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A Qualitative Assessment of the Private Sector Antimalarial Distribution Chain in Uganda, 2009

September 2012



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Definitions

Antimalarial: Any medicine recognized by the WHO for the treatment of malaria. Medicines used solely for the prevention of malaria were excluded from analysis in this report.

Artemisinin and its derivatives: Artemisinin is a plant extract used in the treatment of malaria. The most common derivatives of artemisinin used to treat malaria are artemether, artesunate, and dihydroartemisinin.

Artemisinin monotherapy (AMT): An antimalarial medicine that has a single active compound, where this active compound is artemisinin or one of its derivatives.

Artemisinin-based Combination Therapy (ACT): An antimalarial that combines artemisinin or one of its derivatives with an antimalarial or antimalarials of a different class. Refer to combination therapy (below).

Combination therapy: The use of two or more classes of antimalarial drugs/molecules in the treatment of malaria that have independent modes of action.

Distribution chain: The chain of businesses operating from the factory gate/port of entry down to the retail level. Also sometimes referred to as downstream value chain. In this report, the terms distribution chain and supply chain are used interchangeably. More specifically, the 'private commercial sector distribution chain' refers to any type of public or private wholesaler who served private commercial outlets, as well as private commercial wholesalers who served public sector or NGO outlets so that any transactions between public, NGO and private commercial sectors are noted.

First-line treatment: The government recommended treatment for uncomplicated malaria. Uganda's first-line treatment for *Plasmodium falciparum* malaria is artemether-lumefantrine, 20mg/120mg.

Mark-up: The difference between the price at which a product is purchased, and that at which it is sold. Sometimes also referred to as margin. In this report, the terms mark-up and margin are used interchangeably. May be expressed in absolute or percent terms. Because it is common for wholesalers to vary their prices with the volumes they sell, minimum, mid and maximum mark-ups were calculated in this report using price data collected from interviewees. Key findings on price mark-ups at the wholesale level are reported using mid mark-up data. As maximum and minimum selling prices were not collected at the retail level, only one set of absolute and percent retail mark-ups is calculated.

Absolute mark-up: The absolute mark-up is calculated as the difference between the selling price and the purchase price per full-course adult equivalent treatment dose. In this report, absolute mark-ups are reported in US dollars.

Percent mark-up: The percentage mark-up is calculated as the difference between the selling price and the purchase price, divided by the purchase price.

Monotherapy: An antimalarial medicine that has a single mode of action. This may be a medicine with a single active compound or a synergistic combination of two compounds with related mechanisms of action.

Non-artemisinin therapy (nAT): An antimalarial treatment that does not contain artemisinin or any of its derivatives.

Non-WHO-prequalified ACTs: ACTs that do not meet acceptable standards of quality, safety and efficacy as assessed by the WHO Prequalification of Medicines Programme, or have yet to be assessed as such. (See WHO prequalified ACTs below)

Oral artemisinin monotherapy: Artemisinin or one of its derivatives in a dosage form with an oral route of administration. These include tablets, suspensions, and syrups and exclude suppositories and injections.

Outlet: Any point of sale or provision of a commodity to an individual. Outlets are not restricted to stationary points of sale and may include mobile units or individuals.

Purchase price: The price paid by businesses (i.e. wholesalers or outlets) for their most recent purchase of an antimalarial product from their suppliers. This is different from selling price (see below). Prices are shown in US dollars.

Rapid-Diagnostic Test (RDT) for malaria: Sometimes called "dipsticks" or malaria rapid diagnostic devices, assist in the diagnosis of malaria by providing evidence of the presence of malaria parasites in human blood. RDTs do not require laboratory equipment, and can be performed and interpreted by non-clinical staff.

Second-line treatment: The government recommended second-line treatment for uncomplicated malaria. Uganda's second-line treatment for *Plasmodium falciparum* malaria is quinine.

Selling price: The price paid by customers to purchase antimalarials. For outlets, these customers are patients or caretakers; for wholesalers, these customers are other businesses or health facilities.

Treatment/dosing regimen: The posology or timing and number of doses of an antimalarial used to treat malaria. This schedule often varies by patient weight.

WHO-prequalified ACTs: ACTs that meet acceptable standards of quality, safety and efficacy as assessed by the WHO Prequalification of Medicines Programme. This is a service provided by WHO to guide bulk medicine purchasing of international procurement agencies and countries for distribution in resource limited settings, often using funds for development aid (e.g. Global Fund grants). More details on the list of prequalified medicines and the prequalification process may be found on the WHO website at: <http://www.who.int/mediacentre/factsheets/fs278/en/index.html>.

Wholesalers: Businesses that supply other businesses, which may include retailers or other wholesalers. In this report, wholesalers are classified further into more specific categories defined by the type of businesses that they supply. As some wholesalers will supply different types of businesses (e.g. both retail outlets and other wholesalers), these categories are not mutually exclusive and such wholesalers may appear in multiple categories. These are defined below.

Terminal wholesalers: Wholesalers that supply retail outlets *directly*.

Intermediate wholesalers: Wholesalers that supply other wholesalers *directly*.

Primary or top wholesalers: Wholesalers that import and/or receive supplies *directly* from manufacturers.

Abbreviations

ACT	artemisinin-based combination therapy
AETD	adult equivalent treatment dose
AL	artemether lumefantrine
AMFm	Affordable Medicine Facility - malaria
AMT	artemisinin monotherapy
AR	artemether
AS	artesunate
ASAQ	artesunate-amodiaquine
ASMQ	artesunate and mefloquine
CMD	Community Medicine Distributor
CQ	chloroquine
DHA	dihydroartemisinin
DHA+PP	dihydroartemisinin and piperazine
HBM	Home-based management of fever for children
INT	intermediate level (wholesaler of supply chain)
IPT	intermittent preventive treatment of malaria
IRS	indoor residual spraying
ITN	insecticide treated net
JMS	Joint Medical Stores
LSHTM	London School of Hygiene & Tropical Medicine
MOH	Ministry of Health
MQ	mefloquine
nAT	non-artemisinin therapy
NDA	National Drug Authority, Uganda
NGO	non-governmental organisation
NMCP	National Malaria Control Programme
OS	ACTwatch Outlet Survey
OTC	Over-the-counter
PACE	Program for Accessible Health, Communication and Education (Uganda)
<i>Pf</i>	<i>Plasmodium falciparum</i>
PMI	US President's Malaria Initiative
POM	prescription only medicine
PSI	Population Services International
RDT	rapid diagnostic test
SP	sulphadoxine pyrimethamine
UGX	Uganda Shilling
WHO	World Health Organization
WS	Wholesaler

Executive Summary

In Uganda, as in many low-income countries, private commercial providers play an important role in the treatment of malaria. To design effective interventions for improved access to accurate diagnosis and effective malaria treatment, there is a need to understand retailers' behaviour and identify the factors that influence their stocking and pricing decisions. Private commercial retailers are the last link in a chain of manufacturers, importers and wholesalers, and their supply sources are likely to have an important influence on the price and quality of malaria treatment that consumers can access. However, there is limited rigorous evidence on the structure and operation of the distribution chain for antimalarial drugs that serves the retail sector.

The ACTwatch Supply Chain Study, one of the ACTwatch project components, aims to address this gap by conducting quantitative and qualitative studies on distribution chains for antimalarials in the ACTwatch countries (Nigeria, Cambodia, Benin, the Democratic Republic of Congo (DRC), Madagascar, Uganda and Zambia). This report presents the results from qualitative interviews with antimalarial drug wholesalers, retailers and other key stakeholders conducted in Uganda between February and April 2009. A summary of the key findings is given below. To provide a complete description of the supply chain for antimalarial drugs, this report should be read in conjunction with the report on the results of the quantitative supply chain survey also conducted as part of this study [1], available at www.actwatch.info.

- The private commercial sector distribution chain for antimalarials consists of a limited number of manufacturers, importers and large wholesalers based mainly in Kampala operating at the higher levels of the chain, and many smaller wholesalers located in commercial hubs across the country, who then sell antimalarials to a range of retail outlets that primarily include pharmacies, private clinics and drug shops.
- While retailers typically collected their orders from suppliers, wholesalers had orders delivered to them. Suppliers used a variety of methods to deliver orders to customers, most commonly through the use of company-owned vehicles. Manufacturers and importers typically employed sales representatives to take and deliver orders, and established distribution networks covering most of the country; while smaller wholesalers sometimes used various other means to transport orders to customers located further afield, including using shared vehicles, or sending packed orders through public transport networks.
- Vertically integrated business models, where a large importer or manufacturer owns and operates a number of subsidiary wholesalers located in different parts of the country, were a notable feature of the private wholesale pharmaceutical sector and were used as a means of capturing more market segments of the national pharmaceutical market.
- Although the wholesale pharmaceutical sector in Uganda is widely perceived as competitive, businesses cooperated in a number of ways. The most common was through membership in a formal trade association, which generally served to assist businesses with regulatory compliance, but also functioned as a platform for collective representation and political lobbying for businesses operating at higher levels of the distribution chain. Informal networks of private pharmaceutical businesses owned and operated by members of Uganda's prominent South Asian community were another notable feature of the distribution chain in Uganda, which also facilitated cooperation among businesses.
- Coartem and artemisinin-based combination therapies (ACTs) in general were widely accepted as effective treatment for malaria among private sector wholesalers and retailers, but many believed that older antimalarials, such as chloroquine and SP, remained effective. While respondents did not

necessarily consider these older antimalarials to be superior to ACTs, many believed that their comparative affordability was a key driver behind their continued demand by consumers. As such, many respondents were critical of the treatment policy change in favour of ACTs and also of the ban on the import and domestic manufacture of chloroquine and SP, which were perceived to have been implemented without making adequate provisions for an affordable alternative antimalarial that could be sold in the private sector.

