, I remember, when I took my wife to the government hospital for treatment, they prescribe drugs for me which were not available in the hospital pharmacy, ... so, the retail shop are more efficient in taking adequate care of patients.” (R 10)

“My children were vaccinated by the government team and a problem has arisen which deserves urgent attention, which is why I have brought them here.” (R 06)

“Sometimes, it is very difficult to have access to a general hospital or a primary health care centre, so I decided to come to a convenient place whenever am feeling pains or have to buy drugs.” (R 07)

Putting all of these together would clearly project convenience as an important consideration in a consumer health seeking behaviour equation.

6.4.4 Social embeddedness and credit potential

The quality of being seen as credit worthy appeared to be yet another idea consumers of health care evaluated in their decision making process. Related to credit scope was the implicit role of relational buying where social links determined where a consumer bought drugs. This notion is underpinned by these responses to interview questions.

“Yes, but due to our familiar nature, the person often give me drugs on credit.” (R 03)

“When I don’t have the money, I go to my regular customer for credit, so whenever I have money, I come and pay him.” (R 05)

“..., but in a place where the seller and I are familiar, then credit selling too would be possible even in the hospitals, but everything depends on familiarity. (R 06)

“You know they are our friends and part of us, so they sometimes give us on credit, and sometimes, we give them the little money that we have, and then balance them in the future.” (R 09)

A central theme that runs through all the responses is the concept of familiarity with a drug shop provider. This reveals some form of strategic behaviour on the part of the consumers, considering their difficult financial context and drug knowledge weakness. The concept also exemplifies the importance of social embeddedness in consumption utilization behaviour, where familiarity serves to build trust and acceptance. Even though exit consumer interviewees explicitly mentioned a role for credit transactions, all observed drug purchases were paid in cash as no credit transaction was directly observed. The place of credit consideration of utilization may therefore be anticipatory and purely strategic. However, this behaviour signifies the importance of financial safety mechanism in health care systems.

6.4.5 Perceived severity of disease

The perceived severity of a malaise also determined consumers' utilization choices. A broad range of diseases were presented in patent medicine shops, which have broadly been classified into aches/pains, making up 78% of complaints, fevers 13%, and diarrhoea and vomiting 9%. The detailed listing of specific complaints consumers sought treatment at patent drug shops is presented verbatim in Box 6.2 below.

Box 6.2 Types of complaints treated at patent medicine vendor as described by consumers

1. Fever
2. Malaria
3. Headache
4. Diarrhoea
5. Chest pains
6. Eye pains
7. Abdominal pains
8. Stomach ulcers
9. Typhoid fever
10. Waist pains
11. Tooth pains
12. Vomiting
13. Loss of appetite
14. Body maintenance
15. Urinary pains
16. Accident
17. Body pains

Source: Exit research questionnaires, 2012

The group of aches and pains include complaints as headache, chest pains, eye pains, and abdominal pains. Others are waist pains (low back pain), tooth ache, urinary pains and body pain (general body aches). Fevers consist of symptoms as fever, malaria and typhoid fever. The duration of disease symptoms varied widely, from one day to symptoms lasting a year as reported by consumers, but simply classified into acute disease for symptoms lasting no longer than seven days and chronic disease for ill-health longer than seven days (Morrisy et al. 1989). 73% of surveyed consumers had acute symptoms and 80% of the sample was seeking care for the first

time. The analysis indicates that patent medicine vendors treat a significant number of people seeking orthodox care for the first time, who have a form of ache/pains in the acute phase of the disease process. This finding was also borne out in exit interviews:

“I normally try to address little problems from the retail shops, because the cost are less expensive compared to the hospital bills, I therefore go to hospital for treatment only when the situation is beyond the control of retailers medicine shops sellers.” (R 04)

“Well, I feel the medicine store sellers too are of help, because in emergency situations, they address immediate problems that may arise ...” (R 04)

“My illness is no severe, but when it is severe, I go to the hospital, so minor illnesses are brought here, but severe ones are taken to the hospital.” (R 08)

Choosing to use patent medicine shops for diseases considered as minor may be a reflection of consumers’ perception of provider knowledge base in these outlets as poor and low quality of their practice as argued in Section 6.3.2 above.

6.4.6 Constrained utilization

For other consumers, patent medicine shops provided the only real source for any form of orthodox medications and therefore, the decision to use them is one by default.

“I cannot stop because I have no alternative means, even in most cases, they hawk these drugs.” (R 05)

“Well, we just buy them because we don’t have alternative, not minding whether they’re genuine or not ...” (R 07)

“You know they are the only people available, and as such, we have no choice ...” (R 07)

The section has analysed motivations influencing consumer utilization choices of patent medicine vendors, despite the many issues of the quality of services in these shops. In the following section, consumer expectations of this market are explored.

6.5 Consumer Expectations

Consumer expectations in respect of the market were sought in key areas as banning of patent medicine vendor shops, handling of providers and the role of government and its regulatory agencies and are presented below.

6.5.1 Banning of patent medicine shops

In Nigeria at the moment, there seems to be a growing consensus among formal regulatory agencies and formal pharmacy operators about scrapping of drug retailing by vendors. Therefore, asked if patent medicine vendor practice be banned, all interviewees strongly opposed the notion. These are the thoughts of one respondent:

“Government should not scrap it, because they are helpful, especially in times of difficulties, like now I’ve no enough money to go to the hospital, so medicine stores should not be scrapped.” (R 06)

Similarly, another buyer put it even more strongly this way:

“The government will kill us, because not all of us will be able to go to the town for hospital ...” (R 08)

The many deficiencies identified in the market notwithstanding, it is unequivocal that consumers valued this group of medical entrepreneurs highly and want them retained.

6.5.2 Provider training and qualification

Patent medicine vendor clients desired that providers improve their educational training and enhance their qualifications to boost their competences. These expectations were communicated in passionate appeals to drug shop providers succinctly:

“It is advisable that they further their education so that they will treat people well” (R 05)

“... and to the medicine store sellers, they should not relent in trying to further their education and update themselves with adequate knowledge.” (R 03)

“I will advise the federal, state and local governments to organize workshops that will further enlighten these practitioners, and also make a law that will mandate training for the retail shop practitioners like the health technology, health management institutions. That will help a lot, since most of them gained freedom from apprenticeship, this will improve rural services, which they offer.” (R 09)

6.5.3 Regulation

Consumers also expressed the prospects of seeing improved regulation of practitioners, to ensure that the right standard of health care is provided.

“There should be a regulatory body that should be seeing over their respective affairs, let them not take it as their own personal business, let them be checked.” (R 01)

“Yeah, it is the government that ensure that drugs are available. Therefore, the government should check the activities of the medicine store sellers, ensure that fake drugs are not sold to patients.” (R 05)

“Moreover, medicine stores are of great importance, so I feel, it should not be closed. If only the government wish to be fair, it should look for better means that will improve services, thereby ensuring that it is qualified personnel that should dispense.” (R 09)

These expectations from drug shop consumers are supported by their perceived inappropriate qualifications and practice of providers, their poor regulatory compliance and weak regulatory enforcement. The imperatives for them may have arisen from their poor technical knowledge of diseases and drugs, heightened by drug consumption by even vulnerable members of the society such as the young and elderly, all driving the ardent calls for improved regulation.

6.6 Summary Findings

In this chapter, it has been shown that consumers perceive patent medicine vendors as offering important health services, but beset with quality issues around provider qualifications and competences, much as with drug effectiveness. Consumers continue to use these drug shops despite these deficiencies for their cheapness, nearness, drug availability and quickness of services. Other considerations in the decisions to patronize drug shops identified include social connectedness, access to credit, and perceived severity of disease and in some situations utilization is constrained because of lack of a viable alternative option. The consumers themselves demonstrated poor technical knowledge of diseases and drug use, weak understanding of regulations governing patent medicine retailing and no knowledge of regulatory implementation and enforcement. Retail drug users however showed strong desire of high value services for money. Despite this predilection, observable indicators of drug qualities as NAFDAC registration number or drug expiry dates are not looked out for by drug buyers, even though some had this knowledge. Overall all, consumers exercised considerable freedom in utilization choices signifying a good general familiarity with the market. All consumers looked forward to greater government role in the market through ensuring better provider training and qualification and improved regulatory oversight as ways of ensuring better performance of the market.

6.7 Discussion

Most consumers surveyed and interviewed said they resorted to the use of patent medicine vendor shops based on user experience. These influences were attributable to elements of convenience as closeness to home, long opening hours, absence of waiting times, affordable charges and potential for credit buying. These health care behavioural metrics have been corroborated in other studies (Amin et al, 2003; Brieger et al. 2001; Cross and MacGregor, 2010; Goodman et al. 2007a; Goodman et al. 2004b Goel et al. 1996; Igun 1987; Snow et al. 1992; van der Geest 1987).

The findings of the use of patent medicine vendors as sources for treatment in acute phase of ill-health has been reported by other investigators in Nigeria (Igun 1987) and elsewhere in Africa. Also, basing a decision to use a patent medicine outlet for

what is considered as minor illness and recourse to the formal sector for more severe ill-health has been documented in other African settings in the context of malaria treatment seeking behaviour (McCombie 1996; Lindblade et al. 2000; Molyneux et al. 2002). The very high patronage of medicine shops by individuals seeking care for the first time in an illness episode demonstrates the fact that in rural settings, patent medicine vendors may in fact be a first port of call for health care as also pointed out by several other investigators in Nigeria and elsewhere (Brieger et al. 2004; Iweze 1987; Salako et al. 2001). By and large for some consumers, patent medicine vendors may have become viable alternatives for clinics and hospitals and Primary Health Clinics (PHCs) in particular, and acting as competitors in a real way. The fact that patent medicine shops act as points of first contact for care has policy implications, because the accuracy of diagnosis and correct treatment of ill-health early in the course of a disease is a major determinant for long term health outcome and underscores a need for some level of technical competence of these providers.

Traditionally, patients make very few decisions themselves concerning their health. However, consumers in this study had a free rein to the purchase and use of drugs, as also observed in other Nigerian settings by Brieger and colleagues (2004) and elsewhere by Kamat and Nichter (1998). This consumer behaviour has been understood as beneficial in fostering self-care and confers on people control over their health care experiences (Levin 1980). However, free access of consumers to just any kind of medications and the potential danger of toxicity, drug abuse and drug pressure on the society has been emphasised in the literature (Igun 1983; Jeffery et al. 2007). WHO has also shown that several microbes, including malaria parasite have developed resistance to most commonly used drugs. In the case of malaria for example, this led to the discontinuation of Chloroquine mono-therapy, as well as anti-folate therapy in favour of Artemisinin Combination Therapy (WHO 2001). The unfettered use of drugs by the public therefore, poses an important drug pressure challenge for public health policy.

The study findings also bring out the mismatch between everyday expectations of consumers in terms of quality of care and the medical knowledge base and therefore the quality of practice of patent medicine vendors. Information giving to customers

on health matters was observed to be a minor component of the interactions between providers and consumers, as also reported by Brieger et al. (2004) in Nigeria and elsewhere, but related phenomenon (Chalker et al. 2000; Goodman et al. 2007a). Other publications have equally noted wide variation in the amount and accuracy of information given by drug shop retailers to their customers (Indalo 1997; Maiga 2003; Ongore and Nyabola 1996; Twebaze 2001; Nshakira et al. 2001). The description of patent medicine vendors more as economic agents than as repositories of health information adequate for clinical transactions has also been highlighted in the international public health literature (Brieger et al. 2004; Cross and MacGregor 2010; Goodman et al. 2007b; Kamat and Nichter 1998).

The results have in addition revealed the deep rooted inadequacies in the current Nigerian national health care system, regarding spatial availability of health care facilities, supply of essential health commodities, particularly drugs and a critical mass of well-trained human resource for health, as has been highlighted by other researches (WHO 2006). These have also stressed that where there is adequate public supply of quality healthcare, consumers are less likely to patronize untrained providers.

Furthermore, the thesis findings highlight the vexing issue of weak regulations and inadequate regulatory enforcement on the part of government, a characteristic of many other health systems in Africa (Goodman et al. 2007b; Kumaranayake et al. 2000; Hongoro and Kumaranayake 2000; Wafula et al. 2012; Wafula et al. 2013).

Economic theory of consumer choice and utility maximization makes explicit assumptions of a clear sense of the utility of the product to be consumed, knowledge of the rate of change of marginal utilities and the ability to compare marginal utilities of a consumption bundle. These ideas are frequently encapsulated in the axiom of the fully informed and rational consumer. In the real world however, the model does not always predict accurately how people are going to behave, because consumers are not always fully informed about the choices they make. This means that for some consumption decisions, consumers may not be able to know and evaluate all their possible options and their associated opportunity costs. Behaviours in this market best match these limitations of the neoclassical consumer choice theory. From the

survey result, majority of drug consumers were purchasing a product for the first time in that episode of ill health and therefore might not have had the requisite experience to make informed decisions about their options for maximizing health outcomes. Moreover, consumers are poorly informed regarding disease symptoms and manifestations and might not have been making the best choices of the medications they bought, added to the perceptions that providers also lacked adequate knowledge and clinical expertise, the uncertainty of what consumers bought in this market is even more complicated. For the consumer therefore, it turns out that this is a situation of choice based on best guesses as predicted by the public choice model. Information asymmetry is a dominant feature of healthcare markets and dots the body of economic literature (Arrow 1962; Feldstein 1973). This is the case in this market too. Evidence equally exists in published work of non-utilization of information by consumers generally even where it was available to inform choice making, similar to the gaps in utilization of knowledge of drug quality signals by consumers to discipline the market as found in this study also (Bugvi et al. 2014).

Economic theory also posits that the consumer is a rational individual who is capable of thinking and making logical choices. However, consumers of health services are much of the time not able to firmly evaluate the utilities of all possible treatment options and may not also be able to say with all certainty if a treatment actually cured a disease or a favourable outcome resulted from other factors. The assumption of rationality of the consumer therefore does not provide useful insight in understanding of consumer behaviour in this study, even though the research has shown consumers doing their utmost given their socioeconomic circumstances to get the most. This underscores the role of policy in improving public information dissemination covering health and health care by all relevant organizations and institutions as a strategy for improving population health and health outcomes.

6.8 Conclusions

The thesis has analysed consumer behaviour in the market as one of constrained optimization, with buyers doing their all to get the best value for money. There are general uncertainties around most provider competencies and consumers have multiple information gaps concerning diseases and appropriate drug utilization. Virtually all patent medicine vendor consumers recognize and acknowledge the important role of patent medicine vendors in their communities, characterising them as indispensable.

To summarize this market so far, the thesis has demonstrated pervasive failures in this market: imperfect competitive market structure, poor provider knowledge of diseases and drugs, low quality issues, wide spread regulatory infringements and low consumer information base of the market. These therefore provide justification for the case of government intervention in the market. The research next undertakes to analyse the overarching concept of regulation which cuts across all components of the market relationships.

CHAPTER 7: PATENT MEDICINE REGULATION IN NIGERIA

7.1 Introduction

The role of regulation is pivotal to all elements of the structure-conduct-performance evaluative framework, which formed the fulcrum of this thesis and provided the analytical tools for understanding the relationships in this market to this point. This chapter undertakes a description and analysis of the nature of regulation of patent medicine vending in Nigeria and concludes the series of results analysis, which commenced in chapter 4.

Drug production, distribution and consumption in Nigeria falls principally under the regulatory purview of the Pharmaceutical Council of Nigeria (PCN) and the National Agency for Food and Drug Administration and Control (NAFDAC), with the Federal Ministry of Health of Nigeria (FMOH) articulating policy frameworks for their modus operandi. Therefore, the data analyzed in this chapter is mainly based on documents retrieved at these agencies and interviews with their key officers. Other national agencies with ancillary roles in drug regulation also exist: the National Drug Law Enforcement Agency (NDLEA) and the Consumer Protection Council of Nigeria (CPC). The former is strictly mandated with the regulation of narcotic and abuse-prone substances, which are not used routinely in health care and not considered important in this study. The Consumer Protection Council is vested mainly with the responsibility of protecting the interest of the consumer generally, which also includes healthcare consumption, hence was adjudged relevant in the study.

Prior analyses in Chapters 5 and 6 revealed inadequate regulatory knowledge, weak regulatory enforcement and poor compliance by both suppliers and demanders of pharmaceutical products in the patent medicine market in Katsina-Ala: all of which cast severe doubts relating to effectiveness of the nation's regulatory institutions. Unanimity of opinions among both patent medicine vendors and drug consumers of the desirability of regulation was also demonstrated. This chapter therefore,

undertakes to analyze how the patent medicine market is regulated with a view to identifying opportunities for regulatory improvement. It opens with the description of what regulators understood their roles to be, in section 7.2, and then the analysis of the portrait of patent medicine vendors in the eyes of regulators in section 7.3. This is followed by the responses of regulators to the demand of patent medicine vendors for an expansion on the list of drugs they could sell in section 7.4. The processes of regulatory enforcement are explored in section 7.5, while regulatory challenges are put under the search light in section 7.6. Section 7.7 summarizes and discusses the chapter findings in relation to regulatory effectiveness and winds down with conclusions drawn in section 7.8.

