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

November 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.

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

First-line treatment: The government recommended treatment for uncomplicated malaria. Zambia's first-line treatment for *Plasmodium falciparum* malaria is artemether-lumefantrine, 20mg/120mg. At the time of data collection, the brand of artemether-lumefantrine, Coartem, was being distributed free of charge from public sector facilities using public sector-specific packaging in order to differentiate it from the Coartem being sold in the private commercial sector.

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).

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. Zambia'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.

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 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 |
| ANC | antenatal clinic |
| AR | artemether |
| AS | artesunate |
| ASMQ | artesunate and mefloquine |
| CHW | community health workers |
| CQ | chloroquine |
| DfID | UK Department for International Development |
| DHA | dihydroartemisinin |
| DHA+PP | dihydroartemisinin and piperaquine |
| IMCI | Integrated Management of Childhood Illness |
| INT | intermediate level (wholesaler of supply chain) |
| IPT | intermittent preventive treatment of malaria |
| IQR | inter-quartile range |
| IRS | indoor residual spraying |
| ITN | insecticide treated net |
| LSHTM | London School of Hygiene & Tropical Medicine |
| MEC | mutually-exclusive category of wholesalers |
| MOH | Ministry of Health |
| MQ | mefloquine |
| MSL | Medical Stores Limited |
| nAT | non-artemisinin therapy |
| NGO | non-governmental organisation |
| NMCC | National Malaria Control Centre |
| OS | ACTwatch Outlet Survey |
| OTC | over-the-counter |
| <i>Pf</i> | <i>Plasmodium falciparum</i> |
| PMI | US President’s Malaria Initiative |
| POM | prescription only medicine |
| PPS | probability proportional to size |
| PRA | Pharmaceutical Regulatory Authority |
| PSI | Population Services International |
| RDT | rapid diagnostic test |
| SFH | Society for Family Health/Zambia |
| SP | sulphadoxine pyrimethamine |
| UN | United Nations |
| WHO | World Health Organization |
| WS | wholesaler |

Executive Summary

Alongside the public and non-profit sectors, private commercial providers are also sources of malaria treatment in Zambia. 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 (Zambia, Cambodia, Benin, the Democratic Republic of Congo (DRC), Madagascar, Nigeria and Uganda). This report presents the results from qualitative interviews with antimalarial drug wholesalers, retailers and other key stakeholders conducted in Zambia between February and May 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 structured supply chain survey also conducted as part of this study [1], available at www.actwatch.info.

- The hub of the private commercial distribution chain for antimalarials is Lusaka, and most wholesalers and retailers operate as independent businesses, rather than franchises or vertically integrated models. Private sector businesses generally view the public sector as competitors, particularly as public facilities provide the first-line treatment, artemether-lumefantrine (AL) predominantly branded as Coartem, free of charge to patients. However, public sector stock outs continue to make it viable to sell ACTs in the private sector, including alternative brands of AL to Coartem, which is unaffordable for many Zambians.
- Because most antimalarials must be imported into Zambia, many respondents operating at all levels of the distribution chain had opinions regarding importation. Overall, the import market was perceived as difficult to enter, mainly due to the high transaction costs involved, including the fees charged by the Pharmaceutical Regulatory Authority to register products. Sole distributorship arrangements between foreign suppliers and Zambian importers were also perceived to be common. These factors work to create a high degree of market concentration at importer level.
- Choice of antimalarial supplier was influenced by many factors related both to the products stocked (e.g. product variety stocked, availability and price) and to business practices (e.g. established relationship, availability of credit, reputation, discounts and added value services offered); while the choice to stock certain products was primarily driven by demand.
- Selling prices were largely determined by the price paid to purchase the antimalarial from the supplier, but other factors affecting selling prices included operating costs (e.g. transport and delivery), competition, and product expiration dates. Price discrimination was common among retailers and wholesalers, who considered their customers' ability to pay and also existing relationships. Volume discounts were often also commonly given to customers.
- Suppliers were more inclined to deliver orders to customers located in the same vicinity, which was often one of the responsibilities of supplier sales representatives.