- Respondents indicated that antimalarial prices were largely determined by supplier selling prices, but also by competition and product availability. Increasing scarcity of chloroquine and SP as a result of the regulatory efforts described above was a common example used by respondents to illustrate its upward pressure on product prices.
- Private sector wholesalers and retailers received most of their information about antimalarials and malaria treatment from their suppliers and other private sector sources, and much less so from government sources. To illustrate, many respondents described feeling unprepared for the changes that followed the ban on chloroquine and SP, and the adoption of ACTs due to the lack of adequate participation of private sector actors or patients and poor communication of the policy changes by public sector partners.
- Respondents viewed the current pharmaceutical regulatory regime positively, as many felt that regulations were easy to comply with and helped to maintain high standards within the sector. Class C drug shops were often viewed by other business types as the weak link in the private sector distribution chain. Many respondents believed that these shops often evaded inspection by regulatory authorities and violated regulations by selling prescription-only medicines. Moreover, respondents argued that the regulations did not require those staffing Class C shops to have the appropriate skills/qualifications to prescribe and administer treatment.
- Rapid diagnostic tests (RDTs) were not widely available among private sector wholesalers and retailers because they were not commonly used. This was mainly due to their relatively high price, poor awareness of RDTs and the updated treatment guidelines recommending confirmation of diagnosis among businesses and consumers alike, and a historical reliance on presumptive treatment of fevers as malaria.

1. Introduction & Objectives

In Uganda, as in many low-income countries, private commercial providers play an important role in the treatment of malaria. To design effective interventions for improved access to accurate diagnosis and effective malaria treatment, there is a need to understand retailers' behaviour and identify the factors that influence their stocking and pricing decisions. Private commercial retailers are the last link in a chain of manufacturers, importers and wholesalers, and their supply sources are likely to have an important influence on the price and quality of malaria treatment that consumers can access. However, there is limited rigorous evidence on the structure and operation of the distribution chain for antimalarial drugs that serves the retail sector.

This study aims to address this gap and constitutes an integral part of the ACTwatch project, a multi-country programme of research being conducted in Uganda, Cambodia, Zambia, Nigeria, Benin, Madagascar and the Democratic Republic of Congo (DRC). The overall goal of ACTwatch is to generate and disseminate evidence to policy makers on artemisinin-based combination therapy (ACT) availability and price in order to inform the development of policies designed to increase rates of access to effective malaria treatment. Along with the Supply Chain Study, the ACTwatch project also includes Outlet and Household Surveys led by Population Services International (PSI) and the Program for Accessible Health, Communication and Education (PACE) in Uganda.

The objective of the Supply Chain component of ACTwatch is to document and analyse the supply chain for antimalarials and rapid diagnostic tests (RDTs) for malaria using quantitative (structured survey) and qualitative (in-depth interviews) methods for studying providers operating at each level of the chain. This report presents the results from qualitative interviews with antimalarial drug wholesalers and other related key stakeholders conducted in Uganda between February and April 2009. In order to provide a complete description of the supply chain for antimalarial drugs, this report should be read in conjunction with the report on the results of the structured supply chain survey also conducted as part of this study [1], available at www.actwatch.info.

2. Country Background

Economic Profile

Uganda is a landlocked country in East Africa that shares borders with the DRC, Kenya, Rwanda, Sudan and Tanzania. It was one of the first Sub-Saharan African countries to embark on liberalisation and pro-market policies in the late 1980s following several decades of political and social upheaval, and since then Uganda has enjoyed many years of economic growth and stability. [2] Annual growth in gross domestic product (GDP) has remained consistently high, averaging 7% in the 1990s, but slowing somewhat to 5.8% in 2010 [3]; the per capita GDP in 2009 (current USD) was estimated at \$483. [4] The Ugandan economy is heavily dependent on agriculture, which employs over 80% of the workforce; more than 85% of the country's 33.4 million people live in rural areas. [3] Strong economic growth has enabled Uganda to make substantial progress in human development. Most notably, it is on track to meet the 2015 Millennium Development Goal of halving poverty, having reduced the proportion of people living in poverty from 57% in 1992/93 to 31% by 2005/06. [2]

Health System

In 2007, about 6.3% of GDP was spent on health, of which just over a quarter (26.2%) was public expenditure accounting for 9.8% of total government expenditure in the same year. [4] Of the remaining private expenditure, a significant proportion is financed as out-of-pocket payments; however, the mission and non-governmental organisation (NGO) sectors both constitute important sources of health spending in Uganda. [5] Following decentralisation of the health sector in the 1980s, physical infrastructure is relatively well-established and operates across a variety of levels. The MOH provides overall stewardship of the health sector through formulation of national policies, setting of quality targets, mobilisation of resources, and monitoring and evaluating of overall sector performance. Services are delivered by different operational levels: community (village health team, health centre I), parish (health centre II), subcounty (health centre III), county (health centre IV), district (general hospital), regional (referral hospital) and national (referral hospital) levels. Although 71% of the health infrastructure is owned by the public sector, the mission sector and private (for profit) sector also play a role, owning 20% and 9% of health facilities in Uganda in 2006, respectively. [5] User fees are not charged for services received in public facilities, and medicines can also be obtained free of charge; however, poor availability of medicines, increased incidence of unofficial charges, and limited geographical access to free public services have reduced the impact of user fee removal in Uganda. [6, 7] Despite this public sector dominance with respect to ownership, these factors have led many to turn to the mission and private sector for health services. Because these sectors do not provide services and drugs free of charge, this has implications for equity of access, particularly as there is no national health insurance scheme and private insurance coverage is low. [7]

Pharmaceutical Sector

The pharmaceutical sector in Uganda is regulated by the National Drug Authority (NDA), which is responsible for the registration of all products prior to importation and sale; regulating the marketing of pharmaceuticals; licensing of pharmaceutical manufacturers, importers, exporters, wholesalers and retailers; and for quality management and post-marketing surveillance. [5] Pharmacy practice is supervised and regulated by the Pharmaceutical Society of Uganda. The medicines distribution system in the public sector is centralised, with procurement pooled at the national level and organised through the National Medical Stores (NMS), an agency of the Ministry of Health (MOH). The mission sector is also important in Uganda for medicines delivery and treatment, and procurement runs parallel to the public sector, with national level procurement through the Joint Medical Stores (JMS).

Regarding the private sector, consumers access pharmaceuticals through several types of outlets, including registered pharmacies, private health facilities and drug shops. While drug shops are permitted to retail a range of over-the-counter (OTC) medicines only, known as Class C drugs, prescription-only medicines (POMs), the class of drugs to which antimalarials technically belong, are occasionally sold over-the-counter in both drug shops and retail pharmacies without a prescription. [8, 9] Despite not being authorised to dispense pharmaceuticals, general retail shops, such as grocery stores, dukas (i.e. small shops selling consumer goods), and market stalls, have also been noted as important sources for essential medicines [8]; however, recent studies give a mixed picture regarding the importance of these types of retail outlets for antimalarials, with availability ranging from 0.4% of general retailers [10] and 0.6% of market vendors [11] to and 45% of retail stores. [11] In order to improve retail level access, ACTs were reclassified as OTC medicines in 2008. [12]

Malaria Epidemiology and Control Strategies

In Uganda, malaria was reported to be responsible for 30-50% of outpatient visits, 15-20% of admissions, and 9-14% of inpatient deaths. [13] Uganda ranks sixth worldwide in number of malaria cases and third in number of malaria deaths, and the overall malaria-specific mortality is estimated to be between 70,000 and 100,000 child deaths annually in Uganda, a death toll that far exceeds that for HIV/AIDS. [13] In 95% of the country, the malaria epidemiology is stable with perennial transmission at high levels and relatively little seasonal variability. Children-under-five and pregnant women are the most vulnerable groups for infection. The remaining 5% of the country consists of seasonal epidemic-prone areas in the highlands and along the eastern and north-eastern regions bordering Kenya and Sudan respectively. *Plasmodium falciparum* (Pf) is the predominant parasite species.