7.2 How Regulators Understood their Roles

When asked to describe their roles, regulatory staff perceived themselves variously as inspectors, regulators, controllers and educators of pharmaceutical and pharmacy practice, as well as consumer protection in Nigeria. Below are excerpts of their evaluations:

“It is charged with the responsibility among others of regulating and controlling the education and practice of pharmacy in all its aspect and ramification. The PCN been empowered by this enabling law, it has its statutory function by the same law among which are: the determination of the standard of knowledge and skills to be attained by any person who proposes to practice pharmacy profession in Nigeria, updating the register from time to time, to stick to the code of ethics of the practice of the profession” (PCN)

“The law establishing the Pharmaceutical Council of Nigeria, grants me the authority to inspect and regulate pharmacy practice in Nigeria in all its aspects and ramifications.” (Benue State regulator)

“Our mandate is to regulate and control specific products otherwise known as regulated products and the products are food, drugs cosmetics, chemical devices, soap and detergents, drinks including bottle water. The mandate is very clear NAFDAC is to regulate the manufacture, importation, exportation distribution,

advertisement, sales and use of these products otherwise known as regulated products.” (NAFDAC)

The officer went into details of the scope and scale of the agency’s responsibility thus:

“When we are talking about use, we mean that at the point of dispensing the product, the product must be properly dispensed with proper information that will enable the patient to use the product rationally, in such a way that the patient should have an idea of the drugs he want to consume, the dosage and the storage condition so that the same product that is supposed to alleviate the problem of illness, will not be the one that will endanger the lives of the consumers.”

Both PCN and NAFDAC appear to be involved in regulating pharmacy practice, which would appear to be a source of potential regulatory overlap and conflict.

Still on their perceived roles, another regulator said:

“We are to provide speedy redress to consumers’ complaints. We are also to enlighten consumers and remove any substandard product that we see. So in essence, we are on the feedback side of regulation.” (CPC)

These excerpts would support the induction that all the regulators were well informed of their lawful duties of ensuring that only effective and safe health products reach public domain, as well as providing a platform for informing consumers and redressing user complaints.

However as shown in Chapter 5, patent medicine vendors had alleged multiple and overlapping regulatory functions and the seeming overlap in some responses above, the researcher put this question to one regulator and this was his thought:

“Let me clear this here that in regulation of drugs, there are two basic agency of government; we have NAFDAC and Pharmacist Council of Nigeria. The Pharmacist Council of Nigeria regulates the practice of pharmacy and also licenses the premises where drugs are stock and offered for sales. In the case of NAFDAC, we regulate the products itself because NAFDAC is empowered to license the product for sale and

when you license a product, there are conditions that the production must have satisfied, and there is a need to always monitor in such a way that the moment the conditions are no longer there, that license that had been issued for the product is no longer valid. That is the reason why the agency has the mandate to monitor the distribution and storage condition of drugs that have been licensed.” (PCN)

His counterpart at the opposite agency also expressing his viewpoint on the same issue said:

“I don’t think so because the functions are well streamlined; one is to license the premises, that this premises is fit for the products that you want to venture into, the second agency is to actually monitor and control the product stock there. As long as these two agencies know their core functions, and stick to it I do not envisage any conflict of interest.” (NAFDAC)

The responses suggest there is no regulatory overlap between the main regulators of pharmaceutical distribution chain in Nigeria.

7.3 Patent Vendors in the Eyes of the Regulators

Regulatory staff characterized patent medicine vendors variously as untrained pharmaceutical merchandizers, more appropriate for rural areas and fit only for the delivery of basic household remedies as first aiders. Patent medicine vendors were also framed as law breakers:

“In Nigeria first and foremost, we recognize pharmacist, the pharmacy technician and for the purpose of pharmaceutical care and services in the remote areas and basic household remedies, we recognize the patent medicine vendors.”(PCN)

He went further:

“This is to make available to the community basic household remedy that may serve as first aid or drugs that could render palliative measure before patient access relevant health care services. This group of people does not qualify to practice as such by reason of any formal education but by way of coming on board as a stop gap mechanism to provide pharmaceutical services.” (PCN)

Another regulator said:

“Retail medicine vendors are supposed to fill a gap that is created because pharmacists are not in that community and because the operators of patent medicine shops are not highly skilled in the art of medicine, most of them are probably school cert. holders (O’Level) and they are not professionals. Generally they serve the need of a certain class of people which is providing the immediate health need. Therefore the intricacy of what it takes to know what a particular drug can do, they are not as knowledgeable as expected. As a result of that, patent medicine vendors are limited to stock and dispense certain category of drugs which we call over-the-counter drugs. Those drugs are considered to have wide safety margin.” NAFDAC

A state level regulator expressed his views this way:

“They are not trained remember, I told you that being able to read and write in English language you don’t have any other prerequisite qualification, so you are not trained.” (Benue State regulator)

Arguing further, he framed medicine vendors as unethical and often practiced in breach of the rules of healthcare.

“If you go out to their shops, you will be seeing it oh. They hide the prescription drugs in some places, and when you request, they will take it from the carton. If you want to buy ampiclox for example, they will bring it out from the carton. They do not display on the shelves for people to access. Also, some of them stock even more than a pharmacy shop. We are talking to them on wholesale too. They are not supposed to do wholesaling, certain vendors are involved in wholesaling, when you want to do wholesale, you have to register as a pharmacy and you need a pharmacist as a partner, you can only do retail, not wholesale.”

The researcher at this point, sought to know what regulatory measures had been deployed in the light of this experience, and the response:

“I have not seen, but only heard about such behaviours they exhibit, but my advice goes thus: that they should be able to distinguish clearly to the patients what they can do and what is beyond their capability. If such patient is to be referred to the hospital,

then they should recommend as the need arise, they should not sell or give priority to money making but rather consider quality of their services and as such avoid extreme exploitation of patients.”

Regulators have said patent medicine vendors are untrained and unskilled in the art of pharmacy and medicine. They flaunt the rules by engaging in unlawful practices as sale of prescription only medicines, wholesale and handling of cases beyond their competencies. The implication of this statement is that regulators appeared aware of regulatory infringement by patent medicine vendors, but possibly tacitly permitted them.

7.4 Expanding Drug List of Patent Medicine Vendors

In chapter 5 of the thesis, it also emerged that patent medicine vendors, all wanted an expansion on the list of drugs they were permitted to sell to include some prescription drugs, given that in most cases they were the only source of drugs for consumers. Federal and state regulators were asked for their views about this and their views are presented below:

“We cannot allow them to sell any drug they want. They were brought on because of shortages of qualified pharmacists. Now that we are producing more pharmacists and pharmacist technicians, we may soon ban patent medicine vendors” (Federal Ministry of Health)

“That will not possibly happen, as a matter of fact that cannot come to be. You cannot because of that singular reason have the entire list deregulated. For example you have a patent medicine vendor possibly in a remote area, it is expected that the PMV should be able to refer, that is the essence of referral.” (PCN)

“Now coming to CPC to increase their list I don’t think is proper, because they are not safe to handle that, even as a pharmacist, the doctors are the ones to prescribe. If you must give them the authority to stock those products, they must be attached with some pharmacies alongside.” (CPC)

“No, there is no law, and no law will allow them, because they are not trained if they are doing so, they are doing it at the risk of the patients; somebody is not trained on

the course of antibiotics to give, you are not trained on diagnosis, how should I allow them to sell drugs like that? If you give them the limelight, you are doing it at the risk of the people in the rural areas. (Benue State regulator)

When reminded that patent medicine in the research field sold most prescription drugs openly, he said:

“That one you see, my hand can’t give them an open pay check because I didn’t make the law. I didn’t draw out the list for them. If I am keeping a blind eye to what they are doing, (when I talk of I, I mean the pharmaceutical inspection committee, don’t take that it is I. I, because it is a committee that I am just the chairman), it is not a license. So what they are doing is illegal. If you go and catch them with the drugs, they have nothing to do about it; our own is to go to court. They have no permission to sell those drugs, so for the fact that we are silent does not mean that they have liberty, they are not licensed to sell those drugs.”

“At this point I want us to realize that drugs are essential commodities. Drugs are products that can determine whether someone will survive or not. Better put, the use of drugs affect human life seriously. Therefore, it is better to allow someone who is knowledgeable, who knows the art and science of drugs to be the custodian of drugs. Remember where we started, that generally 100% operators of patent medicine stores are not professionals, they know little to nothing about medicine ” NAFDAC

Regulators appear unwilling to expand the list of drugs patent medicine vendors may sell, citing public safety concerns, even though they seem fully aware providers were actually selling prescription drugs already. They argued that patent medicine vendors were poorly trained and therefore, not qualified to administer regulated drugs.

7.5 Regulatory Approaches

A wide range of regulatory strategies and interventions were said to be adopted by regulators in the process of regulatory implementation and enforcement. These have been broadly classified under themes as standard setting and eligibility testing, information dissemination and awareness creation and coercion and sanctioning.

Below are answers to inquiries exploring strategies deployed in regulatory approaches.

7.5.1 Provider licensing and quality control

“An intending candidate for that trade applies to the committee, screened by the committee and recommended as eligible or otherwise to PCN to further process and admit the person into that category of practice. Upon the admission there is an orientation programme for patent and proprietary medicine vendor’s license holders. This programme is one of the things used to bring them on board, introducing them to what they are expected to do as patent medicine vendors. They are given the right orientation, they are put through some basic education requirement, they are trained on what to do, what their shops should look like, the basic tenet of the practice they are going into and the need to appreciate the fact that what they are intending to trade in is not an article of trade as it were, but drugstore which affect human lives and physiology.” (PCN)

“We interview them, we give them a written examination and we interact with them face to face, when we go out on inspection.” (Benue State regulator)

“Any NAFDAC regulated product that does not carry NAFDAC registration number according to the definition of fake product, that product will be tagged a fake product.” (NAFDAC)

“About the issue of quality and availability of drugs sold directly to consumers, we invite drug sellers for stakeholders meetings. We call them once in a while, like the one we have finished some time ago with the banking industry, all of them came, and issues of consumer interest are discussed. The same thing we do for the drug industry, we’ve done this two or three year ago.” (CPC)

The licensing process of patent medicine vendors involves interviews and screening of prospective vendors and physical inspection of the shop by state officials, while the quality of products sold is ensured through checking of drugs for identification of NAFDAC registration number and moral suasion. These approaches appear to be infrequent, occurring every two to three years in principle.

7.5.2 Provider training

“We have continuing education programme for patent medicine vendors. This continuing education programme is a bi-annual programme, in every two years every PPMV (proprietary and patent medicine vendors) are expected to access the programme to keep them updated as to what is expected of them, to refresh their knowledge and to keep them abreast of any new developments in the practice of the profession but not without setting the limits as to the scope of their practice.” (PCN)

“NAFDAC have taking the lead in recent time by conducting training workshops relevant to their activities as to how they can improve the practices of patent medicine vendors in such a way that they will stock only drugs within their category, drugs licensed by NAFDAC and that they are also stocked under the appropriate conditions that will maintain the efficacy and safety of the product itself. Recently the Director General of NAFDAC had taken the campaign to traditional rulers as to empower them to know what is expected of them at the same time also empowering the patent medicine vendors to know their limitation and making sure that the practice is done appropriately. By so doing they will be able to serve the rural communities better without fake drugs or expired drugs.” (NAFDAC)

Training opportunities offered to patent medicine vendors included two yearly refresher workshops to update knowledge and practice, coaching on proper drug storing techniques and recognition of knowledge and practice limits. Traditional rulers involvement is being pioneered.

7.5.3 Consumer protection

“We have done radio programmes to educate consumers on how to take medications and enlighten them better on what to do if someone reacts to some products. We advise them to consult their doctors. We’ve been advising on compliance with the dosages and food and drug interaction, things like that.” (CPC)

“That’s what call centres are supposed to do, and we do have channels through which consumers who have complaints can reach us. We have phones, emails and websites.

We do awareness in churches and mosques, so that the opinion and religious leaders can be carried along on these awareness programmes.” (CPC)

“We interact with them through public enlightenment, public enlightenment comes in so many ways, we use electronic media, print media and one of the programme NAFDAC has ongoing now is a programme called NAFDAC and your health, which is aired every Wednesday on Nigerian Television Authority (NTA). I am also aware that that we use television stations like African Independent Television (AIT), and Channels, radio stations and newspapers. Apart from providing them with necessary information useful for their health, the present management has sort of empowered the consumers to be able to differentiate on the spot between genuine and fake drugs. NAFDAC is working in collaboration with manufacturers where by the manufacturers incorporate certain digit numbers on their products which can be texted to a particular phone controlled by NAFDAC and immediately, everything that relates to the drug comes out which include date of production, expiry date, NAFDAC registration number and so on. To me that is a way of interacting with the consumer to let them know their rights. Also on our own without consumers coming to lodge complaints, we go ahead to do what we call full marketing surveillance. During this period what we do is pick particular drugs that we know are prone to faking that could have environmental challenge we scrutinize them randomly in different parts of the country and NAFDAC come on air to tell the whole nation the state of the quality of such drugs and batch. From time to time NAFDAC is interacting with consumers. NAFDAC also organize phone in programmes that you can talk with the Director General of NAFDAC, Deputy Director in charge of protocol, Deputy Director in charge of drugs information centre to tell them the state of drugs. NAFDAC have offices in all the states of the federation including FCT. Our officers in the states are open and free to the consumers, the consumers can interact with our officers, they can lodge complaints and their complaints will be entertained and appropriate actions will be taken. I can confidently say that NAFDAC interacts a lot with the consumers.” (NAFDAC)

Consumer empowering techniques used is mainly mass media (electronic and print), targeting health seeking and health utilization and provision of consumer complaints

channels. An instant drug quality verifying mobile phone initiative is also being rolled out and disclosure of relevant information is also provided.

7.5.4 Sanctioning of regulatory infringements

Agencies also discussed what they did in situations of regulatory breach on the part of patent medicine vendors and their views are as presented below:

“What NAFDAC does is to evacuate those drugs confiscate and destroys them. NAFDAC has task forces in each state of the federation for inspection.” (NAFDAC)

“The law is not cast in stone or iron, whichever one. There are exceptions where the decision is left to the state, because in some local governments, you will not be able to find shops. These people cannot find shops to rent to operate their business, except in complexes like you are saying and so, when we get such cases, we are not rigid. Like in Katsina-Ala, how many pharmaceutical shops do you have? They are supposed to be two but one is not even functioning very well and so we give room. We have been to the market and notified them that they are not supposed to cite businesses in the market area, and they have been given quit notice. When we go back there, we are going to lock those shops.” (Benue State regulator)

Responding to specific observations about sanctioning of erring vendors in the researched site, the officer said:

”When the law begins to work, they will see it. Particularly now, we are handicapped, because we cannot carry them and go and lock those who are perpetuating this illegal health practices, but the task force on fake and counterfeit drugs is being reconstituted. In fact, I have the final copy to publish ... and when we go out, the law mandates us to confiscate, to arrest and to lock, and to prosecute. Until that is done, they won't listen.”

He also added:

“we have given them enough time this year, as many as don't register in the coming year, we are going to lock the shops that have not registered, then we will face the product compliance that you are talking about.

Sanctioning and enforcement approaches included confiscation of products and prosecution, but it would appear frontline regulatory staff never wielded the big stick, preferring to allow vendors more time to meet regulatory norms. This might suggest that regulation was selective and random or regulators tacitly refused to implement practice standards, allowing local realities to temper sanctioning of erring vendors in rural areas. These inferences do much to stimulate a fertile theorizing of the causal influences on regulatory behaviours of officials in this study. Section 7.5 therefore examines the challenges of regulating patent medicine vendors on a broader Nigerian context.

7.6 Challenges of Regulating Patent Medicine Vendors

Regulators identified a plethora of constraints inimical to effective regulation of patent medicine retailing in Nigeria. These are discussed in-depth under main sub-categories below.

7.6.1 Inadequate funding

“On our own part there are challenges like the insufficiency of fund with which we need to get so many things done; we need to manage within the budgetary allocation of the federal government. Also inadequacy of logistics to manage the activities of these people we need vehicles, we need to reach the remote areas, to do that we need personnel. Though we have our offices in all state of the federation including the FCT but they are all located in the state capitals and the people in this category are not only in the state capitals we need to go to the remote areas therefore we need more personnel. As it is shortage of staff is major challenge.” (PCN)

“We need money to employ many hands, that’s one of our pressing challenges.” (CPC)

“We are supposed to have what we call state consumer committees and local government consumer committees by law, but because we do not have the money, but Benue will soon do that as well as other states. It is step by step, every state need to have a state consumer committee.” (CPC)

The funding gaps have meant that regulation was poorly implemented and enforced, especially in the rural areas as stated in these quotes. Funding of regulatory agencies is from fixed budgetary allocations and inadequacies existed in areas as critical staffing, logistics and infrastructural support.

7.6.2 Uncooperative manufacturers

“The little challenges we have is that the manufacturers don’t want to cooperate with us.” (CPC)

“The challenge is the issue of production of fake drugs, you have premises that are neither licensed by the Pharmacist Council of Nigeria to go into production, and neither is the product licensed by NAFDAC for production and release to the public. You see them producing paracetamol syrup and even some tablets, we have a challenge with production of fake products in Nigeria.” (NAFDAC)

“..., fake and counterfeit regulated products is a global phenomenon, it is not peculiar to Nigeria. They know that any product without NAFDAC number will not be easily accepted by the public so, there are few cases where people fake NAFDAC registration number as well. We also have cases where some people use NAFDAC number from a different company and print on their own products.” (NAFDAC)

These excerpts reveal the inability of regulatory agencies to control profit maximizing organizations engaged in drug manufacture, who appear to continue to side-step rules of pharmaceutical manufacturing. Faking of NAFDAC registration number is another dilemma of regulators.

7.6.3 Institutional constraints

Several aspects of institutional issues were frequently alluded to by regulatory official as limiting effective regulation. The list includes policy inconsistencies, judicial constraints and fragmented inter-agency collaboration, and is presented in that order.