- Respondents also considered supplier sales representatives as important sources of information on antimalarials. Other important sources of information included the commercial and professional pharmaceutical associations to which many businesses belonged. However, respondents expressed the desire for more targeted information and training directly from government and regulatory authorities, particularly regarding policy and programme changes relevant to malaria treatment.
- Overall, respondents viewed current regulations as reasonable and well complied with, but raised several issues. Regarding licensing, smaller retailers (e.g. drugs shops) viewed the requirement to employ a pharmacist as a barrier that led many businesses to operate without a proper license. Respondents also acknowledged the presence of counterfeit antimalarials, the existence of a black market for antimalarials, and the problem of public sector ACTs leaking into the private market, although these problems were perceived to be small. The ban on the sale of oral AMT was widely perceived as effective.
- Although the recommended first-line treatment for uncomplicated malaria, predominantly branded as Coartem, was being provided free of charge in public facilities, respondents felt that frequent public sector stock outs forced many patients to seek treatment from private outlets. Because Coartem was widely viewed as unaffordable for most Zambians, some respondents chose to stock cheaper alternatives, such as generic ACTs and non-ACTs. RDTs were not commonly sold by private sector wholesalers and retailers, as many felt that RDTs were too expensive and that microscopy continued to be the preferred method of confirming diagnoses.

1. Introduction & Objectives

Alongside the public and non-profit sectors, private commercial providers are also sources of malaria treatment in Zambia. 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 Zambia, Cambodia, Uganda, 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 Society for Family Health (SFH) in Zambia.

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 of antimalarial drug wholesalers and other related key stakeholders conducted in Zambia between February and May 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 [1] also conducted as part of this study, available at www.actwach.info.

2. Country Background

Economic Profile

Zambia is a landlocked country located in Southern Africa sharing borders with Angola, the DRC, Malawi, Mozambique, Namibia, Tanzania, and Zimbabwe. The population is approximately 12 million people of which an estimated 65% live in rural areas. In recent years, Zambia has experienced relatively high economic growth, with a gross domestic product (GDP) growth rate ranging between 5.7% and 7.0% from 2008 to 2010, and per capita GDP estimated at US\$ 1,500 in 2010. [2] Historically, the country's economy has relied heavily on the copper mining industry; however, the government has made efforts to diversify by promoting agriculture, tourism, gemstone mining and hydro-power, relying on a private-sector-led model of economic development. [3] In 2009, the government launched the second phase of the Private Sector Development Reform Programme which aims to accelerate and broaden private sector growth. [4] Despite this, 85% of the labour force was engaged in agriculture in 2004, while only 6% were employed in the industrial sector and 9% in the service sector; 50% of the estimated 5.5 million labour force were unemployed; and a majority of the population was estimated to live below the poverty line. [2]

Pharmaceutical Sector

The pharmaceutical sector is regulated by the Pharmaceutical Regulatory Authority of Zambia (PRA), which is responsible for the registration of all products prior to importation and sale, the licensing of pharmaceutical manufacturers, importers, wholesalers and retail pharmacies, and post-marketing surveillance. [5] With only limited domestic pharmaceutical manufacturing capacity, the country relies heavily on the importation of medicines. The public and NGO/mission pharmaceutical sectors both follow a highly centralised model for medicine procurement and distribution [5], while less is known about the structure and operations of the private pharmaceutical sector. All private pharmaceutical importers, wholesalers, and retail pharmacies are required to employ a pharmacist registered with Medical Council of Zambia. The PRA issues several types of license, for the importation, wholesale and pharmacy retail of medicines. Hospital pharmacies also require a specific license from the PRA, while the Medical Council of Zambia maintains a register of private clinics. Drug stores are registered with local governments, rather than licensed by the PRA, and are not required to employ a pharmacist. These retail outlets are common and should only dispense over-the-counter medicines, but in practice also dispense prescription only medicines. Other common sources of over-the-counter medicines in the private sector include grocery stores and other general shops that focus on the sale of fast moving consumer goods. Neither medicine prices or mark-ups in Zambia are regulated.