The National Malaria Control Strategy 2005/06-2009/10 focuses on the needs of the most vulnerable groups and includes interventions such as insecticide treated net (ITN) distribution through campaigns and antenatal clinics; indoor residual spraying (IRS) with a focus on low risk and epidemic-prone areas; universal access to ACTs and improved diagnosis; and intermittent preventive treatment (IPT) for pregnant women with sulphadoxine-pyrimethamine (SP). Targets of 85% coverage for each intervention were set for 2010. [14] For ACTs, the aim is to increase access through public and non-government organization (NGO) health facilities, the community distribution system for medicines (home-based management of fever) and the private sector. By 2009, 33% of children under five years of age and 44% of pregnant women were sleeping under ITNs, 33% of pregnant women were receiving at least 2 IPT doses, 6% of households had received IRS and 14% of febrile children were promptly treated with an ACT. [13]

National Treatment Policy

In 2004, the National Malaria Control Program (NMCP) adopted artemether-lumefantrine (AL) 20mg/120mg as the first-line treatment for uncomplicated malaria within the formal health sector, and artesunate plus amodiaquine (ASAQ) 50mg/153mg as an alternative first-line. In April 2007, the NMCP changed its treatment policy for Home-Based Management of Fever for Children (HBM) from SP + chloroquine (CQ) in the form of a locally manufactured product with the brand name 'HOMAPAK' to AL (see below for scale-up plans). Quinine is recommended for treatment of severe malaria and is available at health centre IV and hospitals. According to national policy, consultation and treatment of uncomplicated malaria in all age groups is to be provided in all public health facilities and via community outreach programmes free of charge. Oral artemisinin monotherapies (AMT) have been banned in Uganda since 2007.

The policy on diagnosis at the time of the survey was for all adults and children over the age of five to have confirmed diagnosis through microscopy provided for free in public health facilities. Although Rapid Diagnostic Tests (RDTs) were being introduced through pilots in facilities without microscopy, a national policy document on the use of RDTs was not yet finalised at the time of data collection. Microscopy availability was limited to health centre level III (subcounty level) and higher levels. Although the policy was confirmed diagnosis, the necessary capacity was not available in many health centre level III facilities (the ACTwatch Outlet Survey in 2009 found that microscopy testing facilities were available in only 43% of public health facilities [10]), and hence, diagnosis of malaria remained largely clinical.

Antimalarial Treatment Distribution and Delivery

In 2006, Uganda began rollout of AL as first-line treatment, selecting the branded drug, Coartem, for distribution in public health facilities. This was followed in 2007 with the introduction of AL at the community level through the HBM programme via volunteer Community Medicine Distributors (CMD), two of which are selected and trained per village and who receive drugs through the existing public sector distribution chain. First introduced in 10 districts in 2002 using the HOMAPAK combination noted above, the HBM programme was scaled up to cover all districts in Uganda by 2005 [15], although coverage by 2009 remained patchy. [13] By 2010 the HBM programme had effectively been abandoned due to chronic shortages of AL, and the national policy on community level care has since changed to integrated community case management, which provides care for children under five for malaria, diarrhoea, pneumonia, and care for neonates through voluntary village health teams. [12]

A project piloting a subsidy to increase ACT access through the private sector, particularly through drug shops, was launched in September 2008 in the mainly rural districts of Budaka, Pallisa, Kaliro and Kamuli. The project, run by the Consortium for ACT Private Sector Subsidy, used Coartem labelled with a green leaf distributed to retail outlets through existing private sector channels and aimed for AL to be sold at a consumer price ranging from UGX 200 to UGX 800 (USD\$ 0.10 to US\$ 0.38) depending on the dosage. In the first year, approximately 700,000 doses of AL were made available through this project, and early observations showed that availability of subsidised ACTs among drug shops rapidly increased, their affordability rose in the private sector, and drug shops seemed to charge reasonable mark-ups. Six months following introduction of the ACT subsidy, the number of children receiving treatment had increased and the augmented ACT uptake had eroded the market share of ineffective antimalarials, such as chloroquine. [16] Advocacy in the form of active participation of local government and opinion leaders, and community mobilisation including radio, print and point-of-sale materials were seen as essential to ensure uptake of the subsidised ACTs.

According to results from the ACTwatch Outlet Survey completed in September-October 2008, ACTs were most commonly available among public health facilities (over 80%) and registered pharmacies (over 55%), but much less so among private health facilities (less than 20%) and drug stores (less than 5%). Non-artemisinin therapies (nATs), on the other hand, were carried by more than 85% of all outlet types in Uganda. [10] In terms of treatment seeking behaviour, the ACTwatch Household Survey conducted shortly thereafter in early 2009 showed that only half of all children with fever were treated with an antimalarial, and among those treated, only 36% received an ACT; while the remaining children were most likely to receive an nAT. The same study also showed that private health facilities were the most common sources of these treatments (42%), followed by public health facilities (24%), while 21% of children received an antimalarial that was already in the home; pharmacies were the source for less than 10% of antimalarials to treat children. [17] These results reflect the overall importance of the private sector in access to antimalarials in Uganda.

3. Methods

3.1. Scope of the supply chain survey

The Supply Chain Study was conducted amongst wholesalers who operated in the private commercial distribution chain that served the antimalarial drug retailers described in the ACTwatch Outlet Survey report. [10] The term 'private commercial sector distribution chain' refers to any type of supplier (e.g. public or

private) who served private commercial outlets as well as private suppliers who served public and NGO outlets, and the focus of the study is on suppliers who operate from the point where commodities leave the factory gate or port of entry down to those directly supplying retailers. Overall, the study consisted of two components: (i) a cross-sectional structured survey that collected data on the structure of the private commercial sector supply chain for antimalarial drugs, wholesaler characteristics and business practices, wholesale outlet licensing and inspection, wholesaler knowledge, qualifications and training; and wholesale availability, purchase prices and mark-ups for antimalarials and rapid diagnostic tests, (ii) qualitative interviews with a subset of wholesalers and retailers included in the structured survey, and other key stakeholders relevant to the operation of the private commercial sector distribution chain for antimalarials and RDTs. The report presents the results from the second component. The methods and results from (i) the structured survey of wholesalers are described in a separate report [1] that can be found on the ACTwatch website at www.actwatch.info.

3.2. Sampling & data collection procedures

3.2.1. Key Informant Interviews (KIIs)

These interviews were conducted with important public and private sector stakeholders situated at the top of the supply chain, such as government officials involved in the delivery and funding of health care, and in the regulation of drugs and business; the most significant antimalarial importers and wholesalers; and representatives of organisations such as associations of wholesale pharmacists or pharmaceutical manufacturers. Key informants in the country were identified through a comprehensive review of relevant documents and through consultation with actors familiar with the country's supply chain.

Using a semi-structured interview guide, the participant was asked questions about the overall antimalarial and RDT supply chains for the country, and their own role in these; broad estimates of the number of suppliers at each level; and their perceptions of key factors affecting supply and the effectiveness of regulation. Interviews were conducted by a member of the research team and notes were taken by a trained research assistant.

3.2.2. In-Depth Interviews (IDIs)

In-depth interviews (IDIs) were conducted within a sub-set of antimalarial providers sampled as part of the structured supply chain survey and the ACTwatch Outlet Survey. The IDI method was chosen to facilitate collection of data on complex issues, subjective perceptions and opinions of staff, and the exploration of sensitive commercial and regulatory issues, which are not readily addressed using quantitative methods. To ensure inclusion of a diverse mix of businesses, respondents were purposively sampled from a range of commercial hubs across the country, across various settings (e.g. urban, rural, accessible, remote) and across various levels of the supply chain, from retail level to the top of the supply chain. Wholesalers were then classified into three different categories for analysis: (i) primary wholesalers at the top of the supply chain (i.e. importers or those who are supplied directly by manufacturers); (ii) intermediate wholesalers (i.e. wholesalers that supply other wholesalers); and (iii) terminal wholesalers (i.e. wholesalers that supply retailers). Retailers and terminal wholesalers were further classified according to location: (i) remote, (ii) moderately accessible, and (iii) accessible. Retailers were also selected to ensure some variation in outlet type (e.g. registered pharmacy, drug shop, private clinic).

Interviews were conducted with the person in the business most informed about antimalarial trade by a member of the research team and notes were taken by a trained research assistant. Using a semi-structured interview guide, the participant was asked questions about key aspects of market structure (e.g. horizontal/vertical integration); key aspects of provider conduct (e.g. transport of drugs, credit, source and cost of capital, marketing techniques, vertical restraints, how prices are set, competition and collusion, how stocking and supplier choices are made, perceptions of the appropriateness of regulations and the enforcement capacity of authorities); cost structure; and the role of antimalarials in their portfolio (i.e. how do they compare to other product groups in terms of mark-up and share of sales values).

3.2.3. Data collection procedures

Both types of interviews used an information sheet and a consent form. All data collection tools were provided in English, piloted by trained data collectors, and further revisions were made to adapt the tools to the specificities of the Ugandan context. Before each interview, the researcher provided the information sheet, stated their name, the institutions involved, aims of the study, nature of questions to be asked and length of the interview. Each respondent was given the opportunity to ask questions at any time before, during and after the interview, and received the contact details of the local research coordinator. Interviewers then invited respondents to participate in the study and obtained written consent, or where this was not possible, oral consent was obtained and witnessed by a member of the research team. Interviewers emphasized that individual information was confidential and that no information would be passed on to regulatory authorities or competitors. Information from KIIs and IDIs was supplemented by review of relevant documents on antimalarial regulation and policy.

3.3. Data analysis

3.3.1. Interviews conducted

In total, 12 key informant and 33 in-depth interviews were conducted in Uganda (Table 3.1).

Table 3.1: Number of in-depth interviews across distribution chain levels

Business type/Distribution chain level	Number of interviews
Retailer*	15
Terminal wholesaler	6
Intermediate wholesaler	6
Top wholesaler	6
Total	33

* Five retailer interviews were conducted each in accessible (2 pharmacies, 2 drug shops, 1 clinic), moderately accessible (4 drug shops, 1 clinic), and remote (4 drug shops, 1 clinic) areas.