7.6.3.1 Policy inconsistencies

“The authority to regulate the PPMV was reverted to PCN in April 2003 by ministerial directive; it used to be under the purview of PCN for a time, there after it was delegated to various ministries in the state later to Local Governments then back to the State Ministry Of Health and then to PCN for various reasons. At the time, there was an abuse of the issuance of licenses to just anybody, people who are not eligible to have it were issued the license. Then the license was abused to the extent that proliferation of fake and substandard drugs in Nigeria was traced to this to unrestricted issuance of PPMV licenses. It was not until April 2003 by ministerial directive that the authority to regulate them was reverted to PCN so it was after that that what we have put in place like the guidelines for the issuance of license, PCN approved drug list, orientation programme and continuing orientation programme came in. The groups of people who have not accessed the continuing education programme are those who have not gone through the orientation programme and are not licensed by PCN. What am saying is that not all patent medicine dealers are registered with PCN, we have to start with advocacy and sensitization to get them registered immediately the ministerial directive was passed. It was in 2004 that we started issuing out the application form, we brought so many of them on board and as at today we have over 56,000 PPMV registered with PCN but I can tell you that we have multiple of that number that are practicing as patent medicine dealers who are yet to make themselves available for PCN for the purpose of registration, annual license, education and possibly reorientation. Some of them are restricting the regulatory activity of PCN as it affects their trade of practice.” (PCN)

This comment suggests that the policy inconsistency created two classes of patent medicine vendors: the regulated and unregulated retailers, with the size of the latter many times over that of the former. It also pointedly acknowledged commencement of systematic regulation of patent medicine vendors only from 2004.

“Recently NAFDAC is one of the agencies that were ordered to vacate the ports in Nigeria so most of the times when these items are smuggled in, NAFDAC official are not permitted to be there, it is only in Lagos International Airport that we are

present. Up till now NAFDAC officers do not have direct access and that is a challenge.” (NAFDAC)

This comment conveys another policy somersault by government that is inimical to drug import regulation.

7.6.3.2 Judicial constraints

“You mentioned two things; you are talking of proximity of the sellers to each other and selling of prescription drugs. Well, for some time back, in the early 90s up to 2003, there was a court injunction from the vendors that restrained the ministry from licensing and regulating them. Things were haywire; they were doing the things they want to do, until 2003 when that issue was resolved. Then regulation started in earnest, so, we are starting from the scratch. What we are doing is trying to buy them in without using force, to register. So, that was the main thing. So all the efforts that we’ve been doing for quite long now, is to get them registered and get their license renewed and let them know that, now we have people watching over them. So our target now is not on product compliance, it is to get them registered and renew their licenses.” (Benue State regulator)

This remark implies that effective regulation was stymied by protracted legal tussle which influence is external to the regulator.

“The Pharmacist Council of Nigeria has a lot of litigation from various stake holders; various stake holders in the past have had course to institute cases against PCN so it is not unexpected. There are packets of litigation, litigation that the national body of NAPMED was like did not subscribe to, there are packets of litigations like that from some factions, and among them they have even litigations within the association. Just like in this country we have history of so many professional association and societies where members within the society instituting cases against the professional association or professional regulatory body so it is not unexpected and I don’t think it can form an item of news.” (PCN)

The many and prolonged litigations against the PCN, meant that the agency for much of the time, did not enforce any regulations.

7.6.3.3 Inter-agency collaboration

Only one agency explicitly acknowledged a cordial working relationship with other drug regulatory bodies.

“We collaborated very well with NAFDAC, as a federal government agency, we collaborate with all these agencies. We have MOU, standing MOU with NAFDAC. We have a good relationship with them and sometimes have joint market or enlightenment programs.” (CPC)

Between the key regulators of patent medicine vendor practice, their views were less direct:

“Another challenge is the fact that we have one or two regulatory body that are infringing on our statutory regulatory functions; we have some regulatory body who approach this people and by the way of propaganda are more popular than PCN, they get to be more respected than PCN by the patent medicine dealers who fear them. Today the patent medicine dealers confides that there seems to be an over whelming regulatory policing, PCN will go there; NAFDAC, NDLEA will also do the same. The PCN that has been given the charge of the regulatory mandate is the one coming last which might as well be seen as the one adding to the overwhelming number of regulators. As such rather than fighting those who are infringing on the regulatory function of PCN, they rather fight PCN.” (PCN)

Asked of regulatory conflict between the two key drug regulatory agents, the NAFDAC official said,

“When it comes to patent medicine vendors it has not been as pronounced”

“Yes because we do monitor their activities through surveillance, we go there to look at what they have and then advise them. Most of them have good storage condition we also expect that those in the rural areas should have the same because of the enlightenment that is going on by NAFDAC and am also aware that the Pharmacists council of Nigeria do the same.” (NAFDAC)

“Between PCN and NAPMED there is a good relationship but I cannot say here that it’s all jolly in all states of the federation. Be that as it may we try to get them to partner with us” (PCN)

These views suggest sublime regulatory conflict between the Pharmacy Council and the National Agency for Food and Drug Administration and Control as well as weak inter-agency coordination.

7.6.4 Geographical challenges

Several geographical challenges were mentioned by regulatory authorities that posed particular barriers to effective regulatory enforcement and are discussed below.

7.6.4.1 Large geographic land mass

An official, who felt the agency was doing good, was confronted with the finding in Chapter 6, that patent medicine vendor consumers in Katsina-Ala reported having no knowledge of the agency. He said:

“Apart from the head office that we have here in Abuja, we have offices in Lagos, Bauchi, Katsina, Awka, Port-Harcourt, Oshogbo and Sokoto. The Council also established response centers in Local Governments Areas which will partner with the National Orientation Agency to make sure that these information get everywhere. We have been to Makurdi also, and all local governments in Benue state were invited. You can see that we are really trying. The country is large, we know where these problems are and we are trying to overcome them.” (CPC)

Continuing, he added,

“Like I said earlier, about 3 minutes ago, we have the challenge of establishing our local state consumer committees at the state level. Every state is supposed to have the office, but you know we can’t be everywhere, it is not possible. What we have now is zonal offices which are 7, but in essence should be 36.”

The official is clearly accepting the daunting challenge of effective coverage of the entire country, which can be linked to the issue of inadequate funding discussed in section 7.5.1.1 above.

7.6.4.2 Trans-border smuggling of drugs

Regulators also cited porous border control as a source of free flow of unregulated drugs and a source of challenge for drug regulation.

“..., it is a fake product and such products do not necessarily come to the country through the official route. We are aware that smuggling by all means is still there, those products do not pass through the regulation procedure of NAFDAC.”

“The challenges are many but just to mention a few; one, our borders are porous. When am talking about the porosity of borders, I am not limiting it to the north alone: in the places we are having boundary with the sea, people come in through the sea, it will be difficult to monitor everybody. Like in the South-South people go into the high sea whereby they can exchange and bring any article in, they do not pass through customs whereas in the northern part of the country, across the northern boundaries everywhere is a road so people can always come in.” (NAFDAC)

This regulatory challenge implies that medicinal products enter the shores of Nigeria through routes that are illegal and not controlled.

7.6.5 Social factors

Regulators identified several social issues that tended to constrain the success of regulatory efforts. The issues are presented below.

7.6.5.1 Low public interest for information

“Nigerians are uninterested in information. I was just telling somebody of how the First Lady has launched a program to recruit 200 Nigerian ladies to drive Taxis here in Abuja. The launching was very elaborate and all the media houses carried it for days, but he was not aware of it all. So you can see the level of interest that Nigerians have for getting information. That is the problem. The case of Benue State for example, we organized an awareness program for road-side food handlers, the Mama put, last year. We chose Benue state because it is the food basket of the nation and it was an elaborate programme that was well attended by the First Lady of the state, so I am very surprised that people in Katsina-Ala did not mention anything about CPC. We have our radio programmes, even today, every Wednesday 8:30-9.00am, for the

past years, even today we spoke about issues we have resolved, that consumers brought to us. It is just lack of interest by people to get information to use.” (CPC)

This statement would suggest public lethargy to information seeking and apathy to utilization of available information.

7.6.5.2 Uncooperative patent medicine vendors

“With the patent medicine vendors one of the challenges as I mentioned before has been that many of them are yet to come on board under the regulatory control of PCN, they are still resisting as a result of one apprehension or the other and they have been practicing without any control. Recently NAPPMED members came to complain that they are feeling bad because their income is beginning to dwindle, there is a decline in what they make as against what they use to make in the past and that drug hawkers on the street have taken over their activities and those ones are trading on drugs and making more money. They said they were feeling that they were been over regulated and many of their colleagues were getting discouraged and don’t want to even trade on drugs any longer because drug hawkers have taken over.” (PCN)

He explained further:

“One challenge on the part of patent medicine vendors is that before the regulatory mandate was given to PCN in 2003, they have been doing what they like, there was no practice scope or limit, many of them I want to believe are still stocking prescription only medicine. They have been making money from stocking these drugs and all of a sudden there is regulatory provision that says this is an approved drug list and you should not sell this category of drugs. Those that are making money from prescription only drug will want to make money from it and such a person will never want to submit, will never want any regulatory control. Some of them store this pharmaceutical product under unacceptable conditions and now you are telling them to improve on the storage condition of the drugs by a way of possibly investing more in their shops, to improve the outlook, to keep records and so many provision of the guidelines, they won’t naturally want to do that. When you want them to come around to get educated and keep them abreast with the developments in the

pharmaceutical world and you ask them to pay a token fee of 1000 Naira, it is a challenge to some of them because they find it difficult to part with such amount for such education.” (PCN)

These comments reveal the perceptions of regulators why patent retailers appear to resist regulation. This border on opportunity cost of compliance with regulation and financial disincentives of paying for refresher training workshops.

“Pharmacy as a profession in Nigeria is now been seen to be fighting everybody; when you embark on regulatory activity, what everybody sees is that you are fighting them so those are the issues in Nigeria. Given the level of illiteracy and the economic pressure, I think it has come to do nothing than to add to the regulatory challenges of PCN that I want to agree is happening and you can now imagine, the Community Health Extension Workers (CHEWs) have their own association, so any attempt to regulate patent medicine shops or patent medicine practice is like you are fighting the CHEWs, the Community Health Officers, the Nurses, the unemployed graduates from various other courses, the retirees. Everywhere in this country because drugs is profitable, everybody wants it to be an-all-comer’s game or business. So that is another regulatory challenge we are facing, it’s not easy.” (PCN)

Another regulatory puzzle regulators say they encounter from this statement is the multiple health professional cadres that have resorted to patent medicine retailing and the recourse to their professional associations to resist regulation.

7.6.5.3 Unemployment pressure and social connections

“To address your question head-on, given the fact that in this part of the world, an holistic view of the economy that we run is buying and selling. For survival instinct today, one of the easiest means of survival among people is the buying and selling of commodities. Healthcare is one of the basic needs of life and the emerging trend of need for drugs due to emergence of diseases and new health trend today has made graduates of Biomedical sciences like Biochemistry, Physiology and so on, to find a good means of income in opening chemists. At times when some factions among the Patent Medicine Vendors are filling petitions, you will know from the level of their write-up that these are not people who could just ordinarily read and write, you see

on the pages of paper that graduates are involved and of recent, a field assessment have shown that many graduates who could no longer find jobs in Nigeria are just falling back to opening chemists, so that is another terrible challenge.” (PCN)

“I can only tell you that it is not completely eliminated, remember the level of unemployment in the country. Many people go into establishing patent medicine store as a mean of getting themselves engaged” (NAFDAC)

The sense in this statement is that regulators have become sympathetic to practitioners, since they are striving to eke out a living. It explicitly affirms a trend of highly educated individuals entering patent medicine vending business and a continuing spiralling growth of this industry. It also means that the trade is increasingly been undertaken by well-educated individuals.

“Even at that, there are elites, rich men that also travel abroad just as you go into provision store and pick whatever you like, they also go there to pick some drugs they feel will sell in their own stores. In fact those drugs they consider it very cheap because bringing them in, they are not going to pay any revenue to the government and by so doing most unlicensed drugs come into Nigeria” (NAFDAC)

7.6.6 Miscellaneous issues

The Pharmacy Council was asked about patent medicine vendors’ allegation regarding predatory regulation and his view was,

“That does not apply to PCN; no category of practitioners under PCN can come out to say that. As a matter of fact you hear many of them say that PCN is very friendly and nobody keeps us away from regulating him or her by giving us anything. To process their license and their application with us they pay only a token of 500 naira which is documented and receipted. If there is anyone making such complain let him file a petition because am not in any picture of such complaints coming to PCN from any quarters.” (PCN)

It also emerged that restrictive policies were been implemented targeting patent medicine vendors, as one regulator revealed.

“patent medicine vendor are not only found in the rural areas some of them are in the urban areas but am glad to tell you that the Minister of Federal Capital Territory in collaboration with pharmacist Council of Nigeria made it mandatory that patent medicine owners cannot operate within the urban areas. What it means is that they are to move to the rural areas. There is also another condition that within certain meters of a pharmaceutical location, a patent medicine must not be found which means that with time, their activities even though may not be completely eradicated but certainly will be minimized.” (NAFDAC)

This reveals contemplation of banning of patent medicine vendor shops in the future.

Granted that the Pharmacy Council is saddled with the regulation of pharmacy practice in Nigeria, the question was asked how it thought access to essential drugs for rural communities could be improved. One official answered:

“The approach to that has to be multi factorial, it is not the work of PCN to get all the road networks in Nigeria perfect or good, and it is not in the purview of PCN to have various infrastructural amenities in place, which all have bearing to health care provision. As such, I will recommend a multi-sectoral approach. If we have good road networks it makes referral easier, if all our health care facilities are well structured, funded and equipped, things will be better. Health care delivery is not within the purview of PCN, it cuts across all the levels of governments from the Federal Government to Local Government. I think what we have to do is to go by the way of multi sectoral approach and to also make sure that things are put in proper perspective. When things are in place, PCN too, in carrying out its mandate will find the job easier to do. That is my summary on that.”

Further asked to predict when The Council would have replaced untrained and unprofessional retailers in patent medicine outlets with professionally trained individuals across the country, the official said,

“You say tentatively how many years then I ask another question to probe that question further in saying would all parts of Nigeria have had infrastructural facilities or social amenities by whatever number of years you want to propose? That is the question that is very pertinent and I don’t think anybody can answer that.

This response suggests important implications for patent medicine practice for Nigeria: the practice may remain a prominent feature on the health landscape of the country for an unforeseeable future.

7.7 Summary Findings and Discussions

Specifically, this chapter has explored regulating patent medicine vending in Nigeria very broadly, unpicking the nature of current regulation of patent medicine retailing and what regulatory instruments are deployed to align practice with public health policy objective of access to effective and safe drugs. The analysis also highlighted critical areas of regulation where gaps exist. In this section, summary findings are highlighted and a discussion of key findings in the context of current knowledge from other African countries is undertaken.

Findings are that the regulation of patent medicine vendor practice is premised on the traditional approach of bureaucratic and administrative control, with regulators aware of wide spread regulatory infringements by practitioners. Frontline regulators are unable to enforce full compliance with regulatory standards, rather adapting to a *laissez faire* disposition de facto. Added to this is the further finding that regulation is pluralistic with weak inter-agency coordinating mechanism, which appeared to have resulted in sublime conflicts between the key regulators. Furthermore, regulation is undertaken by distantly located federal and state regulators, with no corresponding local government level offices and personnel, thus giving rise to very irregular inspection of providers locally and almost no sanctioning of inappropriate behaviours of practitioners. It also emerged that regulators tacitly allowed regulatory infractions and concessionary practices on the part of practitioners to allow them time to meet up with specified standards. All formal regulators perceived patent medicine vendors as untrained and unprofessional providers of basic healthcare best permissible in difficult to reach areas, where no formal pharmacies exist. For the same reason of not being professional, patent medicine vendors are deemed not suitable for expansion of drug list they are currently allowed to trade. Regulators at all levels were inundated with an array of regulatory constraints on multiple fronts, revolving around economic, social and political factors very broadly. These specifically included inadequate funding, staff shortages, policy inconsistencies, litigations and judicial

bureaucracies. Others are poor public uptake and utilization of available health information, resistance to regulation by patent medicine vendors, uncooperative drug manufacturers and regulatory fragmentation. Finally, it also has been demonstrated that there is weak collaboration between patent medicine vendors and regulators and indications of potential banning of the former with a hope of encouraging qualified pharmacists and pharmacy technicians to establish practices in rural areas. This intended proscription of patent medicine vending appeared to be at the core of distrust of the Pharmacy Council by patent medicine vendors.

Regulation of drug shops in Africa has a long past but a short history, with only recent efforts at systematic documentation in this Knowledge sphere. Consequently, few studies were uncovered that closely examined the phenomenon in economic literature on regulation. Notwithstanding this limitation, relevant relationships were established with other readings.