Health System

Zambia's health system is dominated by the public sector: of the 1,327 healthcare facilities in Zambia, 85% percent are government-run facilities, ranging from health posts to large tertiary hospitals; while 9% are private sector facilities and 6% are NGO/mission facilities. Geographic access to healthcare varies widely with 99% of urban households residing within five kilometres of a health facility, compared to 50% of rural households. [6] Since 1993, government health facilities have charged user fees for the majority of services, but fees were removed for publicly provided primary health care services in rural areas in 2006 which dramatically increased health service use in these areas following implementation. [7] By 2006, it was estimated that over 80% of those seeking care visited public sector facilities, with the remaining visiting facilities in the non-profit and private sectors. [8] Despite these efforts to improve access to health services, there is still considerable room for improvement in national health indicators. Life expectancy in 2006 for both men and women was below 45 years and nearly one in six children die before reaching their fifth birthday, with malaria acting as a key driver of child mortality. [9] In 2007, the country had an estimated 4.3 million clinically diagnosed cases of malaria, accounting for 36% of outpatient visits, 48% of the disease burden among children below five years of age, and up to 20% of maternal deaths. [10]

Malaria Epidemiology and Control Strategies

Malaria is endemic throughout Zambia. Between 90% and 100% of the population are at risk for infection, with peaks occurring during the rainy season between November and April. Despite widespread endemicity, certain areas of the country can be characterised as hyperendemic, mesoendemic, or epidemic prone. The predominant parasite is *Plasmodium falciparum* (Pf) which accounts for the vast majority of infections. [11] The National Malaria Control Strategy identifies pregnant women and children under five as the population groups most at risk. Key malaria prevention and treatment interventions include distribution of insecticide treated nets (ITNs) through campaigns, antenatal clinics (ANCs) and the commercial sector; indoor residual spraying (IRS) in urban and peri-urban areas; intermittent preventive treatment (IPT) for pregnant women through ANCs; and administration of ACTs through health facilities with increasing focus on confirmed diagnosis using microscopy or RDTs. [12] A recent study that examined the progress and impact of the

national control strategy showed that, by 2008, 68% of households had at least one ITN or had received IRS and a similar proportion of pregnant women (66%) received at least two doses of IPT. [13]

Malaria Financing

Malaria prevention and treatment in Zambia is largely supported by international donors. The key malaria partners include the Global Fund, the World Bank, the US President’s Malaria Initiative (PMI), UNITAID, and the UK Department for International Development (DfID). The NMCC received US\$ 39.2 million during the Global Fund Round 1, US\$ 42.7 million during Round 4, and US\$ 17.7 million during Round 7 for a range of malaria prevention and treatment interventions. The World Bank provided US\$ 20 million through its 2005-2010 Malaria Booster Project for health systems strengthening and small community grants. PMI awarded US\$ 9.5 million in 2007 and US\$ 14.8 million in 2008. UNITAID has provided support for the procurement of 1.1 million ACT doses since 2007.

National Treatment Policy

In 2003, Zambia became the first African country to adopt the use of ACTs over chloroquine, selecting artemether-lumefantrine (AL) as the first-line treatment, sulphadoxine-pyrimethamine (SP) as the alternative first line treatment in pregnant women and children less than 5kg, and oral quinine as the second-line treatment in cases of failure of first-line drugs in all age groups (Table 1). Severe malaria is treated with quinine. In Zambia, ACTs are classified as prescription-only medications and are therefore not sold legally through unlicensed private sector providers; and availability of ACTs has remained largely restricted to the public sector, registered pharmacies and private facilities. [10, 14, 15] In 2003, the Ministry of Health placed a ban on the use of oral artemisinin monotherapies (AMTs) for the treatment of uncomplicated malaria to delay the emergence of resistance to ACTs [16]; however the results from the ACTwatch Outlet Survey in 2009 indicated that oral AMTs were still widely available in the private sector (e.g. oral AMTs were available among one-third of registered pharmacies stocking antimalarials). [14] The National Malaria Control Centre (NMCC) recommends parasitological diagnosis for all patients with suspected malaria at hospitals and health centres with laboratory facilities. Clinical diagnosis is recommended where laboratory facilities are not available. Children under five years of age are treated based on laboratory diagnosis in health facilities where available, and otherwise are evaluated and treated according to the Integrated Management of Childhood Illness (IMCI) algorithm.