3.3.2. Analytical approach

One or two team members read all interview notes to identify the main themes or experiences identified by respondents. An initial coding structure was developed based on the research questions and existing literature, which was then applied to interview notes and revised as analysis proceeded. All interviews for a given country were coded by a single member of the research team, but to ensure consistency of codes applied by different team members across different countries, co-coding exercises were conducted at the

beginning of the coding process where two researchers independently coded a minimum of 5 interview transcripts which were then compared. Any discrepancies were discussed and agreed between coders. Coding and analysis was conducted using NVIVO software.

4. Results

4.1. Market Structure

During the interviews, wholesaler and retailer respondents were asked a range of questions about the general structure of the distribution chain for antimalarials. Specific topics included the range of products, sellers and buyers at different levels of the chain; barriers to entering the pharmaceutical market; competition; and integration within the chain, such as vertical integration (i.e. where a single enterprise operates related businesses at different levels of the distribution chain, as in the case of a domestic manufacturer supplying wholesalers operated by the same owner) and horizontal integration (i.e. where a single enterprise operates more than one similar business at the same level of the distribution chain, as in the case of a retail chain).

4.1.1. Range of products

- At the time of data collection there were 11 domestic pharmaceutical manufacturers in Uganda; however, only six of these were producing antimalarials, including a wide range of non-artemisinin therapies (nATs), a few artemisinin monotherapy (AMT) injectables, and some ACT products, none of which were WHO-prequalified. As such, many antimalarials were still being imported. To demonstrate, local manufacturers were producing 24 (13%) of the 182 antimalarial medicines registered with the NDA in 2007. [11]
- One domestic manufacturer indicated that they were producing several non-artemisinin therapies, including quinine, chloroquine and SP, but that most of the chloroquine and SP was destined for export to Kenya (ID 33).
- Most wholesalers stocked a variety of antimalarials, including ACTs, AMTs, and nATs such as quinine and SP; while most retailers, particularly drug shops, described stocking only nATs, often referring to these products by their brand rather than generic name (e.g. Fansidar instead of SP). The range of antimalarials stocked by most retailers included SP, chloroquine, amodiaquine and quinine, while retail pharmacies and private clinics interviewed also stocked ACTs, including AL.
- Most of the wholesalers stocking ACTs also stocked the recommended first line drug, artemether-lumefantrine (AL); most of these products were generic versions of the originator AL product, Coartem, which was stocked by very few wholesalers.

4.1.2. Range of sellers and buyers

- Most domestic manufacturers, importers and large wholesalers were located in or near Kampala.
- Purchasing new antimalarial stock directly from manufacturers was reported at all levels of the wholesale chain, but was less common as one moved down the chain from top-level to terminal wholesalers. A similar pattern was reported regarding purchasing from importers, where more intermediate wholesalers described purchasing stock directly from importers than terminal wholesalers. Very few retailers, on the other hand, reported purchasing directly from importers or manufacturers as they often could not purchase in sufficient volumes.

- Wholesalers operating at the top of the chain, including JMS, also described public sector customers (e.g. NMS) as important clients, accounting for a considerable proportion of their sales.
- It was common for importers to have exclusive distribution rights over individual foreign-produced medicines. Reflecting this practice, one wholesaler who purchased directly from importers described knowing exactly which businesses imported the products he needed, but that this also constrained his choice of suppliers (ID 25).
- Most respondents stated that they had several antimalarial suppliers. Suppliers were based primarily in Kampala, but also in a number of large commercial towns throughout the country. In contrast to wholesalers, retailers based outside of Kampala tended to purchase from local suppliers, rather than from those located in Kampala.
- Several wholesalers and retailers reported operating within an integrated business model. For example, one Kampala-based retail pharmacy was being supplied by another retail pharmacy also located in Kampala which had the same owner (ID 16). There were also several examples where large Kampala-based importers owned and supplied subsidiary wholesalers and retailers located in other, typically more remote, areas of the country (ID 8, ID 27, ID 33). In some cases, operations were highly centralised where the head office would conduct a range of activities, such as marketing, on behalf of subsidiaries (ID 27). One respondent working at a subsidiary said that a benefit of operating within this type of vertical arrangement was that they used a rolling accounting system which allowed them to smooth out any peaks or dips in revenue over a longer period of time (ID 8).



Figure 4.1: Pharmaceutical wholesaler/retailer outside of Kampala

4.1.3. Competition

- Although most respondents acknowledged the existence of competitors, their perceptions of competitors and competition varied and were somewhat affected by location and business size. For example, in the pharmaceutical wholesaling districts of Kampala and other large commercial towns where the density of wholesalers was relatively high, competition was perceived to be more intense, with several respondents considering every other wholesaler as a competitor. Others, however, felt that their business did not face any 'real' competition as they were the largest business in the area and accounted for much of the market share (ID 21, ID 3). An importer believed domestic manufacturers to be competitors who had unfair advantages because consumers and the government preferred buying domestic products to support the local economy (ID 6, ID 30, ID 33).
- Several businesses at retail and wholesale level also viewed public health facilities as competitors because patients were able to obtain Coartem from these facilities free of charge. However, they also noted that many customers came to them demanding Coartem as it was widely publicised in the media and often unavailable from government facilities due to stock outs; although, some respondents described still referring consumers seeking Coartem to public facilities because the private sector price was often unaffordable (ID 3 & 4). In a few instances, retail pharmacies did not feel threatened by the free treatment being distributed by government facilities as they believed public sector Coartem to be inferior to the commercially packaged or socially marketed versions (ID 16 & 27). No respondents viewed NGO or faith based organisation (FBO) wholesalers or retailers as competitors.

4.1.4. Barriers to market entry

- Respondents at different levels of the distribution chain listed several barriers to entering the private commercial pharmaceutical sector.
- A few respondents explained that starting a retail or wholesale business required large amounts of initial capital, with some specifically mentioning the expense of obtaining an operating license from the NDA; although one retailer disagreed and described having access to advice on starting a business and funds through a microfinance programme when setting up her clinic (ID 3).
- Several respondents also felt that the pharmaceutical regulations were very complex and difficult for new businesses to comply with. One of the regulatory requirements mentioned by respondents as a barrier to entry was that new drug shops and pharmacies were required to show that there were no existing competitors in close proximity to the proposed location. Several respondents said that this discouraged some prospective entrants as they could not set up their business in a desirable location.
- Regulations also stipulated that drug shops may be staffed by a ‘professional auxiliary staff member’, which included pharmacy technicians, registered/enrolled nurses or midwives, comprehensive nurses, clinical officers, public health dental assistants or anaesthetic assistants; while wholesale and retail pharmacies must be supervised by one registered pharmacist. Pharmacists in Uganda may only be employed by a maximum of two separate businesses, but may deputise their responsibilities to a ‘professional auxiliary staff member’ in their absence, two of which must be employed full-time by the business. Nevertheless, several respondents felt that, combined with a perceived shortage in the number of registered pharmacists in the country, these restrictions made it difficult to find an available pharmacist to supervise their business.

4.2. Provider Conduct

Respondents at both wholesale and retail levels were asked questions related to a diverse range of business practices. Topics included choice of supplier, product selection, price-setting, restocking practices, cooperation among businesses, sources of capital, and others. Under price-setting, respondents were specifically asked to discuss mark-ups and factors that may cause price variation, such as second degree price discrimination (i.e. discounts based on volume) and third degree price discrimination (i.e. price varies by attributes such as location or by customer segment).

4.2.1. Factors influencing choice of supplier

- The most common factors influencing choice of supplier mentioned by wholesalers and retailers were the prices offered, product availability, variety, and the perceived quality of the products. For most respondents, these selection criteria were often mentioned in combination, but price was the most commonly mentioned. Choice of supplier was constrained when choosing among importers due to exclusive distribution rights for specific antimalarials (ID 25).
- Other factors that were mentioned by several respondents included convenience (e.g. proximity of the supplier to the business) and availability of credit facilities. Delivery services and general customer service were also mentioned, but by fewer respondents. For retailers outside of the capital, proximity also seemed to be an important factor as more of these respondents were supplied by local wholesalers rather than by those based in Kampala.
- Most respondents stated that they had several suppliers, but also said they would be willing to change their supplier, based mainly on the prices offered or availability of products. For example, one retailer indicated that he would change his supplier if they did not have everything he wanted in stock (ID 17). A

few stated that they had only one or two suppliers and would only change suppliers if necessary (e.g. to make emergency purchases in case of stock outs). Some retailers stated that they would sometimes send customers to competitors when they were out of stock of a product demanded by a customer.

- Respondents also described different ways of attracting customers. Several retailers attempted to differentiate themselves from competitors by offering added-values services, such as diagnostic facilities. On the other hand, others tried to compete more vigorously by selling the same products and product categories as competitors operating at the same level of the distribution chain, or by locating their business in either the same or a strategically better location.