The adoption of a command and control approach to the regulation for patent medicine vendor in Nigeria appears inappropriate to the study context. It was shown in chapters 5 that patent retailers viewed their role as offering first aid and complementing the formal sector and in some cases, they were actually the only viable option of essential medicines for consumers. Retail drug consumers in chapter 6 rated patent medicine providers as providing important services, further describe them as indispensable, in the context of non-availability of higher quality alternatives. Yet the regulatory frameworks do not reflect these realities and for example remain guided by a narrow range of drug list which failed to match community needs and has been openly exceeded by patent medicine vendors. This bureaucratic and rigid approach has been identified as the commonest form of regulatory strategy applied in most low and middle-income countries (Ensor and Weinzierl 2007). It has for instance been reported in Tanzania and Zimbabwe also (Goodman et al. 2007b; Hongoro and Kumaranayake 2000; Kumaranayake et al. 2000), and in this model, regulation focuses largely on registration of practitioners, the registration of drugs and licensing of business premises. It may mean therefore that quite often, regulators may not seem to recognize the gap between need and appropriate regulation. However, in this study it appeared regulators recognized this

mismatch between the contextual realities of rural dwellers and policy requirement, which may offer a possible explanation for the less rigid implementation of regulation and insistence on strict adherence to regulatory standards. Similarly, the unpreparedness of regulators to accept a possible extension on the list of drugs retailers sell to reflect practical needs also point to dissonance between need and intervention, although it is recognized that for this policy change to occur, there may necessarily be predated appropriate legislative approval by the legislature. This inclination to withhold a greater role definition for patent medicine vendors contrary to need and de facto practice is not confined to the Nigerian context, as similarities do occur elsewhere in Africa (Brieger 2002; Goodman et al. 2007b). These demonstrate regulatory inappropriateness and inadequacies.

Most consumers expressed dissatisfaction with the competence of patent vendors who have had no formal training in health care to provide good quality service and this questions the appropriateness of the regulatory criterion that mere ability to read and write in English language as a sufficient entry requirement in to a business of such highly technical competence.

The study has also uncovered a lack of basic regulatory law for the establishment of patent medicine practice in Nigeria, which brings another dimension to regulatory inappropriateness. From its origin in 1936 to date, no specific law guiding the practice of patent medicine has been articulated and it has remained a licensing function of the Pharmacy Council of Nigeria, despite its importance and extensive network. This gap might have paved the way for the conflicts and protracted legal adjudication between regulators and regulatees, and constituting a potential source for the regulatory ineffectiveness observed. Elsewhere also, it has been argued that once private markets are left unregulated for so long they become formalized with vested common interests and become extremely difficult to regulate successfully subsequently (Kumaranayake et al. 2000). The plural nature of agencies involved in drug related regulation in Nigeria may also provide a lens for understanding regulatory deficits discovered in this study. Where multiple regulators with overlapping roles have occurred, fragmented policy implementation has been observed to result (Kumaranayake et al. 2000; World Bank 1997).

There were several evidences of inadequate regulatory enforcement in the studied market. One relevant consideration to this understanding is inadequate budgetary allocation, which caused shortages of regulatory personnel, constrained infrastructure and operational logistics and hence, ability to cover the vast geographical spread of the country adequately. Studies elsewhere in Africa have also documented weak regulatory implementation and enforcement linked to extensive network of the private sector and the limited budgets available to regulatory agencies (Bennett and Nganlande-Banda 1994; Matsebula et al. 2005). Frequent policy changes by government is another factor that might have contributed substantially to the regulatory failures: in this study there were repeated switching of oversight control over patent medicine control from the PCN to the state ministries of health and then to the local authorities prior to 2003 and then a reversal back to the PCN after 2003 period. Equally important to understanding of regulatory inadequacy in the country is the new policy which ordered NAFDAC out of sea and air ports as another case of policy reversal, which has the potential to significantly impact negatively on regulatory effectiveness. Where policies are not well designed to align with realism, frequent shifts are inevitable and government failure to regulate private drug retailers in low and middle income countries has been blamed on setting of unrealistic policies or their inconsistencies (Ensor and Weinzierl 2007).

Patent medicine vendor resistance to regulation and drug manufacturer uncooperativeness where also reported as reasons for regulatory ineffectiveness by regulators. Economic considerations could have been responsible for these behaviours. Taking the patent medicine vendors for example, during the regulatory transitory period of 1990 to 2003, regulation became dysfunctional with no inhibitions to the range of drugs they stocked. Compliance in the new era of regulation meant lower revenues from a more limited stock list. The unwillingness of vendors to pay to attend refresher workshops designed to update their knowledge and practice skills, can also be understood from economic lens of the outlays acting as financial disincentives. Another economic reason for opposition to regulation from vendors may have arisen from the perceived rivalry between patent retailers and pharmacists who run formal pharmacies and the expressed threats of official banning of patent medicine vending in Nigeria by the Pharmaceutical Council of Nigeria,

franchised by pharmacists. Regulatory compliance by patent medicine vendors in the circumstance would also have been understood to mean ceding substantial market advantage to pharmacists. Similar pecuniary considerations may be conceptualized for the uncooperative labeling of drug manufacturing concerns reported by regulators. In all the scenarios analyzed, a combination of high compliance costs and weak sanctioning potential are argued to have created fertile ground for regulatory ineffectiveness (Ensor and Weinierl 2007; Kumaranayake et al. 2000).

Although retailer allegation of making unofficial payments to regulatory officials was out-rightly refuted, it is possible this would have been the case, given the pervasive culture of corruption in the country. In Tanzania, Wafula and colleagues (2013) did find deep rooted corrupt practices of varied forms among regulatory officers. These assumed the forms of institutional payment of bribes to inspectors, inspectors aggressively demanding bribes and cases where drug sellers paid bribes for infringements uncovered during inspections. Elsewhere in Uganda also, it was demonstrated that unofficial practices of public health workers were related to gaps in government policy enforcement and effectiveness (McPake et al. 1999).

Demand side efforts of regulators to create informed consumers, might have failed as a result of many possible explanations like the medium and language of communication, but crucially important to the creation of this gap might have been the mode of generating the information communicated. Health information appeared to emanate from the top without inputs from consumers of what specific information needs they require. This assumption is based on consumer poor knowledge of existence of the different regulatory agencies and their functions as reported in chapter 6, which suggests weak interactive information generation and communication by these agencies. The information intended for the public has therefore been ineffective in achieving the desired health behaviour change in consumers as intended. It has been reported that mutual trust is critically important in the utilization of information and forms an important determinant of information effectiveness (Thiede 2005), a condition that appeared lacking in this study site. The finding of supposedly non-utilization of information provided by regulatory agencies by both medicine vendors and drug consumers may therefore be attributable to lack

of trust due to the non-interactive nature of information production. It has been argued that untrustworthy information source may offer low use value for users (Yesudian 1994). For the retailers in particular, financial incentives may be another explanation for gap between knowledge and practice reported in this study (Wafula et al. 2013).

Also the thesis reported regulators conceding to many lapses in regulatory provisions which could have contributed to regulatory ineffectiveness. For instances, they acknowledged that formal pharmacies were lacking in rural areas and patent medicine vendors were the sole sources of medications for consumers in these places. This understanding may explain why regulators turned a blind eye to regulatory infringements, opting rather to give retailers more time to meet up with requirements. This agrees with other studies in much of sub-Saharan, where regulators similarly looked away from shop retailer infractions (Goodman et al. 2007a; Hongoro and Kumaranayake 2000; Kumaranayake, 1997; Tawfik et al. 2002; Wafula et al. 2013). In this context of near non-existence of formal pharmacies to provide prescription drugs and their equally non availability in government facilities either, formal implementation of regulation may not be a good fit in this context. Ignoring the inappropriate behaviours of drug shop providers might equally be a subtle acceptance from regulators that curtailing the behaviours of these widely used providers is simply not doable. This passive attitude of regulators to regulatory breaches by drug shop retailers has been reported extensively in the literature in other settings also (Attanayake and Siyambalagoda 2003; Goodman et al. 2007b; Wafula et al. 2013, Yesudian 1994).

Regulators had decried the high unemployment rate in the country and the recourse of several job seekers to self-employment in patent medicine vending as a means of eking a livelihood, meaning that regulators might have been influenced by feelings of compassion to temper regulatory regimens so that self-employed people remained productively engaged and letting off the steam on unemployment that currently besiege the nation.

In principle, patent medicine retail market regulation purposes to promote attainment of public health policy objectives of access to effective and safe drug services.

Therefore, patent medicine practice regulation in Nigeria would appear to be a good approximation of the public interest theory of economic regulation, which makes assumptions of market failure, well informed and endowed benevolent regulators, pursuing public good. However, with the litany of failures bordering on inadequacy and inappropriateness of regulation highlighted in the thesis, the model poorly matches the observed phenomenon. With explicit evidence of regulatory staff's tacit dereliction of formal roles, which may be linked to multi-factorial aetiologies; including but not restricted to savvy self-interest as pointed out in Chapter 5, the model of private interest of regulation would offer a better explanation of the regulatory regime in the studied market. Overall therefore, regulation of patent medicine market in Nigerian better fits the public choice perspective of regulation than public interest paradigm.

7.8 Conclusions

The evidence discussed in this chapter show that regulators acknowledge patent medicine shops as legal entities, run by unprofessional individuals and whose services remain relevant but to be tolerated only in distant and underserved communities. Regulatory agency officials know the illegal behaviours of retailers in the market but are constrained by multiple challenges and regulation is largely ineffective in terms of both appropriateness and adequacy. These evidences better fit the public choice model of regulation.

The thesis has now established an imperfectly competitive retail drug market plagued by pervasive regulatory infringement on the part of providers against a backdrop of chronic inappropriate and inadequate regulatory controls and progresses to address the weakness in the market in terms of access to effective and safe drugs and solutions are proffered in the next chapter.

CHAPTER 8: IMPLICATIONS OF FINDINGS FOR ACCESS AND REGULATION

8.1 Introduction

This chapter jointly undertakes to address objectives four and five of the thesis, which are to investigate the implications of the interplay of market structure, provider conduct, consumer behaviour and regulation for access to quality and safe essential medicines in patent medicine vendor markets in rural areas of Nigeria. It also undertakes an exploration of the policy implications of the insights gained from the study and makes recommendations of how best to attain the aforementioned public health goal. Therefore, findings from chapters 4 through 7 have been weaved into a synopsis of the de facto patent medicine vendor market in Katsina-Ala, the researched field in section 8.2, while their implications for access and policy are discussed in sections 8.3 and 8.4 respectively. The chapter ends with a summary of key issues and conclusion in section 8.5.

8.2 Summary Research Findings

The market structure has been shown to be imperfectly competitive harbouring both elements of monopolistic and oligopolistic structures as demonstrated in chapter 4. It was discovered in chapter 5 that providers had low technical knowledge of both medicine and pharmacy and exhibited widespread regulatory breaches: medical consultations with customers, drug prescription, poor dispensing practices, non-renewal of licenses and the sale of unauthorised drugs. Patent medicine retail consumers in chapter 6, acknowledged the important role of patent medicine vendors for their health care needs, describing them as indispensable. They however expressed deep quality concerns with regards to drugs and provider competence at the same time. Despite the recognized deficits, consumers cited convenience as the principal motive for continued use of patent medicine vendors, even where more formal healthcare facilities were found in some cases. For example, closeness to home, cheapness, quickness services, longer opening hours and courtesy formed key considerations for preferring patent retail medicine outlets. Insights also emerged that

patent medicine regulation was ineffective: inappropriate to local needs for health care and inadequate in terms of supervision, inspection and sanctioning of infringements. The latter is the finding of the penultimate chapter and all findings are presented as a model of this retail drug market in figure 8.1 below, highlighting the overall implication for market performance.

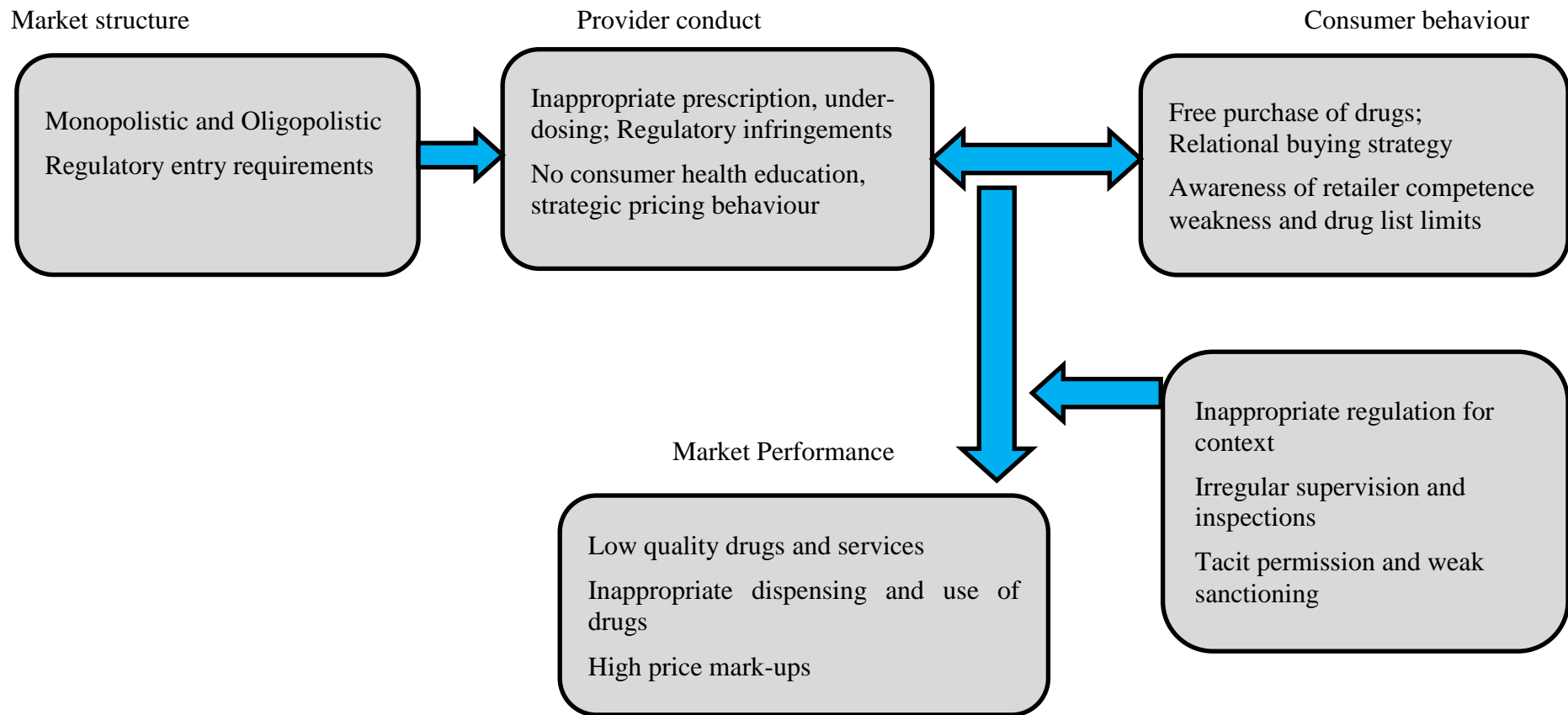


Figure 8.1 Patent medicine market performances in Katsina-Ala

8.3 Nature of Competition and Implications for Effective Access

In Chapter 2 of the thesis, one access framing was the “the degree of fit between the client and the health system,” (Penchasky and Thomas 1981; Thomas and Penchasky 1984), and the evaluative framework by McIntyre and colleagues (2007) was adopted for understanding the nature of access in this study. The framework differentially distinguished three major aspects of access comprising availability, affordability and acceptability dimensions and their indicator variables against which the market performance is compared.

The thesis evidence supports the argument that patent medicine vendors improved geographical and temporal access to medicines generally in the researched local council by virtue of the fact that when compared to government and other non-governmental health facilities in the area, consumers preferred retail drug shops given their relative closeness to homes, long opening hours and prompt and quick services. Other market attributes that increased drug access and utilization of medicine vendor outlets were relative cheapness of drugs which contrasts with the fee uncertainties in formal facilities, friendly and courteous attitudes of providers, availability and range of perceived quality drugs, free access to drugs in-store and potential for credit: the latter considered important due to the low socioeconomic status of most community members and illness uncertainty. Patent medicine vendors lived in their host communities and this social embedment created and fostered trust and confidence in community members, thereby enhancing greater acceptability and their high usage for health care than the more distantly located formal health facilities. These attractive characteristics of the market satisfy the variables encapsulated within the availability, affordability and acceptability dimensions of the access framework adopted in this study (McIntyre et al. 2007). These factors to a large extent can be seen as enabling high coverage of the population and improving the promptness of health care seeking. On the contrary, poor access to finance emerged as a key constraining influence on access for consumers through narrowing the drug inventory of retailers and consumer ability to pay for health care. Also limiting affordability and therefore access to essential drugs is the high transaction costs, attributable to multiple taxations (business and regulatory) and informal

payments to public officials and consequently, the impact on prices charged for drugs.

On the demand side, poor incomes of community members who form the bulk of customers in drug shops constituted another barrier to accessing needed drugs in the market, as borne out in consumer interviews and observed purchase patterns of sub-optimal doses on some instances. However, whilst poor regulatory inspection and sanctioning would have allowed retailers to stock essential prescription drugs (even though this is illegal) and expand access for consumers, it also risks important negative quality implications.

A multitude of factors have been identified which are crucial for treatment quality and health outcomes in the short and long terms. These determinants include provider expertise and competence, availability of quality drugs, prompt health care seeking, accurate case diagnosis and appropriate drug prescription and patient compliance with dose regimen (MSH 2012). The evidence in this study demonstrated strong non-price competition along some of these variables in the market, which in a conventional market should predict high quality products and services, but in health care, this may not necessarily so due to the difficulty of observing and valuing technical quality accurately. Relatedly, insights showed further that consumers therefore based their choices of drugs and outlets for most part on their perceptions of quality, familiarity and trust of providers. However, it was observed that there was widespread use of inappropriate prescription of drugs by both providers and clients alike. This observed behaviours brings to the front, the challenges of observing quality associated with health care goods even after use, as some of the customers in the market would likely have been making repeat purchases. Also, in this agency situation, providers are expected to use their greater expertise in health care to the best of consumer interests. However, the distortionary use of this asymmetric information advantage to induce demand and enhance profits appeared rife in this setting such as treating cases that providers had not full competence: a not unusual tendency of self-interest profit maximizers. The range of variables appealing to consumer convenience such as short waiting times, quick consultations and third party buying of drugs may also have contributed negatively in terms of technical quality of treatment provided in the market. Similarly, non-

price competition to improve affordability through sale of sub-optimal doses of medications also tempers technical quality of treatment bought by consumers in the studied market. This particular pattern of drug consumption behaviour has grave treatment outcomes for consumers as well as negative consumption externalities on society in general by promoting resistance development of microbials to antibiotics (SCORE 2004).