Table 2.1: National Malaria Treatment Guidelines

| Condition | Recommendation | Dosage form | Strength |
|---|----------------------------|--------------------|-----------------|
| Uncomplicated malaria | Artemether-Lumefantrine | Tablet | 20mg/120mg |
| Pregnant women & children under 5kg – uncomplicated | Sulphadoxine Pyrimethamine | Tablet | 500mg/25mg |
| Treatment failure | Quinine (oral) | Tablet | 200mg or 300mg |
| Severe & complicated malaria | Quinine (injection) | Ampoule | 150mg/ml |

Antimalarial Treatment Distribution and Delivery

As part of Zambia's implementation of its Global Fund grants, ACT treatment has been procured and dispensed in the public sector free of charge since the end of 2004, nearly all of which has been the brand of AL, Coartem, with public sector-specific packaging in order to differentiate it from the Coartem being sold in the private commercial sector. To ensure rational use of these drugs, the Global Fund also supported procurement and distribution of RDTs and microscopes, and training of health workers in their use. A Round 1 grant from the Global Fund provided sufficient ACTs to cover 28 out of the 72 districts in Zambia between 2003 and 2009, and national scale up commenced with resources from a Round 4 grant from 2005, via health facilities, community health workers (CHWs) and pharmacies. As of November 2008, 11 districts had also started community-based treatment of malaria with ACTs.

ACT delivery in Zambia is also supported by financing from other donors. The World Bank Malaria Booster project provides health system strengthening to improve service delivery, small grants for community-level malaria control, and funding to the Ministry of Health (MOH)/NMCC; UNITAID has supplied 1.1 million ACT doses for community distribution; and DfID has provided funds to redesign Zambia's public sector distribution system in collaboration with John Snow International/DELIVER and the World Bank.

According to the ACTwatch Outlet Survey, public health facilities, private health facilities, pharmacies and drug shops were the most common outlets carrying any type of antimalarial in Zambia in 2009. [14] ACTs were rarely available in unlicensed private sector providers (e.g. around 6% in drug stores, and less than 1% in other types of providers).[14] While the ACTs available in the public sector were predominantly the brand of AL, Coartem, unpublished data from the 2009 ACTwatch Outlet Survey showed the private sector ACT market to be more diverse, with outlets stocking other non-AL ACTs and several other brands of AL, in addition to Coartem. The majority of antimalarial treatments are obtained through public facilities; the 2009 ACTwatch Household Survey estimated that 85% of all antimalarial treatment for children were acquired from the public sector, with 7.5% of treatment for malaria was obtained through private sector sources such as pharmacies, drug shops and private health facilities. [15]

3. Methods

3.1. Scope of the Supply Chain Study

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. [14] 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. This 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 (KIs)

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 activities; the most significant antimalarial importers and wholesalers; and representatives of organizations 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). For the retailers and terminal wholesalers, participants 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, general retailer).

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 Zambian 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. Interview conducted

In total, 10 key informant and 32 in-depth interviews were conducted in Zambia. Table 3.1 gives details of the numbers of interviews conducted. Three interviews (two retailers and one top-level wholesaler) were not completed as respondents refused or did not feel comfortable answering certain questions.

Table 3.1: Number of interviews across distribution chain levels

| Business type/Distribution chain level | Number of interviews |
|--|----------------------|
| Retailer ^{1,2} | 14 |
| Terminal wholesaler | 10 |
| Intermediate wholesaler ³ | - |
| Top wholesaler ¹ | 8 |
| Total | 32 |

1: Includes interrupted or incomplete interviews. 2: Retailers in this category included 3 pharmacies, 4 drug shops, 4 private clinics and 3 general retailers. 3: All wholesalers identified in Zambia were found to sell antimalarials directly to retailers, so are all terminal wholesalers by definition; as such, no purely intermediate wholesalers (i.e. wholesalers selling to other wholesalers exclusively) were identified.