4.2.2. Factors influencing choice of products

- The choice of products to stock was driven mainly by demand, followed by the perceived effectiveness, quality and price of the product.
- When attempting to explain customer demand, one intermediate wholesaler described his customers as very 'product loyal', but that they were also influenced by package design, colour, brand name and perceptions of effectiveness (ID 1).
- Many terminal wholesalers stated that they tried to stock a wide variety of products because being able to completely fulfil customer orders was important for customer retention.
- At retail level, respondents described how regulations prevented drug shops from selling certain medicine classes, particularly ACTs and Coartem; however, many of these respondents also believed that patients prefer to receive these drugs free of charge from government health facilities and would sometimes refer customers looking for Coartem to those facilities.
- While many other retail pharmacies and private clinics and wholesalers stocked ACTs, most did not stock Coartem because its relatively high price rendered it unaffordable for most patients, and when combined with the fact that Coartem is offered for free in government health facilities, there was consequently much less demand for it in the private commercial sector. A few respondents also noted that their suppliers did not stock Coartem or other ACTs. Nevertheless, a number of respondents recognised the advantages of Coartem and ACTs in general compared to older types of antimalarials, including their effectiveness, ease of administration and lack of side effects, and in some instances would stock alternatives to Coartem, such as the branded generic AL product, Lonart, or other ACTs. One importer felt that it was important to offer a highly effective alternative ACT to Coartem, which was the guiding principle behind their choice of antimalarial to import (ID 7).

4.2.3. Availability

- In general, respondents operating at all levels of the chain commented on the growing scarcity of chloroquine and SP on the private market and, to a lesser extent, on the poor availability of ACTs.
- Despite still being highly in demand, both retailers and wholesalers described how it was becoming increasingly difficult to find suppliers of certain nATs, particularly chloroquine, which likely reflected regulatory efforts to reduce domestic production and importation of these products and shift demand toward ACT. Many respondents expressed concern over this trend because of the comparatively high price for ACTs and the lack of an affordable alternative to the older, cheaper drugs, which curtailed demand and reduced access to effective malarial treatment for many consumers. A few terminal wholesalers also commented on how the scarcity of nATs, combined with persistent high demand, caused their prices to escalate, further compounding affordability issues.

- For ACTs, respondents provided more mixed comments regarding availability. For example, both terminal and top-level wholesalers were divided on whether they felt ACTs were readily available from their suppliers; while most retailers felt that their suppliers were often out of stock. One retailer described making several attempts to purchase Coartem only to find suppliers always out of stock, and how this experience led him to stock alternatives, including nATs (ID 22). An importer registered as the sole distributor for one foreign manufacturer indicated that, although this manufacturer did produce a generic version of the government-recommended first line treatment, AL, they did not import and stock this product because it had not been registered for sale in Uganda with the NDA (ID 6).
- Other factors associated in a more general sense with the availability of antimalarials were restocking practices (e.g. shipping delays for imported drugs; see section 4.2.6) and whether it was possible to create demand. The latter refers to detailing, a practice where supplier sales representatives target health facilities and prescribers in order to influence prescribing habits. See section 4.4.1 for discussion on how sales representatives act as sources of information for wholesaler and retailers.

4.2.4. Price setting

Determinants of price

- The most common price determinant mentioned by respondents at all levels of the distribution chain was supplier purchase price.
- A number of respondents also indicated that competition had an important effect on antimalarial prices. For example, one retailer described regularly monitoring price trends by visiting competitors and asking customers about competitors' prices (ID 5).
- As noted in section 4.2.3, many respondents also described how the scarcity of some highly demanded products, such as chloroquine, led to spikes in price.
- A few respondents indicated that operating costs had important consequences for antimalarial prices, particularly those associated with the transport of goods. Some businesses bore the cost of transporting new stock purchased from their supplier, and these expenses were considered when setting their own selling prices. However, there were several instances described where delivery was included by suppliers as an added value service, but it was unclear if these transport costs were already incorporated into the purchase prices set by suppliers. Among top-level wholesalers (e.g. importers), the costs of drug registration, lot quality inspections and clearance charges were also frequently mentioned as factors affecting their selling prices, as were the costs of raw materials for manufacturers (ID 31) and those purchasing directly from manufacturers (ID 25).
- The use of recommended retail prices (RRPs) was not a common practice in Uganda. Similarly, vertical restraints where suppliers provided product selling and retail prices were occasionally mentioned by respondents (e.g. ID 11), but these restraints did not seem to be strictly enforced (see section 4.2.5).
- There was no regulation of medicine prices or mark-ups in Uganda. [5]

Mark-ups

- Retailers described their mark-ups either as percentages relative to the wholesale purchase price or as absolute values in the local currency. Percentage mark-ups ranged between 10% and 50%, and absolute mark-ups between Uganda Shillings (UGX) 100 and 1000 (US\$ 0.05-0.49¹). Retailers indicated that the mark-up varied according to the drug; however, responses on which types of antimalarials attracted the

¹ The average exchange rate during the data collection period (13 February to 6 April 2009) was 2049.16 Uganda Shillings (UGX) to US\$1 (www.oanda.com).

highest and lowest mark-ups differed. For example, while one respondent stated that artemether monotherapy had the lowest absolute mark-up, others said it had the highest. Similar contradictory statements were made about quinine (although it was not always clear if they were speaking about oral or injectable dosage forms, which differ greatly in typical price); although chloroquine was frequently cited as having the lowest mark-up.

- Intermediate and terminal wholesalers reported mark-ups mainly as percentages ranging between 3% and 15%. Respondents explained that mark-up levels depended largely on availability and demand for the product; but similar to retail level, responses varied on which products attracted higher or lower mark-ups, with some saying that 'fast moving' antimalarials had high mark-ups and others saying that the mark-up on such products was low. One respondent reported that the mark-up for chloroquine was the highest because its supply was low (ID 28).
- Top-level wholesalers reported that mark-ups varied according to whether it was a branded or generic product. Mark-ups for generic products ranged between 10% and 25%, while newer products that did not have many competitors could have mark-ups as high as 50% (ID 6).

Price variation

- Most respondents indicated that they typically varied prices for a given product for a number of reasons; however, all but one importer (ID 30) were not willing to reduce prices below cost.
- Discounts for purchasing in higher volumes and values were frequently mentioned at all levels of the chain. One importer said that he would sometimes reduce prices below cost for bulk orders (ID 30).
- A small number of respondents at each level of the distribution chain also described price variation based on characteristics of the customer (i.e. third degree price discrimination). For example, retailers in particular said they would charge lower prices to established customers or to those perceived as poor. In addition, one intermediate and one top-level wholesaler stated that they varied prices depending on which sector they served (i.e. private vs. public) (ID 10, ID 31). However, another respondent explained that, although they usually varied prices, they did not do so for customers who did not intend to resell the products (e.g. schools, NGO/FBOs) as these customers typically paid the 'set' prices (ID 10).
- A few also mentioned that prices could vary due to the negotiating abilities of individual customers, and only one respondent mentioned having to reduce prices in order to quickly sell off stock with an approaching expiry date (ID 25).
- Price variations were also attributed to frequent changes in supplier prices, which according to some wholesalers was largely due to fluctuations in the Shilling-to-US Dollar exchange rate.

4.2.5. Vertical restraints

- Very few respondents described having any restrictions imposed on them by their suppliers or imposing any restrictions on their customers.
- In some instances, respondents did report being given a prescribed selling price by their supplier, particularly if the supplier was the sole distributor for a product (ID 11). However, these restrictions were not always enforced by suppliers and were viewed by some only as pricing guidelines because businesses were ultimately free to set their own prices (ID 12).

4.2.6. Restocking Practices

- Order frequency for wholesalers and retailers varied between several times per week and once every fortnight to only when businesses ran out of stock; although, placing orders once per week was most

common. In a few instances, orders were placed directly with supplier sales representatives; although, this was mostly done over the phone.

- In most cases, orders placed by wholesalers were delivered to them by their suppliers with a frequency ranging between several times per week and only when requested. An importer described that consignments delivered by air were received as frequently as twice per month, while deliveries by ship were received about once every 45 days (ID 30). Apart from emergency purchases, only a few wholesalers reported picking up orders themselves from suppliers.
- On the other hand, most retailers had to collect orders as suppliers did not deliver to them. This was particularly the case for smaller retailers, such as drug shops and private clinics, and for those located outside of the capital. In Kampala, one retail pharmacy operating as part of a horizontally integrated business had new stock delivered by their sister company (ID 16), and one drug shop also reported sometimes having orders delivered; however, he preferred to purchase and collect new stock in person in order to negotiate better prices (ID 13). There was also one notable exception where a drug shop located in a remote location reported having stock delivered by suppliers (ID 23), though, this business was located in a district participating in a pilot study examining the effect of distributing subsidised Coartem through the private sector. See section 4.4.2 for more information on this pilot study.
- When suppliers delivered orders, respondents described a range of practices. Most top-level wholesalers reported delivering orders to customers based across Uganda using their own vehicles and sales representatives, or through a courier service (ID 7, ID 31); while several intermediate and terminal wholesalers considered providing delivery services to be cost prohibitive and were only willing to deliver for orders of sufficient size (ID 21) or to customers only so far outside of Kampala, beyond which, customers would have to collect orders themselves (ID 10, ID 32). However, one of these respondents did make an exception and delivered to some NGO customers located in more remote areas (ID 10). This respondent also described that, in order to transport orders to customers located 'up country', they sometimes shipped packed orders from Kampala to regional cities or towns on public buses, which the customer then collected from the bus station. In such cases, the customer covered the cost of transport. Others also used public transport to deliver order (ID 8). In addition, several respondents described making deliveries using vehicles shared among branches under the same umbrella company or competitors (ID 10, ID 11), and one wholesaler even sent orders with individuals whom they knew were travelling to a particular destination (ID 12). Van sales, where supplier sales representatives sell stock directly from a company-owned vehicle, were mentioned only by a few respondents (ID 8).