In this situation of imperfectly observable quality signalling with price sensitive consumers in poor rural conditions, the potential of crowding out sellers of high quality drugs in the market and entrenchment of a culture of low quality in perpetuity is highly possible: the “market for lemons” phenomenon (Akerlof 1970). These quality concerns require appropriate policy measures to address, and these quality enhancing measures are evaluated in section 8.4.

8.4 Policy Implications

Regulation of pharmaceutical markets is normally targeted at providers, consumers and the industry, using regulatory instruments that best suit the policy objectives which often include universal access to quality, safe and affordable essential medicines (including devices and consumables) and their rational use (Philipson 2002). The study has identified several policy relevant market and regulatory failures that can be improved through policy instruments targeting demand, supply and regulatory variables. This section analyses what feasible approaches government may pursue in order to enhance optimal quality of products and services in patent medicine vendor markets across Nigeria. It argues that systematically improving services and products at patent medicine retail outlets will require integrated programmes that constructively engage with all stakeholders by adoption of regulatory approaches that recognise the appropriate linkages and balance between needs and standards.

Knowledge gaps resonate across the market, which have significant implications for consumer access to effective medicines and their appropriate use. These factors include poor consumer knowledge of drugs and disease manifestation, poor provider knowledge of drugs, inappropriate dispensing practices and inadequate health information disclosure to consumers. For quality sensitive consumers as

demonstrated in this study, who to a large extent consume health care as credence goods with no way of judging the quality of drugs correctly either before or after consumption, the role for greater regulatory effectiveness in ensuring and sustaining high quality products and services is critical. This access policy objective can be attained through rethinking the entire continuum of policy design, implementation and feedback. Findings in this thesis offer insights that can feed into this policy re-engineering agenda. Adopting an economic perspective, the debate will swing between whether government should allocate more scarce resources to tighten current regulatory regimes or seek more cost-effective alternative market control measures. The author will discuss interventions that target consumers, providers and the pharmaceutical industry, drawing parallels with successes and challenges in similar settings in the literature. The thesis recommendations will be hinged on the balance of imperfections in both markets and regulation against the context of high unmet need for health care, explained in part from poor access and critical health worker shortages.

8.4.1 Regulatory strategies

From public health perspective, concerns for improving access to essential medicines in patent medicine outlets and by extension pharmaceutical markets in general must focus on improving availability, affordability and acceptability to quality products and services and their rational use (WHO 2004). Comprehensive drug regulation often would involve related areas as drug manufacture, importation, distribution and sale to end users. It will also include functions as prescribing, labelling, dispensing, licensing, inspection, certification of personnel and in some cases, drug pricing ((MSH 20012). Therefore, strategies to effectively address patent retail market failures must target these essential elements in a holistic approach and the role of regulation that support these inter-related functions are considered along broad themes as regulatory tightening, widening of regulatory scope and institutional capacity strengthening.

8.4.1.1 Regulatory tightening

Effective regulatory control of pharmaceutical industry is said to be neglected in developing countries, but remains indispensable tool in attaining public health goals

of drug quality, efficacy and safety (MSH 2012). To ensure that only efficacious and safe drugs enter the market and ultimately reach the public, stricter enforcement of regulation will appear to work better, particularly on manufactures. Regulatory agencies could insist on drug manufacturers to improve packaging and labelling of their products for consumers, clearly differentiating between age grades in packaging and giving detailed yet accessible information about dosages, actions, side effects and adverse reactions. In addition, manufacturers may be made to include a translation of these drug instructions in the three most popular local languages of Hausa, Yoruba and Igbo to convey critical information which at the moment are communicated solely in English. This change may have multiple advantages. It will address the challenge of inappropriate dosing and poor information giving observed in the study. The policy change can be enforced during drug registration process with NAFDAC. This regulatory intervention should influence improved product quality nationally, with the cost impinging substantially on drug manufacturers and leveraged as a drug registration standard. Whilst potentially enhancing drug instructions, it will also improve contamination and drug degradation linked with poor dispensing practices of patent medicine vendors as well as improved consumer compliance with dosage regimen (WHO 2004).

Also, if drug manufacturers can be made to invest more in research and development of safer chemical entities which offer more specific actions and wider safety margins, then the dichotomy between prescription and over the counter medicines that currently exist and sustain the thinking and unwillingness of regulators to enlarge the list of drugs patent medicine vendors can trade may pale down. This will potentially expand access to safer drugs needed by a large proportion of people generally, and in particular in rural areas where as shown in this study, consumers have near unfettered access to just any drug on demand. However, the implementation of this recommendation may only be partial, given that some of the drugs on the Nigerian drug market are imported from business concerns abroad and therefore, do not fall under the jurisdiction of local Nigerian regulatory authorities. Notwithstanding, the implementation of this policy even at local level alone may help improve the overall pharmacy practice and pharmaceutical development of the country generally.

Both policy recommendations of improved packing and labelling and research and development have implications for the costs and consequently the prices of drugs and their affordability. They may inadvertently drive up prices of drugs and constrain access further for a high proportion of people as unintended outcome, if not well handled

Further evidence from this thesis has shown that regulatory enforcement of pharmaceutical legislation in Nigeria is weak, with regulators citing a range of constraints and patent medicine vendors alleging corrupt behaviours on the part of regulators. With this low threshold for corruption and therefore high potential for regulatory capture of officials, the probability of enforcing adherence by drug manufacturing firms to improve packing and labelling looks low. Likewise compliance with a policy of increased funding of research and development activities would appear unlikely, given the addition to production costs. These profit maximising businesses may find it more profitable to capture savvy regulators than invest in improving their products.

Other than these, the case for global tightening of regulation in the market may not be desirable for public health as evidence in the thesis revealed numerous constraints to this approach. There are for example, consumer demand for essential drugs, frequent government hospital stock-outs, severe funding gaps of government health facilities and repeated staff work-outs in public health facilities over remunerations, all of which might make stricter control approaches undesirable. Therefore, adoption of a command and control strategy to improve quality of products and services in the market will exert a contractionary drag on access to essential medicines for rural peoples and thus not a recommended approach. Besides, it is pertinent to note that regulatory tightening may not even be feasible in the market considering the inspection, supervisory and enforcement weaknesses enumerated in this thesis. Institutional bottlenecks of a multifaceted nature confront all agencies which range include, inadequate and inappropriate personnel, shortages of infrastructure, financing gaps and tacit permission of infringements by front line regulators. For effective implementation of the above recommendations, factors within regulatory institutions will have to be reorganised to provide the enabling environment for

regulatory tightening approaches to be effective, which aspect is discussed in-depth in section 8.3.1.3.

Granted that regulation is effective and yielding improved manufacturing, packaging and enhanced quality signalling features which will most certainly improve the functioning of this market, the poor practice by patent medicine vendors will not resolve. More effective regulation of provider behaviour is a necessary accompanying policy discourse to also explore and forms the subject matter of the following section.

8.4.1.2 Provider practice improvement

In the area of provider conduct, insights from the thesis revealed that drug retailers unanimously recognised the impact of knowledge improvement on enhancing the quality of services, much in the same way as consumers emphasised the need for patent medicine vendors to be certified in relevant health fields and that certification be a precondition for licensing of patent medicine vendor practice. Therefore continuing education programme for patent medicine vendors that recognises this relationship will have a positive influence on provider practice and also meet consumer expectations. Even though the guidelines for the regulation of patent medicine practice in Nigeria stipulates that such trainings be organized once in two years for each vendor, findings in this study showed that continuing medical education programmes for patent medicine vendors were sporadic and far-between. Further insights gained from observations demonstrated that majority of medicine vendors had no formal health training of any form (against consumer expectations), meaning that most consumers would continue to receive inappropriate counselling and medicines for their ailments if the status quo persists. This may result in consumers continuing to get drugs that are not only ineffective, but that also endanger their health (CMP 2003; Abuya 2007). Therefore, increasing the number of patent retailers who can sell common medicines appropriately may go a long way in enhancing the potentials of patent medicine retailers to improve the health of many people in underserved locations. This believe is supported by why patent medicine vendor educational training has been the commonest intervention targeting improved provider performance in sub Saharan Africa (Nigeria inclusive) in the past (Greer et

al. 2004; FHI 360 2013; Oshiname and Brieger 1992; Wafula et al. 2010). The effectiveness of this approach to sustainably improve drug retailer practice has however not been established and here lies its weakness as a sole intervention (Wafula and Goodman 2010). These educational enhancing interventions have focussed on a range of aspects as knowledge and skills improvement to provide appropriate medications, targeting of particular behaviour issues of provider-consumer interactions for example inadequate drug and health education counselling of consumers, regulatory standards and requirements and case referral processes. Reports that have evaluated these interventions have shown that although these initiatives resulted in improved appropriate prescription by providers in the short run, issues as client counselling and history taking did not change (Brieger et al. 2003; Greer et al. 2004; Oshiname and Brieger 1992; Wafula and Goodman 2010). In the main, it has been noted that provider trainings have been irregular and did not improved all aspects of provider behaviour (Marsh et al. 2004; Marsh et al. 1999; Tavrow et al. 2003), hence the thinking that for optimal impact, provider trainings be reinforced with other supportive measures, such as frequent regulatory inspections and support of retailers and community behaviour change information activities (Marsh et al. 2004; Marsh and Kachur 2002; Thiede 2005). Also stressed in these reform arguments is the role of profit motives of providers in constraining the full impact of educational training, and failure of drug retailers to adhere to practices that seemed to contract sales and profit margins have been highlighted (Wafula and Goodman 2010). Additional evidence supporting the conclusion that stand-alone educational training programmes for retail drug sellers have failed to yield satisfactory practice outcomes abound (Goel et al. 1996; Goodman et al. 2007b; Gross and Pujat 2001; Kumaranayake 1998; Shah et al. 2011; Waters et al. 2003). Furthermore, patient demand, advertorials of pharmaceutical and alternative therapies, the internet and commercial interests of businesses contribute to the unending list of other influences that may interfere or distort the impact of provider training interventions alone (WHO 1998). Therefore, patent medicine vendor practice improvement interventions must be systematically integrated programmes that weave multiple effective strategies into one holistic initiative (Gross and Pujat 2001; Shah et al. 2010).

Patent medicine vendors as profit maximizers, theory predict would strongly be influenced by financial incentives and this tendency has been reported among drug retailers in different studies (Patouillard et al. 2007; Shah et al. 2010; Wafula and Goodman 2010; WHO 1998). Therefore integrated provider practice improvement strategies as drug shop accreditation and franchising approaches have been shown to address the limitations of stand-alone provider trainings, by incorporating financial and business incentives in their core design. These strategies have proven as useful tools that enabled better uptake of improved training practices by drug retailers in several places in sub-Saharan Africa (Marsh et al. 2004; Rooney and van Ostenberg 1999; Ruster et al. 2003; Rutta et al. 2011; Rutta et al. 2009; SEAM 2007). The success story of the Accredited Drugs Dispensing Outlets (ADDOs) intervention in Tanzania provides a comparable and appropriate template to adapt. This initiative provides for training and certification of vendors, monitoring of adherence to regulations, expansion of permissible drug list to include selected prescription drugs and facilitated access to microfinance and reliable sources of quality drug stocking wholesale markets as a single intervention (Centre for Pharmaceutical Management 2008; Goodman et al. 2007b). Franchising is another approach that has also encouraged drug shop retailers to meet and maintain practice standards while offering business incentives and have been implemented in Ghana and Kenya, countries with similar contexts to Nigeria (Rutta et al. 2011; Rutta et al. 2009; SEAM 2007). The franchisor sets its standards to be met by franchisees in addition to government's regulatory requirements as well as providing business training, supervision and negotiated access to quality drug supplies. These quality assurance systems have brought improvement in the knowledge and practice of drug retailers, allowed sale of wider range of drugs and enhanced profits as well as opened up new accesses to business improvements (microfinance and reliable wholesale markets), while maintaining regulatory inspection, supervision and support. This way, the initiative has been said to realign the business motives of providers and the public health goals of government in one holistic framework. Both approaches are not mutually exclusive and can help achieve health system goals of access expansion to essential drugs in rural areas and their rational use. Accreditation programme can be established by government regulators targeting areas underserved by qualified pharmacists, while nongovernmental organizations and private bodies can be

encouraged to set up franchise network to improve new and existing patent medicine vendor shops. Both approaches offer more sustainable options to improve provider quality performance than the fragmented irregular provider trainings, as is currently the case. The case for accreditation in the Nigerian context is further strengthened by the stock of trained health personnel already in the patent medicine retailing business, which government only need to encourage and attract through enabling policy.

8.4.1.3 Consumer empowerment strategies

The role of the well informed health care consumer in bringing about improvement in the behaviour of health care providers has been highlighted, because if consumers lack the capacity to obtain and understand health information adequately, they may be unable to make appropriate health and health care choices (Nutbeam 2000). However, a lingering challenge to pharmaceutical regulation is changing the way individuals, particularly consumers understand and use pharmaceuticals. The thesis reported that regulators claimed health and healthcare education programmes ran routinely on radio stations and television channels to empower consumers make informed health utilization decisions, but they lamented that consumers have failed to take full advantage of these opportunities. Most interventions to improve private and informal private pharmaceutical providers in Africa have focussed chiefly on provider training as argued above, interspersed with regulation and supervision, financial incentives, franchising, accreditation and supply provision initiatives. Very limited interventions target consumer health literacy improvement, but elsewhere in Western settings, consumer health literacy has assumed a vibrant place in health care discourse (Baker 2006; Coulter and Ellins 2006). Also, the positive relationship between limited capacity of consumers to comprehend and retain health information and health behaviours, health outcomes and health costs has been demonstrated (Ryan et al. 2011). It is therefore important that health information communication in whatever form must be sufficiently clear to avoid miscommunication for maximum impact. Health information may be of a general nature meant to inform the public of health related issues or specifically for an individual health consumer and communicated verbally or in written form both of which depends however on a person's cognitive capability to comprehend. Limited evidence in the literature show

that no one approach is particularly superior to the other, but used complementarily, they have improved health knowledge and recall and health behaviour, especially when personalized (Ryan et al. 2011; Coulter and Ellins 2006).

The level of involvement of the general public and patients in health knowledge communication and the media of their transmission are crucial also to health information effectiveness in influencing healthcare behaviours of consumers (Thiede 2005). In this study, although the degree of involvement of consumers in generating the contents of the health information programmes by regulatory authorities was not ascertained, it emerged that consumers knew little of diseases and their appropriate treatments, patent medicine regulations or even regulatory agencies and their roles. Putting consumers in charge of healthcare via participatory production and readily access to relevant information offers a most cost-effective way to right the inherent failures highlighted in this health care market, because individuals have the highest motivation to achieve their best interests when armed with timely and accurate information. Information availability and healthcare disclosure as approaches to patent medicine retail regulation will be minimally interventionist in the market than most other regulatory mechanisms would do. Accessible information which differentiates types of good and bad providers and products for example, will enable consumers to enforce provider compliance using market signals of informed buyers making best healthcare choices that guarantee the most value for their money (Grossman 1972). This strategy is argued to probably be the cheapest tool of regulation for low income settings (Ensor and Weinzierl 2007). Moreover, for patent medicine vendors who are locally situated as social actors with binding relationships in their communities, this approach will deepen the opportunity of consumers to exploit this relationship and socially regulate provider behaviours (Kamat and Nichter 1998; Cross and MacGregor 2010).

Whilst it may probably be unrealistic or even unnecessary to expect consumers to understand the details of healthcare technicalities, the benefits of well-designed health communication messages can be substantial (Attanayake and Siyambalagoda 2003). For rural dwellers in particular, lack of access to adequate information has been identified as an important barrier to improvement of healthcare services in remote areas (Bloom and Jing 2003). A series of studies have generated credible

evidence which show that healthcare consumers can utilize health education information in intelligent ways when appropriately and clearly communicated and well-motivated (Leonard 2002; Mackintosh and Tibandebage 2002). This argument is important for health policy: it challenges the general assumptions in the arena that healthcare consumers are ignorant and incapable of making informed health choices especially as relates to local communities. Very importantly also, this suggests that consumers in real terms are constrained to a narrow range of options imposed on them by their financial and geographical circumstances, otherwise, healthcare consumers do actually make sophisticated quality choices of products and services when armed with the right information. For rural communities, this will involve health information and education that is conveyed in everyday language spoken by large segment of the population and written out in simple, plain and easy to understand way. In Nigeria in particular, it could be the three dominant languages or the more general pigin English (an adulterated form of English language).