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 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. Private commercial sector antimalarial distribution chain structure

- Domestic manufacturing of antimalarials is limited. According to list of registered antimalarials obtained in 2009 from the PRA, three domestic manufacturers were producing four generic quinine products (two tablet and two injectable formulations) out of a total of 82 registered antimalarials. The remaining registered antimalarials, including all ACTs, were produced by manufacturers primarily in India and Kenya, with others based in China, Tanzania, Belgium, Denmark and Germany.
- The 2007/2008 PRA register of licenced pharmaceutical wholesalers, also obtained from the PRA during data collection, included 62 businesses of which 56 were also licensed to import pharmaceuticals. Most of these licensed wholesalers (53) were based in Lusaka and the remaining were located in Ndola (4), Kitwe (3) and Kabwe (1). Findings from in-depth interviews reflected this distribution of wholesalers, with many businesses reporting that they procured antimalarials from suppliers in Lusaka.
- At retail level, the 2007 PRA register of licensed pharmacies obtained during data collection listed 44 businesses of which 27 were in Lusaka, 4 were in Ndola, 5 were in Kitwe, 2 were in Luanshya and the remaining were distributed across Chingola, Choma, Kabwe, Kalomo, Livingstone and Solwezi.
- Most of the antimalarial wholesalers and retailers interviewed operated as independent businesses; however, there were several examples of horizontal and vertical integration where several businesses were owned by a single entity. For example, in one instance several pharmacy wholesale and retail businesses were owned by one person and retail businesses were supplied by the wholesale businesses (ID 2). In another, informal, example of integration, one wholesaler operating in the provinces was being supplied by a Lusaka-based wholesaler owned by a relative (ID 24).
- A few intersectoral transactions were also noted where two wholesalers reported supplying antimalarials to public sector customers, such as district-level health facilities (ID 19 & 32).
- Horizontal trading occurred at the top of the distribution chain where some importers reported purchasing antimalarials from other importers when seeking to stock products brought into Zambia by a sole distributor (ID 28) or to source alternative products when their regular supplier experienced a stock out (ID 27).

4.1.2. Competition

- For retailers, discussion about competition was often related to local proximity. For example, respondents often referred to sellers in the same licence category (e.g. drugs shop, pharmacy) within the same town or village as their competitors. Competition at retail level was also augmented by the tendency of similar businesses to offer the same or similar drugs.

- Wholesalers, on the other hand, often considered competitors to operate over a wider geographic area. For example, one terminal wholesaler located outside of Lusaka considered Lusaka-based wholesalers to be competitors for his public sector customers in particular because these customers receive allowances from the government that permit them to offset the costs of travel and purchase lower priced stock offered by wholesalers in Lusaka (ID 18).
- Public health facilities were viewed by many private sector retailers and some wholesalers as competitors because the recommended first-line treatment was available free of charge at public health facilities, leading many potential consumers to seek treatment in the public rather than in the private sector.
- On the other hand, some retailers and wholesalers disagreed arguing that public health facilities were not competitors because stock outs of Coartem often occurred at public facilities. Respondents indicated that these stock outs forced many patients, who may otherwise seek treatment in the public sector, to turn to the private sector in order to obtain antimalarials. Respondents felt that this compounded access issues as Coartem was often either unavailable or too expensive in private outlets. As such, patients who arrive at private outlets with prescriptions for Coartem are often given cheaper alternatives that are more likely to be in stock, such as chloroquine (ID 14). One private clinic respondent asserted that people who use public sector clinics tend to be different from his typical customers (ID 10).