4.2.7. Cooperation among businesses

- Most business did not belong to any type of trade association, but the trade associations that were mentioned tended to serve businesses operating at the top of the distribution chain (i.e. importers and manufacturers), such as the Uganda Manufacturers Association, the Uganda Pharmaceuticals Manufacturers Association, Pharmaceutical Owner's Association (ID 11), and the Pharmaceutical Importers Association. There were also a few mentions of trade associations for drug shops operating within a specified area (e.g. district), such as ABACUS (ID 23) and the Drug Shop Owner's Association (ID 19); however, associations for retailers were not established in all of the areas visited.
- According to respondents, the benefits derived from association membership included receiving training and information on new policies, rules and regulations; assistance in achieving and maintaining regulatory compliance, and preparing for inspections (ID 23); and improving the relationship between businesses and the NDA. Associations were also viewed as essential for representing the private pharmaceutical sector's interests and for political lobbying in order to influence policy.

- Businesses also cooperated in more informal ways. When stocked out of a particular product, some businesses would make ad hoc purchases from a neighbouring competitor or would send the customer to a competitor to supply the product they did not have in stock. Businesses also sometimes consulted one another on patient treatment as not all businesses employed staff with health-related qualifications or training (ID 22). While most respondents emphasised that businesses did not discuss and collude on prices, a few respondents did describe how prices for specific products were sometimes agreed among some businesses, although in many instances these agreements were not implemented.
- Also, informal networks of businesses existed because many pharmaceutical wholesalers and retailers were owned and operated by members of the South Asian community in Uganda. One respondent indicated that a formal trade association did previously exist for these businesses, and when entering the market it was important to engage with this association (ID 7). As a reflection of these informal networks, several respondents referred to other members as ‘branches’ with whom they have ‘mutual understanding’ about cooperation and sharing resources (ID 10, ID 32), and as ‘friends outside of business’ despite being competitors (ID 12).

4.2.8. Sources of capital

- Nearly all respondents indicated that they usually had access to sufficient resources to purchase new stock when needed. Some, however, did describe issues experienced in the past, including instances where planned orders were revised or reduced due to unexpected increases in product prices or due to limited cash flow (ID 15).
- Most respondents described using a combination of cash and supplier credit to purchase new stock; however, many described using only cash and a few used credit only. For some, cash was the preferred method of payment.
- Of those either solely or partly using supplier credit, the most common credit terms provided were for one month, but ranged from one week to 2-3 months, and up to 6 months.
- In a few instances, the mechanism for providing credit was through the use of post-dated cheques issued by the customer to the supplier. For example, one Kampala-based terminal wholesaler paid their supplier using cheques post-dated either 2 weeks or 1 month from the date of purchase (ID 24).

4.3. Sales Revenue and Expenses

Respondents were asked questions about sales revenue, and the costs of starting and operating a pharmaceutical business, including taxes and tariffs, to examine potential cost drivers. Considering the sensitivity of these topics, some respondents preferred to speak in general terms rather than give specific figures. For start-up costs, respondents were asked to estimate how much they would need to spend today if they were to set up another similar business.²

4.3.1. Revenues from antimalarial sales and fluctuations

- When asked about the proportion of total revenue generated by antimalarial sales, responses varied both within and across distribution chain levels.
- Among top-level wholesalers, revenues from antimalarials accounted for between 1% and 21% of total revenues; 15% to 30% among intermediate-level wholesalers, and 10% to 15% among terminal

² The average exchange rate during the data collection period (13 February to 6 April 2009) was 2049.16 Uganda Shillings (UGX) to US\$1 (www.oanda.com).

wholesalers. The greatest variation was observed among retailers for whom antimalarial sales comprised between 25% and 80% of total revenues. This reflects the heterogeneity of business types selling antimalarials at this level, with antimalarials accounting for between 20% and 80% of total revenues among drug shops, 30% and 67% among private clinics, and 3% and 40% among pharmacies.

- Most respondents experienced fluctuations both in antimalarial sales volumes and revenues from these sales. At retail level, peaks in sales were most commonly associated with the rainy seasons, which typically occur in April-May and September-October with some slight variation across the different regions. At wholesale level, responses were more varied with some experiencing reductions in antimalarial sales at times when households must pay school fees, and peaks when demand for antimalarials is high at lower levels of the distribution chain (e.g. as retailers anticipate the rainy season, or when household income increases during harvest time).

4.3.2. Cost structure

- Respondents were asked about their typical expenditure on a number of recurrent expenses, including rent, electricity, inventory, water, telephone, regular and casual employment salaries, stationary, marketing, fees to the NDA or associations (e.g. PSU), insurance, freight and security. While many respondents were willing to share this information, some of the data collected from individual wholesalers was incomplete, and others were more reluctant to share this information.
- Across all levels of the distribution chain, expenditure tended to be highest for inventory, followed by salaries of regular employees and rent. While there was considerable variation in the typical amounts paid for each of these expenses among businesses operating at the same level of the distribution chain, as expected those operating at higher levels tended to spend more than those operating at lower levels. For example, expenditure per month on salaries was typically between UGX 1.2 to 42 million (US\$ 586-20,496) for top- and intermediate-level wholesalers, between UGX 0.8 to 2.2 million (US\$ 390-1074) for terminal wholesalers, and between UGX 25,000 and 1.5 million (US\$ 12-732) for retailers. Compared to wholesalers, salary expenses tended to be the greatest recurring costs for more retailers. Several respondents also considered distribution costs to be excessive. (Also see section 4.2.6 on restocking practices)
- While most respondents stated that they paid their own staff, there were a few businesses that had sales staff from suppliers embedded within their own workforce (ID 11, ID 16, ID 6). Sometimes referred to as 'sales representatives', these embedded employees were paid by the supplier, rather than by the wholesaler.
- Respondents also described having to pay a range of different taxes, including corporate, local and value added taxes; however most were reluctant to reveal how much tax they typically paid. In a number of instances, respondents confided that they were not paying any type of tax at all. Local taxes were most often paid in the form of trading licences obtained from local governments, and a few respondents also considered some salary deductions for employees, such as those for the National Social Security Fund and employee income tax deducted at source (e.g. PAYE), as other forms of taxes.

4.3.3. Start-up costs

- Respondents were asked to estimate the initial costs required to set up a similar business in four broad categories, including furniture and fittings, initial stock, equipment and vehicles. In some cases, respondents were unable to estimate these costs for certain categories.
- For wholesalers, the largest start-up costs by a considerable margin were for the initial purchase of stock, which ranged between UGX 0.5 and 500 million (US\$ 244-244,000). This was also the case for

most retailers, who estimated the amount of capital required to make the initial purchase of stock to range between UGX 0.3 and 10 million (US\$ 146-4880); however, for several retailers, the initial costs to purchase equipment or furniture/fittings constituted the largest start-up costs. Among retailers, initial costs for furniture and fittings ranged between UGX 0.4 and 400 million (US\$ 195-195,200), and between UGX 60,000 and 10 million (US\$ 29-4880) for equipment.

- Few respondents reported initial start-up costs for the purchase of vehicles, and those that did tended to be top-level and terminal wholesalers (only one retailer reported this start-up cost) and estimates ranged between UGX 0.1 and 22 million (US\$ 49-10,736).

4.4. Non-Regulatory Interventions

Non-regulatory intervention is a general term used to describe activities designed to influence provider conduct and business practices within the pharmaceutical distribution chain that do not involve regulatory action. These activities may be driven by actors in the public, private, parastatal or civil society sectors, and may include training of providers, information dissemination, marketing, demand generation, etc.

4.4.1. Provision of information

- Most respondents explained that their primary source of information on antimalarials and drugs in general were suppliers and their sales representatives, who typically provided them with updated information on new products, drug effectiveness and new policies, often in the form of product posters, pamphlets and leaflets. Respondents acknowledged that much of this information was provided in order to influence their stocking decisions.
- In addition to information dissemination, some respondents also described how sales representatives gathered market intelligence for manufacturers and importers.
- Workshops organised either by suppliers or the government (e.g. NDA or district council) were another common source of information for wholesalers and retailers. However, a number of respondents indicated that they had never attended such workshops; rather, their boss or a colleague would attend who then shared the information with colleagues.
- Many other sources of information on antimalarials were mentioned by respondents, including different forms of media, such as various websites, television advertisements and radio talk shows; staff from health facilities and health professionals; trade associations, as well as the British National Formulary, a reference manual containing information on prescribing and pharmacology of all medicines available on the British National Health Service. For those operating within a vertically integrated business model, respondents also cited their head offices as important sources of information on antimalarials.
- Many respondents described providing information to their customers, including advice on selecting antimalarials, proposing alternatives in case of stock outs, and opinions on which antimalarials they considered effective.