Although assessment of the processes and content of consumer education programmes of the Nigerian regulatory authorities was beyond the scope of this study, limited evidence from the effectiveness of efforts to educate drug shop consumers in Africa show that successful consumer health education interventions have to be underpinned by the principle that the information must emerge from an interactive and participatory process that incorporates the concerns of consumers and its clarity of presentation so as to be understood by the ordinary individual in the society (Thiede 2005). Therefore, while the mass media may have presented an efficient approach to the Nigerian regulators because of wider coverage, its effectiveness could have been hampered if the audience made no meaning of the messages or even did not access them. Moreover, evidence from the west has shown that while mass media campaigns may raise the awareness of consumers, the effect is often short lived (Coulter and Ellins 2006). Other more cost-effective and efficient ways the Nigerian regulators may consider will be the communication of the same health information broadcasts in local languages and use of strategies like engagement of national and local celebrities as health ambassadors to supplement their efforts, particularly in rural areas.

To fully put rural healthcare consumers in the forefront of their health, market regulation will also require an accessible consumer redress mechanism also. Consumers in this study did not know of the existence of the Consumer Protection Council, whose mandate included consumer feedback of their experiences in the market place. Increasing consumer visibility by creating enabling environments for consumers to have a voice within the health system may offer an additional flexible way of regulation in resource constrained settings, one that will help discipline the market to delivering better quality products and services through harnessing demand power, leveraged by the provision of methods that permit redressing consumer complaints. This will require that the Consumer Protection Council for example, focuses more on creating trusted and user friendly channels for healthcare users to seek redress at the most peripheral levels. The successful use of consumer protection courts in India (Bhat 1996) to address this gap is discussed further in section 8.3.2 of the thesis below.

Another way to empower consumers is strengthening the capacity to identify quality products through quality signalling research and development initiatives. In this regards, the current pioneering of mobile phone drug quality verification is plausible and potentially promising. In this intervention, a consumer scratches up an encrypted number on a drug pack, texts same to a computerised database, and receives an instant confirmation of the drug's genuineness. This intervention appears a cost-effective way of empowering millions of consumers to identify fake drugs, and appears more dependable way than the less reliable indicators as brand name, country of origin or NAFDAC registration number as is currently the practice of most consumers: the latter indicators can easily be faked. The intervention though involving a select product lines at the moment will need to be scaled up to incorporate all drugs currently traded in Nigeria, given its potential cost-effectiveness and reach. The initiative may however not be fully exploited by the vast majority of rural communities who may not own mobile phones or who for most part may not have call time or electricity supply to charge their phone batteries to use when making drug purchase.

Health information and education of the public offers a potentially cost-effective way of enhancing consumer visibility in this market. Such reform initiative may

improve provider-consumer relationships and quality of medicines and services sold and bought in the market. It will give consumers ownership of their health by empowering them to moderate their health behaviours while guiding their health care demand at the same time.

8.4.2 Widening of regulatory scope and re-legislation

This thesis documented ardent calls by patent medicine vendors in the researched market for an extension of the list of drugs they could sell, including antibiotics and it was observed that they actually sell a wide range of prescription-only drugs including anaesthetic drugs and surgical consumables. In some of the researched area and from reported patterns of utilization in the literature, patent medicine vendors function as the only source of primary health care and are also used even where formal health facilities co-exist (Goodman et al. 2007a; Gyapong and Garshong 2007; McCombie 1996; Ruebush et al. 1995). Therefore a case for expanding the allowed list of drugs to include at least common antibiotics as contained in the list of essential medicines for primary health care centres is plausible. The thesis documented arguments of regulatory authorities that patent medicine vendors are untrained and therefore unsafe to dispense prescription drugs, the accreditation programme discussed and recommended above may potentially resolve this dilemma as it has in the similar situation of Tanzania.

Also the study reported that NAPPMED has an internal self-regulatory mechanism that should support members to operate within regulatory limits. Partnering with the association with the aim of exploiting the potential of this internal regulatory mechanism may impact positively on the overall patent medicine vendor regulatory efforts in the area and Nigeria at large. This will be cost-effective, imposing minimal costs on regulators, since it will largely build on the association's self-existing and self-sustaining structures. This strategy should also create an enhanced sense of recognition among the ranks of retailers and probably act as a strong incentive for patent medicine vendors to better comply with regulatory requirements with the intention to improve their status in the eyes of the public. They will monitor their performance and watch-out for unlicensed retail operators and report such to formal authorities for sanctions. Such a body will however need to be monitored closely, otherwise similar organisational self-regulation have only metamorphosed into mere

worker's unions (exhibiting monopoly conduct), rarely disciplining erring members and not proactively monitoring their members (Ensor and Weinzierl 2007).

Patent medicine vendors strongly called for the creation of an autonomous regulatory body, distinct from the professionally constituted Pharmacy Council of Nigeria. Several advantages may accrue from a disparate patent medicine regulatory board: regulatory inspections will be more regular and present a better scope for direct engagement with providers at the local level since this body will concern itself with patent medicine vendors only, while the Pharmacist Council focuses on regulating pharmacists. The approach may give a sense of ownership and recognition to vendors, build trust and improve regulatory compliance among these micro pharmaceutical entrepreneurs. The consideration of this strategy for its potential to improve provider practice can be further argued based on the distinctive characteristics of patent medicine vendors and the market they operate in. However, it is recognized that such policy proposal may be vehemently resisted by professional pharmacists who traditionally view drug matters as a right based on their definition of appropriate knowledge. Government will have to constructively communicate with the pharmacists, clearly explaining the gains inherent in such policy (of task shift) for public health and to the pharmacists as well. This will be necessary in order to win their support for the initiative and correct any misunderstanding of the policy as a way to undermine their standing in the society (MSH 2012). It is however difficult to predict how well this body will fare compared to current regulatory authorities and how it will be shielded from capture by patent medicine vendors (Graddy 1991).

The organization for regulating patent medicine vendor markets in Nigeria does not allocate any role for the peripheral local government authorities, who are de-facto frontline authorities in rural areas. Incorporating this level of government in retail drug regulation has the potential to improve regulatory inspections and compliance by patent medicine vendors in rural areas, with expected improvements in quality of services, expanded access while saving considerable costs (Rowe et al. 2005). It has been argued that local health inspectors are more likely to check patent vendor inventories for unregistered and expired drugs and other regulatory infractions more consistently and also do not require elaborate transportation arrangements and other

costly logistics associated with national or regional level inspections (MSH 2012). Moreover, the sheer size of patent medicine vendor shops in Nigeria makes the current centralized regulatory inspection ineffective. The performance of health services in rural areas have been shown to be strongly related to the extent to which local regulatory systems and accountability structures have been established (Bloom and Jing 2003). To be effective however, local enforcement structures will need to be staffed by properly trained, well incentivized individuals who are appropriately supported to deliver on their responsibilities.

The present educational requirement for drug vendors is the ability to read and write (PCN 2003), which fails to clearly define what that means in terms of level of formal educational attainment. Evidence in this thesis has shown that a third of the 30 provider questionnaire respondents possessed one form of health related training or another. Government can build on this emerging trend and encourage the institutional production of more of this level workforce. The cadre may include community health extension workers, community health assistants, community health officers, pharmacy technicians, nurse assistants and health technicians. Raising the bar of educational standard for licensing of patent medicine vendors to this category of health personnel should be cost-effective and vitiate the need for regular training of providers and possibly the quantum of regulatory visits that is otherwise, currently required for generalist patent medicine vendors. This approach fits into the accreditation programme recommended previously and has been shown to improve drug retailer quality indicators in the ADDOs project in Tanzania (Goodman et al. 2007b; Rutta et al. 2009).

Currently, Nigerian laws seem to offer healthcare consumers no clear protection for healthcare related damages and legal processes to resolve medical disputes are tortuous, lengthy and rare. An explicit system of medical liability will potentially encourage utilization of healthcare services generally, improve quality of products and services and strengthen the national health system performance overall (Bhat 1996). For example the present sanctions embodied in the operational guidelines of patent medicine vendors in Nigeria do not appear to impose appropriate sanctions for regulatory offenders. It generally stipulates a nominal fine of five hundred thousand Nigerian Naira (£ 1,785.00) for infringing any aspect of the guidelines or two years

imprisonment or both concurrently (PCN 2003). This fails to recognise variations in magnitude of offences; therefore, a sliding scale-type punitive approach will be more realistically enforceable. While consumer protection interventions and quality assurance measures are welcome developments in health care markets particularly for the vulnerable, they come at a cost, so consequences as increased user fees and irrational drug use on the part of providers have been documented and concerns about risks and uncertainties that naturally occur with medicines also expressed (Bhat 1996; Slabbert and Pepper 2011). Arguments have also been voiced relative to the effectiveness of redressal systems and its user friendliness. The consumer protection intervention in India serves a useful model for tackling these concerns: there are no court charges, claimants can enter plea on their own and verdicts are made expeditiously (Bhat 1996). These desirable features lend it appropriate in the Nigerian context also, especially for poor rural dwellers, who may not own the resources to undertake the expensive formal legal mechanisms of justice.

8.4.3 Regulatory capacity strengthening

Even if government adopts the new range of flexible regulatory mechanisms discussed above, it still will not diminish government role for example in critical areas as licensing, registration and standards setting and hence the need for an effective regulatory system. Therefore, attracting and retaining skilled regulatory staff remains critically important in any patent medicine vendor reform initiative. Funding gaps were identified as a major barrier to regulatory efforts in the market and have been reported to be a challenge for regulatory agencies in most of Africa (WHO, USAID, FHI 360 2010). One consequence of the funding deficit is weakness in staff capacity development and associated gaps in essential skills and intractable staff shortages. Staff salaries and other financial emoluments are equally poor and work morale is generally poor. A well trained highly motivated regulatory staff complement is indispensable in all of the policy recommendations in this thesis thus far. To acquire the critical mass of employees that will ensure regular inspection and supervision for the required levels of excellence, staff salaries and other proven incentives that motivate workers and discourage corruption and conflict of interests will have to be adopted. While existing resource constraints may not support an expansionary staff policy, a situation of sustained poor staff remunerations will

predispose regulation to capture and create a potential for scarce skilled personnel exodus into industries they are supposed to regulate, both of which compromises public regulatory objectives (Ensor and Weinzierl 2007; Graddy 1991; Wafula et al. 2013). The adoption of all or most of the policies argued in the thesis this far should substantially reduce the need for an excessively large inspectorate division of government and allow for compact and better paid staff strength. Government must also match improved pay with transparent measures that will sanction non-performance and corrupt practices.

Widening access, even to basic drug alone in rural areas will require political goodwill and support to adequately fund the health system. The Nigerian public health system receives just about 5% of the national budget annually, which is a far departure from the minimum 15% agreed on by African Heads of Governments in 2001 in order to strengthen country health systems to adequately provide healthcare services that will bring health systems closer to universal health coverage (WHO 2011). The role of government is likely to remain quite important in access to medicines in rural areas in the years ahead. Government must refurbish existing public health facilities or build new ones and adequately staff and stock them to regain the confidence and trust of the public, particularly poor rural households who face multiple demands on their scarce budgets. This is important since markets by their nature do not provide goods and services to all individuals in a society and even in well-functioning markets, the ability and willingness to pay the competitive market price by consumers remains the only allocative mechanism. Government provision seeks welfare improvement and goods and services are often subsidized in a way that may possibly crowd in the market (Hanson et al 2001). Crowding in the market may stimulate demand and force existing retailers to become more competitive which can possibly result in the improvement of all dimensions of access and market performance (Maiga et al. 2003).

A model of the reformed patent medicine vendor market for Nigeria is here presented:

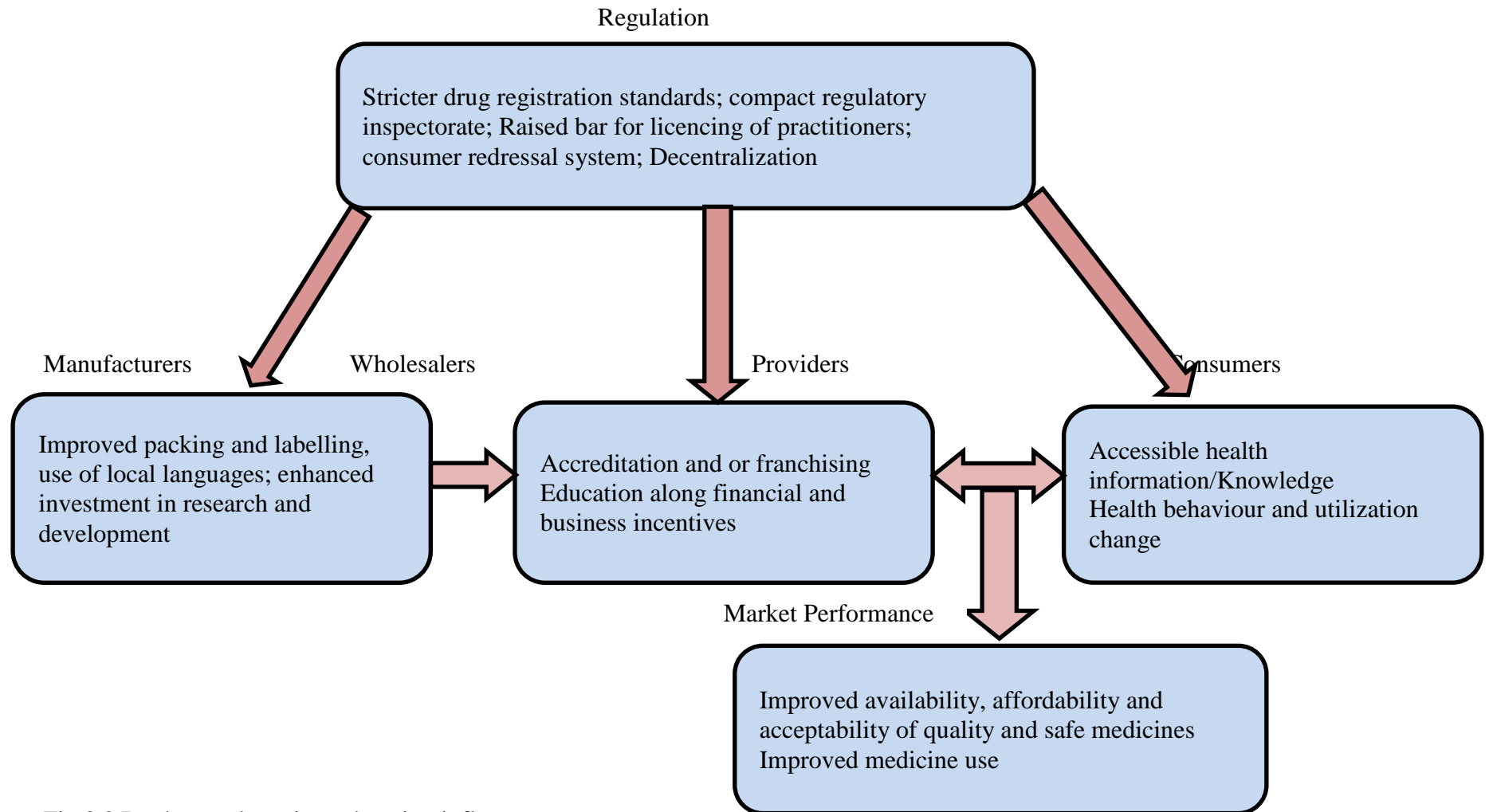


Fig 8.2 Product and service enhancing influences

8.5 Summary and Conclusions

This chapter set out to analyse the performance of the researched patent medicine market by isolating the root causes of failures within the market and making policy recommendations for improving access to quality and safe drugs and their rational use for improving population health outcomes. Adopting the economic lens of Structure-Conduct-Performance paradigm, the thesis attempted to answer the question of whether government should continue to expend scarce health resources to tighten regulatory control or to seek more effective options of correcting the market failure reported. Policy approaches to addressing market and regulatory failures highlighted in the thesis entailed a blend of interventions that target patent medicine vendors, consumers, manufacturers and wholesalers and regulatory systems.

In general, the specific concerns for improving access to effective, safe and affordable essential medicines in patent medicine vendor outlets in rural areas have focussed on improving availability, affordability and acceptability of quality and safe essential medicines. The thesis has therefore argued that rigid regulatory control approaches and stand-alone provider knowledge and skill trainings have not offered sustainable quality improvement behaviours in the market. It recommended an integrated policy approach that encompasses several proven strategies: Strict enforcement of registration standards, drug packing and labelling enforced at the point of registration offers a sustainable way of ensuring that only high quality drugs enter the market. Accreditation and franchise policies are more likely to improve provider knowledge and practice skills while at the same time providing financial and business incentives for improvement of access to effective, safe and affordable medicines more sustainably in this market. The researcher has also canvassed that rural drug consumers have the greatest motivations to make improvements in the performances of medicine vendors in the short and long terms, if they are well informed through an interactive health education communication process which incorporates opinions of the general public.

The realities of the study findings strongly support the recommendation for review of the guidelines for licensing of patent medicine vending in Nigeria. Regulations must align with the needs of targeted population. Therefore, initiatives to expand access to

improve the quality of services and products offered by patent medicine vendors must ensure that drug vendors are legally allowed to sell a select range of prescription drugs, such as common antibiotics. It also has been argued that the technical nature of medicines makes the minimum educational requirement of mere ability to read and write inappropriate: health related training and certification is recommended. Regulatory institutions need to be strengthened through enhanced funding and personnel development to enforce compliance with regulations. This will have to take the form of reducing the need for a large inspectorate division of government to allow for smaller and better paid staff strength, matching improved pay with transparent measures that will sanction non-performance and corrupt practices.