4.1.3. Barriers to entry

- Sole distributorship agreements that grant exclusive rights to a single local importer were viewed by several respondents as a barrier to entering the import market because these agreements limited the potential to establish new relationships with foreign suppliers. For example, a licensed importer described being referred by potential suppliers to existing local distributors with exclusivity rights when attempting to court new suppliers (ID 19). This was also mentioned specifically with regard to Coartem where the manufacturer, Novartis, has granted sole distributorship to a single local importer, Sky Pharmaceuticals.
- Respondents also regarded the high PRA fees required to import antimalarials as creating an additional barrier to entering the import market and working to protect the market share of current importers. These included fees for product registration, retention of registration and import authorisation (set at 2% of the invoice value). However, several importers reported that their foreign suppliers helped to cover all (ID 32) or at least some costs. For example, one importer reported that their foreign supplier contributed half of the fees for product registration and retention (ID 28); while another also received reimbursement for retention fees in the form of free goods (ID 30). See section 4.5.3 for more information on importation and product registration.
- Several terminal wholesalers also took issue with the high fees charged by the PRA to import antimalarials, arguing that the fees rendered the Zambian pharmaceutical market less attractive to foreign manufacturers and also discouraged potential entrants into the import market, indicating that it would be difficult to sell in large enough volumes to adequately recoup the additional costs of importing (e.g. PRA fees). However, one terminal wholesaler from a business that was vertically integrated with another business engaged in antimalarial importing approved of the current import regime as they helped to ensure product quality for consumers by controlling what products were available on the market and by compelling businesses to follow best practices (ID17).
- While most respondents did not express issues with pharmaceutical licensing requirements in general, a few felt it was unreasonable for all types of businesses to be required to employ a pharmacist. This was particularly an issue for small retailers. See section 4.5.1 for more information on licensing.

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. where price varies by attributes such as location or by customer segment).

4.2.1. Factors influencing choice of supplier

- The factors most commonly mentioned by respondents as influencing supplier choice related to the products carried by the supplier. Product availability and purchase price were clearly important to many respondents. Product variety was also valued because suppliers stocking a wider range of products demanded by customers were more convenient and allowed customers to purchase in volumes that would attract promotions, such as discounts (ID 19). This was less applicable to importers, for whom product variety is constrained by sole distributorship agreements; however, some respondents still felt that these exclusivity rights (ID 19) and product registration rules that tie the distribution of a product to the registering entity (ID 32) were factors that limited choice of supplier. Some respondents also mentioned the quality of products stocked and whether products were registered with the PRA (i.e. product registration number is printed on packaging) as important factors.
- Other influencing factors related to supplier business practices. These included whether there was an established business relationship with the supplier, and if the supplier offered credit facilities. Several respondents also mentioned the supplier's reputation and whether they offered discounts or delivery services to customers.
- Most respondents said they would consider changing suppliers, and reasons for changing reflected those factors above, such as product availability, price, quality, and the availability of credit facilities.
- In addition, wholesalers at the top of the distribution chain indicated that their choice of supplier was influenced by the perceived difficulties of establishing relationships with potential suppliers, particularly related to the negotiation of supplier contracts and other agreements. See section 4.1.3 for more information barriers to entry.

4.2.2. Factors influencing product selection and availability

- Wholesalers and retailers reported product stocking choices to be driven largely by customer demand, and as such, most respondents stocked more than one antimalarial. Many respondents also considered the product's registration status with the regulatory authority, while only a few mentioned quality or supplier availability as factors influencing product selection. Some retailers hypothesised that difficulties related to drug importation and registration led to poor availability of some antimalarials among their suppliers; while one retailer reported that the type of license possessed by a supplier limited the types of products stocked, as certain license types do not permit the sales of all types of medicines (e.g. drug shops may only sell over-the-counter products). Similarly, sole distributor agreements and product registration rules were also felt to limit the types and range of products carried by importers (ID 19 & 32).
- Another consideration mentioned by respondents related to product expiration dates, as delays in importing often meant that the remaining product shelf-life was considerably reduced. One importer described that six months of a product's typical two year shelf-life may be consumed by import delays,

and particularly for expensive products, the remaining time may be insufficient to sell all the acquired stock prior to expiration, resulting in a loss (ID 29).