4.4.2. Subsidy for ACTs

- At the time of data collection, a study piloting the effect of a subsidy on specially packaged Coartem (ACT Leaf) was being conducted in four districts (see figure 4.2). As part of this pilot study, ACT Leaf was specifically deregulated from a POM to an OTC so that it could be sold in Class C drug shops located within the participating districts. During data collection, two respondents located within these districts were interviewed (one Class C drug shop, and one retail pharmacy also found to be supplying

antimalarials to drug shops, therefore acting as a terminal wholesaler); as were two other wholesalers located just beyond the periphery of the pilot study area.

- Both retailers participating in the pilot study stocked the subsidised Coartem and were retailing the adult treatment pack at the recommended retail price of UGX 800 (US\$ 0.38). Demand for the subsidised product among their customers was high, likely due to mass promotion activities conducted as part of the pilot study which communicated both the product retail price and where it could be purchased.
- Although demand for the ACT Leaf product was high, the retail pharmacy respondent indicated that its introduction had not greatly affected sales of other antimalarials because many consumers preferred other dosage forms over tablets (e.g. oral liquids), or other brands of antimalarial over Coartem (ID 29).
- The drug shop respondent was supportive of the pilot programme as it helped to ensure that patients were taking more effective antimalarials rather than older drugs, such as chloroquine (ID 23). But she also noted a number of issues, including problems of supplier availability that led to retail-level stock outs of the subsidised product; the fixed retail price that did not allow sufficient profits to be made; poor adherence to the AL treatment regimen where patients continue to take the same number of tablets as for chloroquine; suspicion among consumers about the real intent of the pilot study and about being used as ‘guinea pigs for new drugs’; and poor adherence to the fixed retail price. When elaborating on this last issue, the respondent described how retailers based in very remote areas would purchase the subsidised product from other retailers at the fixed retail price (UGX 800, US\$ 0.39), then remove the pricing printed on the package and to re-sell it for as high as UGX 1500 (US\$ 0.73) to recoup the additional transport costs.
- Wholesalers located near the pilot study area were also generally supportive of a subsidy for ACTs, and were willing to participate, if given the opportunity. Customers often came to them looking to purchase the ACT Leaf product, and one wholesaler said that the introduction of the subsidy pilot had caused price reductions for non-subsidised ACTs (ID 27).

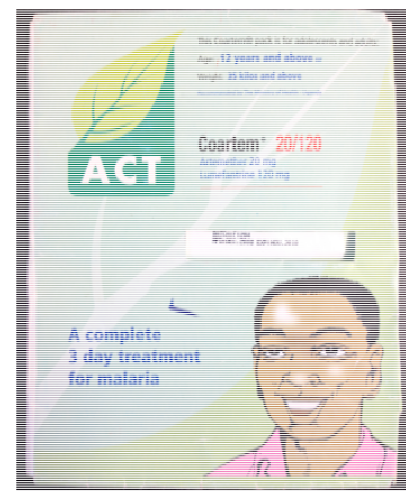


Figure 4.2: Packaging for subsidised Coartem branded as 'ACT Leaf'

4.4.3. Suggestions for non-regulatory interventions

- A number of respondents mentioned the need to improve patient adherence to recommended treatment regimens. To help raise awareness among the general public, respondents suggested providing more training on treatment to drug shop owners and operators, as well as promoting wider use of diagnostics (including RDTs) to support rational use and media campaigns. One respondent also suggested that treatment adherence could be improved if an antimalarial with a shorter and easier regimen was introduced (ID 29).
- In addition to treatment, a few respondents suggested placing more emphasis on malaria prevention through increased investment (ID 13) and more public awareness activities, such as radio programmes (ID 29).
- Another suggestion to improve access to effective and affordable antimalarials through non-regulatory means was to assist prospective retailers wishing to start up businesses in underserved areas to access capital (e.g. bank loans) (ID 15).

4.5. Regulation

Wholesalers and retailers were asked to discuss their opinions on the regulation of the pharmaceutical sector. Specific topics discussed related to business licensing, product registration, bans on particular products or practices, inspections, over-the-counter medications, the black market, counterfeits, sub-standard products, and suggestions to improve regulation of the pharmaceutical sector

4.5.1. Compliance and enforcement

- Respondents generally viewed the current pharmaceutical regulations for their type of business as reasonable and many did not see a need for changes or improvements; however, while most respondents indicated that their business complied with all relevant regulations, many believed that other businesses often did not fully comply. Class C drug shops, in particular, were singled out by several respondents as they were believed to commonly sell medicines beyond the scope permitted by their license (e.g. POMs such as antibiotics, injectables, etc.).
- Reasons suggested for non-compliance were varied. Several suggested that there were too many regulations, with one importer characterising the full scope of regulations facing importers as unrealistic (ID 7), and another implied that even the NDA did not expect full compliance, but rather a 'sufficient level' of compliance (ID 8). Several believed compliance in rural areas (where many drug shops operate) to be lower because inspections of premises were conducted less frequently.
- Nevertheless, these inspections were also regarded by many as reasonable, straightforward and not excessively disruptive. Respondents said that inspections did not cause any problems and provided them with the motivation to operate in compliance with regulations (ID 9, ID 31). Respondents reported that inspections took place at least once a year, some of which were impromptu and unannounced. In addition to the typical checks of storage facilities, licenses, etc., a few respondents also described being audited for stock expiration dates and having to produce official purchase receipts for current stock, perhaps reflecting the perceived rigour of inspections.
- Some, however, were more critical of the effectiveness of inspections, believing that the NDA lacked sufficient capacity, inspections occurred too frequently (ID 30) and caused delays (e.g. release of consignments), some requirements were not being adequately enforced (e.g. licensing), regulations were not applied equally across inspectors (e.g. preferential treatment), and that corruption allowed some businesses to flout some regulations.
- Fear of reprisal (e.g. fines, loss of and refusal to renew licenses, forced closures) was a factor motivating a number of respondents to comply. Several wholesalers and retailers described hearing about such closures through newspapers, television, radio and word of mouth, although only one respondent had personally witnessed this (ID 9). The effectiveness of these measures was sometimes criticised. For example, several explained that businesses forced to close for breach of regulations would often resume operation shortly after under a different name and in a different location (e.g. in a neighbouring house, ID 11). Several respondents described instances where the authorities closed down businesses found to be selling leaked Coartem from the public sector (see section 4.5.5).

4.5.2. Licensing and class C drug shops

- Although most respondents did not have issues regarding licensing, several critical comments were made both about the requirements and the process to acquire or renew a licence, which were believed by some to incentivise operating without one. A few respondents felt that the restrictions on opening new pharmacies or drug shops in close proximity to existing businesses reduced their potential for

success by forcing them to operate in places where they did not want to (e.g. in more remote areas, ID 24), but were also being unequally applied. To demonstrate, a few respondents cited the high concentration of retail pharmacies operating in the pharmaceutical retail and wholesale district in central Kampala. Similarly, some respondents felt that the mandatory requirement to employ a registered pharmacist and the practice limit placed on pharmacists to be associated with a maximum of two businesses were also considerable barriers to obtaining a license given the perceived shortage of pharmacists in the country. Some of these respondents suggested that these professional requirements could be expanded to include other highly qualified health professionals, such as nurses. Respondents also criticised the fees charged to apply for or renew a licence and the processing times, feeling both to be excessive. In a few cases, respondents described how their licences had expired while waiting for their renewals to be processed.

- Much of the criticism related to licensing was directed toward drug shops that are only permitted to sell OTC medicines, also known as class C drugs. The most common concern voiced by wholesalers and retail pharmacies was that they believed many drug shops to be selling other medicines beyond the scope permitted by their licence, placing patients at great risk of receiving inappropriate treatment given that the level of pharmacy training required to operate a drug shop is very low (see section 4.1.4 for details on the staff training requirements for drug shops and pharmacies). Many of these respondents felt that drug shops were not being adequately inspected by NDA officers for restricted and expired products, particularly in rural areas, and that any penalties imposed on non-compliant drug shops were not being sufficiently enforced.
- Conversely, respondents from Class C drug shops felt their licenses to be too restrictive and hindered their ability to improve access to important medicines, such as Coartem. However, it is interesting to note that several of these respondents believed Coartem to be a medicine that could only be distributed through the public sector and were generally unaware that a commercially packaged version was available for private sector distribution (ID 22, ID 19).

4.5.3. Ban on chloroquine and SP

- The policy to gradually phase out the use of chloroquine and SP for the treatment of uncomplicated *Pf* malaria by first halting domestic production and imports was a particularly contentious issue among respondents at all levels of the distribution chain, from manufacturers down to retailers. While a few respondents agreed and understood the need to reduce the use of chloroquine, many felt that the policy was developed and implemented too quickly, without adequate consultation or communication of the change.
- Some respondents felt that the decision to abandon chloroquine use was ill-advised, believing it to still be an effective and affordable antimalarial. These respondents suggested this policy decision did not make use of independent effectiveness data on chloroquine and SP, and reduced access to treatment because private sector ACTs were still too expensive, which left many consumers without an affordable, effective alternative.
- A number of respondents also felt that the rationale behind the policy was not effectively communicated to consumers, particularly in rural areas where chloroquine and SP continued to be popularly regarded as an effective, affordable treatment. As such, persistent demand for chloroquine combined with its diminishing supply caused prices to escalate, further compounding the access problems.
- Similarly, because the sale of existing chloroquine stock was still permitted despite the ban on production and import, many private sector wholesalers and retailers were unclear on the ban's scope and also felt they were not given sufficient time to adjust. One domestic chloroquine manufacturer

expressed his concerns about the continuing viability of his business as a result of the ban (ID 33). Again, suggestions for both better consultation of private sector stakeholders during policy formulation and better communication of the changes were made by several respondents, as were calls for increased engagement and training of retailers (including drug shop operators) who are more likely to have an impact on consumer choices (ID 8).