In conclusion, the thesis has produced evidence that supports the potential role of patent medicine vendors in expanding access to quality and safe pharmaceuticals and taken the stance that licensed pharmacies alone cannot remain the only acceptable delivery channels for retailing essential medicines particularly in underserved rural areas. The attractive features of patent retail drug shops and the long established habits of buying medications from these retailers cannot be wished away. Therefore, constructive engagement with these providers to creatively exploit their potential to expand access to safe and effective medicines while correcting the numerous quality concerns offers the best policy approach: one that will improve retail drug shops performance systematically by setting practice standards, guaranteeing drug and service quality, coupled with a robust monitoring and enforcement mechanisms.

CHAPTER 9: SUMMARY CONCLUSIONS

9.1 Policy Context

Modern pharmaceuticals have drastically reduced morbidity and mortality from most common diseases and offered relief from pain and suffering for millions of people around the world (Henry and Lexchin 2002). A large segment of the world's population particularly in sub-Saharan Africa however, do not benefit from these medical advances and lack regular access to effective, safe and affordable medicines when needed or the ability to use medicines in their possessions rationally (Adome et al. 1996; Amin et al. 2003; Salako et al. 2001; Snow et al. 1992; WHO 2006). Those having access to medicines they require often get the wrong prescription of drugs for their conditions, receive incorrect drug doses or are sold inadequate drug quantities that fit their needs. In rural areas in particular, drugs are prescribed and/or dispensed predominantly by untrained and sometimes unlicensed patent medicine retailers (WHO 2000). The consensus however now, is that these informal providers are important sources of healthcare in Africa and in childhood malaria for example, they are the first point of consultation in about 15-85% of cases (Adome et al. 1996; Amin et al. 2003; Foster 1991; Goodman et al. 2007; Hamel et al. 2001; Marsh et al. 1999; McCombie 1996; Snow et al. 1992; van der Geest 1987). Their high patronage and rising importance centred on their responsiveness to consumer demand suggests that retail drug vendors might continue to be a major source of health care for hundreds of millions of people in the future (McCombie 1996; Ruebush et al. 1995). In Nigeria like most other African countries, drug shops are sometimes the only source of health care for their communities. Therefore from a public health policy perspective of population health maximization, improving access to effective and safe essential medicines and their rational use through patent medicine vendors is a crucial public policy concern.

9.2 Essential Medicines and Rational Drug Use

Essential medicines have been defined as “indispensable and necessary for the health needs of the population. They should be available at all times, in the proper dosage forms, to all segments of society” and they are a core component of primary health care (WHO 1977; WHO 1978). The World Health Organization (1985), further

defines rational medicine use as when “patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community.” Patent medicine vendors have been shown to provide improved access to essential medicines for addressing primary health care in their communities, but failed largely to meet rational drug use criteria: high numbers of untrained patent medicine vendors, poor dispensing practices, irregular refresher trainings, infrequent supervisions and consumer self- medication practices are the main underlying factors that drive and support irrational medicine use in this context and justify intervention in the market.

9.3 Contribution to Knowledge

The study is the first of its kind to undertake to understand demand and supply behaviour from the economic lens of industrial organization (Structure-Conduct-Performance) in a health care market in Nigeria. The study has observed the weakness in this model to capture the significant influence of consumers in the deterministic relationships of market performance. Patent medicine shop characteristics and consumer behaviour in this study site has not been previously reported. The thesis therefore adds to existing academic literature further evidence of the important role of patent medicine vendors (drug shops) in the provision of primary health care and expansion of access to essential medicines, particularly in rural and underserved areas. Consumer convenience factors such as drug availability, closeness to home, relative cheapness of medicines, prolonged and flexible opening hours, scope for credit and perceived drug quality contributed to the acceptability and popularity of patent medicine vendors. Medicine vendors did not only sell medicines, they consulted, prescribed medicines and gave health counselling in some cases, all undertaken for profit motives essentially. They also complemented other formal facilities in the drug supply chain and were the only source of needed medicines in some communities.

The patent medicine vendor market studied combined monopolistic and oligopolistic features of competition, with relatively low entry barriers and exit potentials. Retail providers were diverse comprising mostly untrained sellers with a third having formal health training. Drug prices were fairly uniform in all the sub-markets studied and mark-ups appeared high. Non-price competition was high, but failed to yield

high quality market outcome as evidence of inappropriate drug prescription, inadequate dosing, poor labelling and lack of proper health communication with consumers was widespread and pervasive.

Consumers self-medicated and bought inappropriate medications for self-diagnosed illnesses, which exemplify irrational drug use.

Regulatory failures also existed and were gross. Licensure renewal processing took long, continuing medical education for patent medicine vendors was irregular, supervision, inspection and sanctioning of regulatory infringements were far between, as regulatory officials tacitly permitted infractions. Patent medicine vendors therefore, sold outside of their remit, trading even in prescription only drugs. Consumer and public health education programmes appeared ineffective in creating improved health seeking and health consumption behaviours. The implications were enhanced access to medicines generally for the communities while undermining quality of products and services and the scope for engagement with the public sector.

Overall, the interaction of imperfect competition and ineffective regulation combined to generate a mixed market outcome of improved access, but low quality: the “market for lemons” (Akerlof 1970). The significant overlap of these research findings with prior literature makes a modest contribution to the broader debate on the role of retail drug shops in expansion of access to appropriate health care services in low-income countries in general and Nigeria in particular.

9.4 Thesis Strengths and Weaknesses

Predicating the study on the economic framework of structure-conduct-performance paradigm provided explicit concepts and tools of enquiry, yielding valuable insights that underpinned the policy recommendations of the thesis. The approach allowed data collection and analysis along distinctively important lines of demand and supply components and the unpicking of their complex interactions to understand the incentives and preferences that shape provider and consumer behaviours. Particular strengths were that it allowed a clearer visualization of the relationship between market structure and provider conduct and their impact on availability, affordability and the quality dimensions of product and services in the market. For example it was demonstrated how a less than perfectly competitive market structure can fix and

maintain prices in a market and how also varying information levels and asymmetries distort market performance. It was also possible to show the profit incentives of providers is a dominant force in shaping provider behaviour rather than knowledge and to see the consumer doing his/her all to get the best value for money, given financial and information constraints.

Secondly, the thesis adopted a comprehensive access framework encapsulating availability, affordability and acceptability dimensions, each consisting of clearly identifiable and quantifiable variables. This quality permitted easy analysis of access and the isolation of areas of deficit access in the thesis. Through this framework, the fit of the patent medicine vendor market to the social and economic realities of the communities they served has been amply demonstrated, in terms of their geographic closeness to the people they serve, their social embeddedness which fostered relational buying and enhanced acceptability. Affordability was demonstrated in the purchase of whatever drugs and in whatsoever quantities consumers demanded and scope for deferred payments to be made. High drug prices, weak purchasing power, uncertain quality of products and inappropriate prescribing and dispensing practices were isolated as factors undermining effective access in the thesis.

The thesis provides further appeal by its generalist nature of not limiting the analysis to any particular disease state or a specific drug product as many studies of this phenomenon had towed.

For the data collection activity, its key strength lay in the census of patent medicine vendor outlets in the local council. This provided a frame for selecting a representative sample of providers for provider questionnaires and subsequent data collection activities involving drug retailers. Other important methodological strengths were the data triangulation approach, which improved the richness of data generated and validity of its interpretation. The rapport the researcher was able to develop and nurture with officials and members of the National Association of Patent and Proprietary Medicine Dealers of Nigeria greatly facilitated the research.

Despite the plethora of attractive qualities of the study, several counteracting factors that popped up intermittently are referenced: the small sample sizes of interviews and observations made is recognised and the potential for error effect on

conclusions. This was attributable to time and resource constraint. This flaw closely relates to the important issue of sampling bias that might have occurred in the study regarding the convenient approach criteria of selecting interviewees. In the case of consumer surveys and interviews, household survey was a more appropriate approach but not practicable, owing to cost and data availability. Whilst the researcher took every caution to avoid influencing outcomes in any way, the extent to which participants' awareness of being research subjects and the effect of that knowledge remains a source of potential bias. However, this appeared to have had little influence on providers' behaviours as most never labelled dispensed drugs and sold under-doses, during observational studies. Further, observations were timed at the end of the research gathering activities, a point the participants had become accustomed to the presence of the researcher and may not have seen the need to put up a performance. Also, having been around them for a long time and the author held several informal interactions with the retailers, which supports this position. Mystery shoppers approach would appear more appropriate strategy for obtaining this data, it was not deployed in this study due the challenge of finding credible individuals to simulate this role, considering the time and energies required to locate and train the pool of clients to behave in the desired way. The inability to collect data on prices and market shares of individual vendors in the market were important weaknesses of the study: data on sales volume of vendors was not acquired due to lack of record keeping by retailers and therefore, the concentration indices calculated were based on the numbers of patent medicine outlets and the assumption of symmetry of shop sizes in each sub-market. These proximate measurements therefore remained estimates and did not accurately measure market concentration in the study site. Detailed data on the cost structure of providers were also not collected, which limited the evaluation of price mark-ups in the study. Such data would require longer time to accumulate and even higher level of trust with vendors. Analysis of competition and its implication for access did not capture direct data from the drug supply chain above patent medicine vendors, although these actors actually have deterministic influence on product range and prices of products in patent medicine vendor outlets below. They are also a key source of information for medicine vendors.

The operational definition of market for the analysis of concentration was also challenging. Product market definition was not sufficiently explicit and referred to the entire pharmaceutical products as homogenous while the segmentation of the local council area into 5 sub-markets was purely arbitrary based on the divisions by the local patent medicine vendor association in the local council area for its administrative convenience. These flaws in data collection methods did not enable the researcher to make firm conclusion of the nature of competition in the researched market, underscoring the practical difficulties in defining and understanding market boundaries in economic literature.

9.5 Generalization of Findings

Although the study was conducted in one particular local government area, it nonetheless has highlighted a number of features which seemed to be shared with other studies of the patent medicine market phenomenon across Nigeria and several similar settings in sub-Saharan Africa. The findings and recommendations are therefore, likely to have utility beyond the study site to other parts of Nigeria and sub-Saharan Africa subject to specific contextual realities. The desirability of patent medicine shops in terms of proximity, flexibility, expediency and responsiveness to consumer demand is generally reported in the literature. For example, Brieger and colleagues (2002), Oladejo et al. (2008) and Salako et al. (2001) have reported identical findings in south western Nigeria, while Okonkwo and Okwonkwo (2010) and Okeke and Uzochukwu (2000), came to the same conclusions in their studies of retail drug shops in south eastern Nigeria. These authors also reported low quality of services provided and wide spread regulatory infringements as revealed by this study. On the broader African scene, Goodman and colleagues (2007a), Wafula and others (2013) have demonstrated the same outcomes in Tanzanian drug shops, Greer et al. (2004) in Kenya and van der Geest (1987) in Cameroon. In terms of the market structure of patent medicine vending, the finding of low entry requirement collaborate with the findings of van der Geest (1987) in Cameroon, but differ from high entry requirement (drug shop owners must have a health related training to be registered) reported for the Tanzanian retail drug shops (Goodman et al. 2007a). Also, unlike other retail markets, the Tanzanian market does not embrace the apprentice paradigm of qualifying as a drug vendor. These differences

notwithstanding, the researched market is in some ways typical of patent medicine vending across other comparable African countries which have been studied.

This convergence of literature findings with some of the key thesis findings reasonably supports the generalization of the study findings to similar contexts. However, it is noted that the scope of literature reviewed did not extend to other continents, where very different market and cultural conditions may prevail.

9.6 Further Research

The weaknesses highlighted in the thesis necessitate further inquiry along a number of lines: the cost structure and pricing behaviour of patent medicine vendors needs to be better understood. This will be useful for analysing strategies to address high mark-ups on drugs reported and for which no specific credible strategy for affordable pricing is suggested by the thesis. Characterization of the pharmaceutical distribution chain above patent medicine vendors needs in-depth exploration and the nature of the relationship between them explicitly modelled. Although they play an important role in drug availability, prices, knowledge and practices of drug retailers, this higher level drug distribution chain has been overlooked in the research literature and in most interventions to improve retailer practice (Cross and MacGregor 2010; MSH 2012). This is particularly important with the current ease and speed of access to health information via the internet. Understanding the nature of regulatory constraints encountered by regulators and the motives and incentives of regulatory officials is also required to enable development of more effective regulations and implementing strategies. About 30% of patent medicine vendors in this market had formal health training and a recommendation to benchmark entry requirement by these qualifications; research will be needed to compare the relative performance of patent medicine providers who have health related training against their non-certified counterparts to better understand the influence of formal health training in improving quality of products and services in patent medicine markets. These high priority research aspects will provide comprehensive evidence of the patent medicine market in Nigeria and offer empirical basis for optimal policy actions towards improving

availability, affordability and acceptability of quality and safe essential medicines in rural Nigeria.

9.7 Final Conclusion

The study aimed to evaluate patent medicine vendor market and make policy recommendations on strategies to engage this level of health care providers to expand access to quality essential medicines for Nigerians, most especially in rural and underserved communities. Patent medicine vendors are an important and indispensable source of essential medicines in the rural community studied. However, the quality of services rendered is low. While patent medicine vendors remain the most visible element of the pharmaceutical distribution chain and therefore the focus of most interventions in the past, evidence indicates that these have not yielded the desired result of sustained improvement in the quality of products and services in drug retail outlets. The thesis has therefore argued that for the profit maximising patent medicine vendor who may also be influenced by as diverse factors as consumer demand, regulation and the nature of the pharmaceutical distribution chain further up, more emphasis on measures that target these other determinants of vendor behaviour should be explored in the drive towards achieving universal coverage of effective, safe and affordable essential medicaments for Nigerians, particularly in rural areas. This will require integrated approaches that recognise their inter-relatedness. Specifically, the realities of the study findings suggest a departure from rigid insistence on unenforceable quality standards of regulating patent medicine vending practice in Nigeria and embrace new initiatives to improve the quality of services and products offered in this market. These must systematically ensure that patent medicine vendors are legally allowed to sell a select range of prescription drugs and stock only quality pharmaceuticals, provide accreditation and mandatory health training of providers, guarantee strengthening of regulatory institutions and most importantly, for the consumer who wants a chance to get medicines irrespective of risks, empowerment by provision of accurate and timely health information.

Finally, the weight of collated evidence in this thesis highlights the dilemma for health policy making and enforcement in resource poor settings: the trade-off

between quality and access, and forces the fundamental question of whether low quality should be acceptable for and by the poor.

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APPENDICES

Appendix 1

GUIDELINES ON THE ISSUANCE OF PATENT AND PROPRIETARY MEDCINES VENDOR'S LICENCE

**ISSUED BY
PHARMACISTS COUNCIL OF NIGERIA**

WITH THE APPROVAL OF

**THE HONURABLE MINISTER OF HEALTH
FEDERAL MINISTRY OF HEALTH, ABUJA**

2003

GUIDELINES ON THE ISSUANCE OF PATENT AND
PROPRIETARY MEDCINES VENDOR'S LICENCE

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1. INTRODUCTION

The Licensing of non-pharmacists to stock, market and sell simple medicinal remedies is entrenched in the 1958 Poisons and Pharmacy Act, Cap 152, Poisons and Pharmacy Act 535 Abuja Laws and Pharmacists Council of Nigeria Act 91 of 1992. This was an attempt to redress the lopsided distribution of the very few healthcare facilities, public and private health sector alike, available at that time.

Also, an important element of the National Drugs Policy is the adequate provision, accessibility and availability of essential drugs, which are effective, affordable, safe and of good quality in all aspects of the National Health System.

2. SCOPE

These guidelines are designed to address the issuance of Patent and proprietary Medicines Vendor's License (PPMVL) in the Country under the following headings:

- (i) Licensing authority

- (ii) Eligibility

- (iii) Mode of application

- (iv) Fees for application

- (v) Issuance and renewal of license

- (vi) Validity of license

(vii) Orientation and continuing education for holders of patent and proprietary medicines vendors' license

(viii) Monitoring and inspection

3. LICENSING AUTHORITY

The licensing Authority is the Pharmacists Council of Nigeria (PCN) established under Act No. 91 of 1992.

4. ELIGIBILITY

An applicant for the patent and proprietary medicine vendor's license shall produce evidence to the satisfaction of the licensing authority.

(a) In the case of an individual

- i. that he has attained the age of twenty-one (21) years
- ii. that he is of good character and certified as such by two satisfactory referees
- iii. that such individual shall be able to read and write in English Language and

(b) in the case of a person other than an individual, that the nature of the business is such to warrant the sale of medicines.

5. MODE OF APPLICATION

(i) Application shall be made in applicant's own handwriting indicating the exact location, address where the intended business is to be undertaken. Post Office Box (P.O.Box) or Private Mail Bag (P.M.B) shall not be accepted.

(ii) The application shall be address to the Registrar, Pharmacists Council of Nigeria through the Director of Pharmaceutical Service of the State, where the applicant wants to operate.

(iii) Letters of recommendations from two (2) people as referred to in Section 4 (a) (ii) shall accompany the application. Three passport photographs, all of which will be endorsed by one referee, shall be attached to the application.

The applicant shall forward a current income tax clearance certificate.

(iv) Each application shall be accompanied with a non-refundable application fee.

6. PROCEDURE FOR THE ISSUANCE OF LICENCE

The following procedure shall be adopted for the issuance of Patent Proprietary medicines Vendors License (PPMVL):

- (a) Submission of duly completed application form;
- (b) Interview of applicant by PPMVL Committee in the State;
- (c) Payment of a prescribed inspection fee;
- (d) Inspection of premises shall be carried out by Pharmaceutical Inspectors;
- (e) A satisfactory report to the PCN by the State PPMVL Committee;
- (f) Issuance of license by PCN on payment of prescribed registration fee;
- (g) Applicant shall be issued a booklet containing the list of medicines approved for sale by the licensing authority;
- (h) Attendance at PPMV orientation course.

Note

License holders shall display the license in the shop conspicuously and their business name on signpost in front of their premises. The business name shall also carry the wordings “Patent Medicines Shop” conspicuously written. Such names as “Drug Store” or “Medicines Store” are prohibited.

7. FEES FOR LICENCE

The license fees shall be as specified in **Schedule 1** to these guidelines and Pharmacists Council of Nigeria may review such fees from time to time.

8. CONDITIONS FOR RENEWAL OF LICENCE

The following conditions shall guide the renewal of license:

- (a) All applications must be submitted on or before the 31st of January of each year.
- (b) All licenses are to be renewed annually subject to satisfactory inspection report.
- (c) All license premises for the sale of Patent and Proprietary Medicines shall be subject to periodic inspection by Pharmaceutical Inspectors appointed by Pharmacists Council of Nigeria.
- (d) Evidence of attendance at Continuing Education Programme at least once in every two years.
- (e) Payment of prescribed fees.
- (f) Satisfactory performance by the licensee.

9. VALIDITY OF LICENCE

The license shall expire on the 31st of December of the year of the issuance. However, the licensing authority reserves the right to revoke a license during its validity period if there is any breach, false declaration or documentation.

10. ORIENTATION AND CONTINUING EDUCATION

Every new license holder shall be required to attend an orientation course. Thereafter, the license holder shall be required to attend a Continuing Education Programme, at least, once in every two (2) years. Such courses shall be organized at state level by the Pharmacist Council of Nigeria in collaboration with the State PPMVL Committee.

11. MONITORING AND INSPECTION

Licensed premises shall be subject to periodic monitoring and inspection by Pharmaceutical Inspector(s);

12. ROLES AND RESPONSIBILITIES

(i) The Federal Ministry of Health

(a) Shall formulate relevant policies;

(b) Shall give directives of the general character to the Pharmacists Council of Nigeria relating to the implementation of these guidelines and it shall be the duty of the Pharmacists Council of Nigeria to comply and give effect to the directives.

(ii) Pharmacists Council of Nigeria (PCN)

The roles of the Pharmacists Council of Nigeria (PCN) shall include but not limited to the following:

(a) Shall provide and issue the PPMVL;

(b) Shall provide the receipts for the various fees;

(c) Shall provide the application forms;

(d) Shall disburse funds to states according to the sharing formula as contained in **Schedule II** of these guidelines;

(e) Shall accredit pharmaceutical inspectors;

(f) Shall approve State PPMVL Committees;

(g) Shall enforce sanctions and compliance;

(h) Shall provide approved Patent Medicines list

(iii) State Ministries of Health

(A) Shall facilitate the activities of State PPMVL Committees;

(b) The Director of Pharmaceutical Services (DPS) Shall arrange for pre-approval and routine inspection of new and licensed premises respectively;

(c) The DPS shall collect revenue in respect of PPMVL and pay same to PCN.

(iv) Patent and Proprietary Medicines Vendors License (PPMVL) Committee

- (a) Shall monitor activities of vendors and make quarterly and annual returns to Pharmacists Council of Nigeria (PCN);
- (b) Recommend Pharmaceutical Inspectors for accreditation by the Pharmacists Council of Nigeria
- (c) Shall recommend successful applicants to PCN for license;
- (d) Shall organize Orientation Course and Continuing Education Programme for vendors in collaboration with PCN.

13. COMPOSITION OF STATE PPMVL COMMITTEE

The committee shall compose of:

- (a) Director of Pharmaceutical services (DPS) of the State (Chairman);
- (b) Director of Pharmaceutical Services, State Hospitals Management Board (Member);
- (c) Chairman of State Pharmaceutical Society of Nigeria (PSN) or his representative (Member);
- (d) One representative of NAFDAC (Member);
- (e) A member of the Civil Society nominated by PCN;
- (f) Head of Pharmaceutical Inspectorate Unit in the State Directorate of Pharmaceutical Services (Member/Secretary).

SCHEDULE I

1. No patent and proprietary Medicines Vendor License Holder shall operate unless the under-listed fees have been paid accordingly. The fees so listed shall be reviewed from time to time. **All payment must be in bank draft payable to Pharmacists Council of Nigeria.**

- 2. (a) Application fee -N500.00
- (b) Pre-approval inspection fee -N1, 000.00

- (c) Registration License -N2, 000.00
- (d) Renewal Inspection fee -N1, 000.00
- (e) Registration Renewal -N1, 000.00

SCHEDULE II

1. The Pharmacists Council of Nigeria shall collect all revenue and disburse as follows:

- (a) Application fees - 100% to PCN
- (b) Inspection fees -100% to State PPMVL Committee
- (c) Licensing fees -50% to State and 50% to PCN

14. MISCELLANEOUS PROVISIONS

(a) All Patent or Proprietary Medicines shall be sold in the original container properly secured.

(b) No holder of a PPMVL shall re-pack a patent or proprietary medicine.

(c) Any person who does any act likely to prevent or obstruct the carrying into effect of the provision of these guidelines is guilty of an offence.

(d) A person aggrieved in pursuance to the enforcement of the provisions of these guidelines may appeal to the pharmacists Council of Nigeria (PCN).

(e) The licensing authority shall not issue license to an applicant where the circumstances, not limited to the following, are show to exist, that the applicant is:

- a. bankrupt or insolvent.
- b. an ex-convict.
- c. in disobedience of Council's directives.

d. involved in practices outside the scope of the license

(f) The PCN shall exercise powers generally and do such things that are incidental to carrying into effect the provisions contained in these guidelines.

(g) Any business without a license or who contravenes any other provisions of these regulations shall be guilty of an offence, and is liable on conviction to a fine not exceeding N500, 000.00 or to a term of such fine and imprisonment.

(h) The PCN or its representative shall have power to seal erring premises.

i. Where it is satisfied that a license holder is in breach or in default of his responsibility under the prevailing guidelines or law in force, the licensing authority may, if it deems fit, revoke, withdraw any license issued and/or strike off the name and premises from the register, but without prejudice to administrative charges that may be imposed on the defaulter.

(j) Notwithstanding anything to the contrary in any enactment or law the federal High Court, State High Court, and Magistrate Court shall have jurisdiction to try offences under these guidelines.

(k) The following shall have exclusive powers to prosecute offender (s) under these guidelines.

i. Attorney General of the Federation.

ii. Pharmacists Council of Nigeria.

iii. The Nigeria Police.

Appendix 2

RETAIL OUTLET QUESTIONNAIRE

- Participant's code number
 - Date of interview
 - Interviewer
 - Sex Male/Female
 - Age
 - Marital Status Married
 - Single
 - Widowed
 - Divorced/Separated
 - Others (Specify)
 - Educational level
 - Primary
 - Secondary
 - Tertiary
 - No formal education
1. Professional qualification
2. How long have you worked as a drug retailer?
3. Have you undergone any training since your employment? Yes / No
4. If your answer above was yes, specify

5. How many other staffs work in this facility?

6. What services do you provide?

Drug retailing

- i. Consultation and drug retailing
- ii. Sale and administration of injectables
- iii. Laboratory services
- iv. Others (Specify)

7. Compared to other drug shops around, how qualified are you?

- i. More qualified
- ii. Equally qualified
- iii. Less qualified
- iv. I do not know

8. What factors do you consider in setting your prices?

- a. Transaction cost / expenditure
- b. Prices of other retail shops
- c. Perceived ability to pay of customers

9. What indicators do you rely on to inform this decision?

10. Do you have a past experience of anyone who could not pay for needed drugs? Yes / No

11. If you answered yes above, how did you deal with the situation?

- a. Reduced the price
- b. Deferred payment
- c. Offered exemption
- d. Other forms of payment
(specify)
- e. Refused services

12. What is the gross income from this business? (Give range)

13. What financial constraints do you have with your business?

- 1. Inadequate demand
- 2. Inadequate access to
investment funds
- 3. Taxes
- 4. None

14. Do you receive referrals from other retailers? Yes / No

15. If yes why and if no, why not?

16. Do you refer customers to other drug shops? Yes / No

17. Briefly provide details for your response above.

18. Have you received complaints about your services? Yes / No

19. From what you know about quality of health care, do you think you are providing standard quality of care of would want?
Yes / No

20. Do you have any means of evaluating the quality of the services you provide? Yes / No

21. There exist unethical behaviours by most drug retailers, such as overprescribing in order to enhance profits. Are such practices common?
Yes / No

22. Why do you think consumers come to your shop?
a. Cheaper / Closer / Better quality / Better staff attitude / Drug availability and range / Cleanliness / Others (Specify)

23. Are satisfied with the quality of drugs you sell? Yes / No

24. Do you have a permit to run this business? Yes / No

25. How often do regulatory authorities inspect your facility? At least once each year / infrequently / never had an inspection

26. Are you aware of inspection visits to other drug shops? Yes / No

27. Are you aware of imposition of penalty on any provider for regulatory infringement? Yes / No

28. Are you satisfied with current level of regulatory framework?Yes / No

Appendix 3

EXIT CONSUMER QUESTIONNAIRE

- Questionnaire Number

- Date of interview

- Name of interviewer

- Sex Male / Female

- Age

- Marital status Married / single / Divorced / Widow / Widower /
Others (Specify)

- Level of Education Primary / Secondary / Tertiary/ Others (Specify)

- Occupation

- Main sources of Income Agriculture / Formal employment/ self-employment/ others (Specify)
1. Did you seek services here for yourself or for someone else myself / someone else
 2. If for someone else, what is his / her age?
 3. If for someone else, what are his / her sex Male / Female
 4. How long have you suffered from this health problem?
 5. What do you think is the health problem that has brought you here?
.....
 6. Why did you choose to seek care in this facility? Closeness / Good quality / Cheapness / Drug quality and availability / provider qualifications / Politeness of provider / Relationship with provider/ Others (Specify)
 7. How do you now perceive the services provided today? Satisfied / not satisfied / not sure
 8. Have you sought treatment elsewhere in this episode of ill health? Yes / No

9. If your answer is no, where did go before now? Public facility / Private facility / other drug shops / Spiritual healer / Tradition al healers/ Others (specify)
10. Why did you go to the last place? Closeness / Quality of care / Polite services provider / know someone there / know the facility better / Others (Specify)
11. Who paid for the services provided today.....Self / Third party
12. Where you able to pay all you were asked to pay? Yes / No
13. If no, what happened? Allowed deferment / bought incomplete dose / allowed partial payment / Allowed payment in kind
14. If services provided are paid by third party, indicate who? Private health care insurance / National health insurance / Community insurance / House-hold relatives / Friends / Others (Specify)
15. Do you know what drugs you were given? Yes / No
16. Where you told what the drugs were, how to take them and their side effects? Yes / No
17. Were you told what you were suffering from? Yes / No

Appendix 4

PROVIDER INTERVIEW GUIDE

Activities at outlet:

Perception of role

Motivational factors

Choice of location and Opening times

Job satisfaction and expectations

Professional self-regulation

Finance/income activities:

Types of activities performed

Annual income and variations

Sales strategies

Seasonality of sales

Profitability

Coping strategies for financial constraints

Others

Drug stocking:

Sources, amount, types, and storage of drugs

Costs and cost containment

Factors affecting drug stocks / stock-outs

Others

User charges:

Pricing strategies;

Factors taken in to consideration in price setting, for example, expenditures, prices of other facilities or ability of consumers to pay

Charge per dose for specific illness episode e.g. malaria, diarrhoea

Charge per unit of specific drugs e.g. paracetamol, aspirin

Probe systems allowing for waivers, deferrals, discounts or inability to pay

Appendix 5

CONSUMER INTERVIEW GUIDE

Utilization of retail drug outlets:

Accessibility

Availability and perceived quality of drugs

Experience (satisfaction) with drug shops

Key barriers and suggested solutions

Behaviour and quality of drug shop services:

Availability when needed

Perceived quality

Perceived qualifications of retailers

Strategies to enhance income/ patronage

Others

Prices of drugs:

Experience with user charges

Forms of payments

Effect on health seeking

Strategies to make drugs more affordable

Others

Income:

Types of economic activities

Levels of incomes and variations

Approaches to improve incomes

Appendix 6

REGULATORS INTERVIEW GUIDE

Role of regulatory authorities:

- Powers and functions

- Views about patent medicine vendors

Regulatory challenges

Performances of retail shops:

- Availability and accessibility

- Quality of drugs and services

- Problems and actions taken in the past

Nature of interactions:

- With retailers

- With consumers

- Interagency

Appendix 7

SALES OBSERVATION GUIDE

Premises cleanliness: Clean/Not clean

PCN permit: Yes/No

Did consumer consult? Yes/No

Did consumer present a prescription? Yes/No

Did consumer demand drugs? Yes/No

Did vendor examine client? Yes/No

Drugs sold: Full dose/under-dose

Was name of drug and dosage written out?

Was consumer told adverse events to expect?

How was payment made? Cash/ others (specify)

Comments:



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20 October 2011

Dear Iornumbe,

**Ethical Approval – An economic analysis of retail pharmaceutical market in Nigeria:
Towards access expansion and policy**

Thank you for your response to the letter I sent you following consideration of your application by the Research Ethics Panel.

Dr Jane McKenzie, Convener of the Panel, has reviewed your response to the points you were required to address, and has confirmed that she is happy to take Convener's Action to grant full ethical approval for your research.

A standard condition of this ethical approval is that you are required to notify the Panel, in advance, of any significant proposed deviation from the original protocol. Reports to the Committee are also required once the research is underway if there are any unexpected results or events that raise questions about the safety of the research. Please find the appropriate form for this enclosed.

We would like to thank you for your co-operation and wish you well with your project.

Yours sincerely

A handwritten signature in blue ink, appearing to be 'L. Clapson'.

Lucy Clapson
Secretary to the Research Ethics Panel

Cc Prof Barbara McPake, Supervisor

GOVERNMENT OF BENUE STATE OF NIGERIA

Telephone: 044-533528, 531604
Telegram: COMMHEALTH



MED/261/VOL.1/56

Ref. No. _____

Ministry of Health & Human
Services

P.M.B. 102093
Makurdi, Benue State

Date: 9/11/2011

In replying please quote the number
and date of this letter

Iornumbe Uſar

University of Jos

Jos

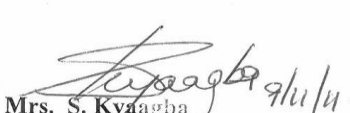
**NOTIFICATION OF APPROVAL TO CONDUCT A RESEACH ON ECONOMIC
ANALYSIS OF RETAIL PHARMACEUTICAL MARKET. TOWARDS ACCESS
EXPANSION AND POLICY IN KASTINA-ALA LOCAL GOVERNMENT OF BENUE
STATE NIGERIA.**

Reference to your letter dated 24th October, 2011 requesting for approval to conduct research on economic analysis of retail pharmaceutical market to wards access expansion and policy in Kastina-Ala LGA Benue State.

I have been directed by the Ethical Committee on Health and Health services has granted provisional approval for you to carry out research on the subject afore mentioned as requested.

You are however advised to note the following ethical issues:

1. The political/Social background of the community you are entering.
2. To make available a copy of the report together with your recommendations, to the ethical committee as soon as the survey is completed.
3. You would be expected to properly explain the purpose of the study to your subject in order to avoid high expectation from them.


Mrs. S. Kyaagba
Director Health Planning

Appendix 9



Queen Margaret University
EDINBURGH

Information Sheet

My name is Iornumbe Usar and I am a research student from the Institute for International Health at Queen Margaret University in Edinburgh. As part of my degree course, I am undertaking a research project for my PhD Thesis. The title of my project is: An economic analysis of the retail pharmaceutical market in Nigeria: Towards access expansion and policy.

This study will investigate the behaviour of both sellers and buyers in a rural retail pharmaceutical market.

The findings of the project will be valuable because it will lead to a better understanding of key influences that determine market performance, and by extension, improved access to pharmaceuticals in rural settings.

I am looking for volunteers to participate in the project. There are no criteria (e.g. gender, age, or health) for being included or excluded – everyone is welcome to take part.

If you agree to participate in the study, you will be asked to fill out a questionnaire/ respond to oral questions, which will be tape-recorded. The researcher is not aware of any risks associated with participating in this study. The whole procedure should take no longer than 30 minutes. You will be free to withdraw from the study at any stage and you would not have to give a reason.

All data will be anonymised as much as possible, but you may be identifiable from tape recordings of your voice. Your name will be replaced with a participant number, and it will not be possible for you to be identified in any reporting of the data gathered.

The results may be published in a journal or presented at a conference.

If you would like to contact an independent person, who knows about this project but is not involved in it, you are welcome to contact Dr Bregje de Kok. Her contact details are given below.

If you have read and understood this information sheet, any questions you had have been answered, and you would like to be a participant in the study, please now see the consent form.

Contact details of the researcher

Name of researcher: Iornumbe Usar

Address: Research Student, Health Policy, IIHD

Queen Margaret University, Edinburgh

Queen Margaret University Drive

Musselburgh

East Lothian EH21 6UU

Email / Telephone: iusar@qmu.ac.uk / 0131 474 0000

Contact details of the independent adviser

Name of adviser: Dr Bregje de Kok

Address: Lecturer, Sexual and reproductive Health, IIHD

Queen Margaret University, Edinburgh

Queen Margaret University Drive

Musselburgh

East Lothian EH21 6UU

Email / Telephone: lecturer@qmu.ac.uk / 0131 474 0000

Appendix 10

Representative patent medicine outlets in Katsina-Ala LGC