4.5.4. Counterfeit, unregistered and substandard drugs & the black market

- Most respondents acknowledged the existence of the black market for antimalarials and pharmaceuticals more generally, and described it as the trade of counterfeit, unregistered or substandard drugs; however, a few had never heard of the black market or did not believe such existed in Uganda.
- When describing the scale of the issue, respondents offered a range of opinions. One respondent believed that the black market was mainly localised to Kampala (ID 11) and another felt that Uganda's black market was much smaller compared to Kenya (ID 30). Citing the declining efficacy of antimalarials such as quinine, one respondent believed that the prevalence of substandard drugs was increasing and attributed it to the growing market share of products imported from China and India (ID 21), while others hypothesised that significant volumes of counterfeit and unregistered drugs were also coming overland from neighbouring countries (Kenya, the DRC and Rwanda).
- Respondents proposed several factors that may be exacerbating the issue of counterfeit, unregistered and substandard antimalarials. Some suggested the high demand and diminishing availability of certain antimalarials (e.g. chloroquine), combined with lengthy bureaucratic processes and the high costs of importing (including NDA fees, clearance, and insurance charges), create powerful incentives to circumvent regulatory procedures. A few others cited lapses in NDA quality assurance measures for imports, characterising batch testing procedures as inconsistent and the overall processes as being motivated more by revenue generating potential rather than consumer protection (ID 33).
- However, a number of respondents asserted that the situation was improving, owing to increased NDA activity and growing awareness of the issues. For example, a few respondents described how audits of stock purchase receipts during inspection were helping to ensure that businesses were being supplied by legitimate vendors; one importer also explained how his customers were now able to return and exchange any unsold stock, thereby reducing pressure on the trade of expired medicines (ID 6); and a retailer described learning to identify counterfeit products (ID 11).

4.5.5. Leakage of public sector Coartem

- Public sector (i.e. free) Coartem being sold illegally by private sector retailers and clinics was an issue that most respondents were aware of, mainly from hearing reports via radio, newspapers or television of the NDA forcing businesses to close. However, very few respondents reported having actually seen these products on the market and only one respondent had personally witnessed a business being forced to close because of selling leaked Coartem (ID 9).
- Many of those who had heard of this issue believed that public sector employees who owned or moonlighted in private sector retailers and clinics were the main source of leaked antimalarials. As such, implementing stricter controls on this practice was suggested as one way to reduce the leakage problem (ID 20), along with introducing more distinct public and private sector Coartem packaging, and measures to increase public awareness of the issue. Several respondents acknowledged that awareness generating activities had been conducted in the past and felt that these had already made considerable impact.

4.6. *Rapid Diagnostic Tests*

Similar to antimalarials, wholesaler and retailer respondents were asked a broad range of questions related to RDTs. Topics included the general supply chain structure for RDTs, price-setting, product availability, regulation of RDTs, and interventions or suggestions to improve access and use of RDTs. However, because RDTs were rarely encountered among private sector wholesalers and retailers, very few respondents discussed these topics.

- At the time of data collection, the national policy on the use of RDTs for the confirmation of malaria diagnoses had not yet been finalised. However, RDTs had already been rolled out to a number of Health Centres II and III as part of a pilot study, with a focus on facilities without microscopy or stable electricity supply.
- The general perception among the few top-level wholesalers who discussed RDTs was that they were not widely used in the private sector, mainly due to their relatively high price, poor awareness of RDTs and the updated treatment guidelines, limited availability, and a persistent familiarity with presumptive treatment. The common practice of self-treating and desire to avoid spending additional resources on RDTs to confirm diagnosis was also said to limit use and demand for RDTs among private sector patients.
- Regardless, the private sector distribution chain for RDTs was believed to be similar to that for antimalarials, but with fewer actors at each level. At the end of the chain, RDTs were expected to be distributed primarily through private clinics and pharmacies, rather than through drug shops.
- The Joint Medical Stores (JMS), the key top-level pharmaceutical supplier to the NGO/FBO sector, also supplied RDTs to a few private wholesalers. The JMS wholesale price for a package of 25 RDTs was UGX 2500 or US\$ 1.22 (ID 34).
- One local antimalarial manufacturer/importer also expressed a desire to enter into the RDT market, mainly to act as an RDT supplier to government (i.e. National Medical Store, facilities and community health workers). At the time of data collection, the business had identified a potential supplier of high quality RDTs, but was awaiting finalisation of the national RDT policy to ensure that the product they wished to import would meet the standards set out in the policy and qualify for government procurement (ID 31).

5. Summary of key findings

Viewed alongside the findings from the quantitative survey of the private commercial distribution chain for antimalarials in Uganda (see [1] at www.actwatch.info), this study has produced new insight into the perceptions and practices of private sector antimalarial wholesalers and retailers in Uganda.

- The private commercial sector distribution chain for antimalarials consists of a limited number of manufacturers, importers and large wholesalers based mainly in Kampala operating at the higher levels of the chain, and many smaller wholesalers located in commercial hubs across the country, who then sell antimalarials to a range of retail outlets that primarily include pharmacies, private clinics and drug shops.
- While retailers typically collected their orders from suppliers, wholesalers had orders delivered to them. Suppliers used a variety of methods to deliver orders to customers, most commonly through the use of company-owned vehicles. Manufacturers and importers typically employed sales representatives to take and deliver orders, and established distribution networks covering most of the country; while smaller wholesalers sometimes used various other means to transport orders to customers located further afield, including using shared vehicles, or sending packed orders through public transport networks.
- Vertically integrated business models, where a large importer or manufacturer owns and operates a number of subsidiary wholesalers located in different parts of the country, were a notable feature of the private wholesale pharmaceutical sector and were used as a means of capturing more market segments of the national pharmaceutical market.
- Although the wholesale pharmaceutical sector in Uganda is widely perceived as competitive, businesses cooperated in a number of ways. The most common was through membership in a formal trade association, which generally served to assist businesses with regulatory compliance, but also functioned as a platform for collective representation and political lobbying for businesses operating at higher levels of the distribution chain. Informal networks of private pharmaceutical businesses owned and operated by members of Uganda's prominent South Asian community were another notable feature of the distribution chain in Uganda, which also facilitated cooperation among businesses.
- Coartem and ACTs in general were widely accepted as effective treatment for malaria among private sector wholesalers and retailers, but many believed that older antimalarials, such as chloroquine and SP, remained effective. While respondents did not necessarily consider these older antimalarials to be superior to ACTs, many believed that their comparative affordability was a key driver behind their continued demand by consumers. As such, many respondents were critical of the treatment policy change in favour of ACTs and also of the ban on the import and domestic manufacture of chloroquine and SP, which were perceived to have been implemented without making adequate provisions for an affordable alternative antimalarial that could be sold in the private sector.
- Respondents indicated that antimalarial prices were largely determined by supplier selling prices, but also by competition and product availability. Increasing scarcity of chloroquine and SP as a result of the regulatory efforts described above was a common example used by respondents to illustrate its upward pressure on product prices.
- Private sector wholesalers and retailers received most of their information about antimalarials and malaria treatment from their suppliers and other private sector sources, and much less so from government sources. To illustrate, many respondents described feeling unprepared for the changes that followed the ban on chloroquine and SP, and the adoption of ACTs due to the lack of adequate participation of private sector actors or patients and poor communication of the policy changes.

- Respondents viewed the current pharmaceutical regulatory regime positively, as many felt that regulations were easy to comply with and helped to maintain high standards within the sector. Class C drug shops were often viewed by other business types as the weak link in the private sector distribution chain. Many respondents believed that these shops evaded inspection by regulatory authorities and often violated regulations by selling prescription-only medicines, and that those staffing these shops were not required to have the appropriate skills to prescribe and administer treatment.
- Rapid diagnostic tests (RDTs) were not widely available among private sector wholesalers and retailers because they were not commonly used. This was mainly due to their relatively high price, poor awareness of RDTs and the updated treatment guidelines recommending confirmation of diagnosis among businesses and consumers alike, and a historical reliance on presumptive treatment of fevers as malaria.

When interpreting the findings of this study, there are a number of issues that need to be considered. First is that the sample selected for interview was purposefully chosen to capture the widest possible range of opinions and experiences of antimalarial wholesalers and retailers, rather than to be statistically representative of the entire study population. In order to protect the confidentiality of respondents and due to the sensitivity of the topics being discussed, interviews were documented using a note taker, rather than recorded. While this may have helped to improve the reliability of the data by allowing respondents to be more at ease, some of the richness and detail of the discourse is likely to have been lost. Some responses are also likely to be affected by social desirability bias, with respondents answering in a way that they think will meet the approval of the interviewer. Finally, data for this study were collected in 2009 and changes to the market since then are likely to have occurred, especially due to the introduction of the AMFm in 2011.

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