- Regarding the recommended first-line treatment, Coartem, respondents indicated that this product was not often stocked by private sector wholesalers and retailers for several reasons. The most common reason mentioned by respondents was its high cost relative to other antimalarials, which reduces consumer demand. Other reasons mentioned included low availability of Coartem among suppliers and competition from public health facilities, where Coartem is provided free of charge (see section 2 for more information on the national treatment policy and section 4.1.2 on competition). However, public sector stock-outs and supply issues did lead some wholesalers with public sector customers to stock Coartem; and some private retail outlets also stocked Coartem as public facilities experiencing stock-outs often re-directed patients to the private sector to fill prescriptions. This elicited further comments about the relative unaffordability of Coartem, which prompted some retailers to admit stocking an alternative, less effective antimalarial (i.e. chloroquine) to dispense to patients instead (ID 14 & 13). Believing that Coartem could only be distributed through public facilities, another retail respondent chose not to stock Coartem out of fear from being accused of selling drugs leaked from the public sector (ID 4).

4.2.3. Price setting

Factors influencing price

- Wholesale respondents indicated that suppliers did not place any restrictions on the way they set their prices (e.g. they did not set or enforce recommended selling prices).
- For retailers and terminal wholesalers, one of the most frequently mentioned factors determining the selling price of antimalarials was the purchase price paid to their suppliers. Several respondents also mentioned fluctuations in exchange rates as an important price determinant, particularly as many products are imported.
- Operating costs were commonly mentioned as a factor affecting price at all levels of the distribution chain, with transport costs related to delivery of orders cited often; however, more respondents operating at the top of the distribution chain mentioned costs (e.g. transport) as an important determinant of price than respondents operating at lower levels (i.e. terminal wholesalers and retailers).
- Competition also appeared to be an important factor and was mentioned by respondents at different levels of the chain. One top-level wholesaler mentioned that they monitor competitors' prices to decide what types of products to import and distribute (ID 29); terminal wholesalers often mentioned that they closely monitor prices in the market (e.g. by asking customers about competitors' prices); and two retailers mentioned visiting other retailers to collect information about prevailing prices (ID 1 & 7).

Factors influencing mark-up

- Practices regarding mark-ups on antimalarials varied by supply chain level and were influenced by a number of different factors.
- At retail level, respondents described mark-ups either as a fixed absolute value per pack sold, or a fixed percentage of the purchase price, ranging from 5% to 100%. Percent mark-ups were affected by purchase prices, with higher priced drugs (e.g. Coartem) typically attracting lower percent mark-ups (i.e. high price, low margin and low volume). Public facility stock-outs were also reported to increase private sector mark-ups due to increased demand and to cause fluctuations in price.
- At terminal wholesale level, percentage mark-ups were the most common mark-up method, and were reported to range from 10% to 40%. Similar to retail level, mark-ups varied by product type, but also

depended on whether the drug was “fast moving”/high volume; however, respondents provided contradictory remarks regarding whether high volume products attracted the highest or lowest mark-up. Other factors affecting mark-up mentioned at this level were the products’ reputation and availability: several respondents said that products with a better reputation attracted higher prices; while products that were widely available attracted lower prices.

- Among wholesalers at the top of the distribution chain, percentage mark-up was the most common approach, and these varied from 10% to 60%. Factors affecting mark-ups among top-level wholesalers included whether the product was “fast moving”, as at terminal level; competition (both number of competitors and their prices for similar products); availability; demand and product reputation. Several respondents indicated that mark-ups generally depended on whether the product was imported or domestically produced (i.e. lower mark-up on locally produced antimalarials), although this seemed to depend on whether the right to sell this product was held by a sole distributor or multiple distributors. If the right to sell a product was with a sole distributor, the mark-up tended to be much higher. One respondent also mentioned total costs of a product (including e.g. transport) as a determinant of the final mark-up added (ID 27), and another mentioned that higher mark-ups were generally added to ACTs (ID 29).
- Across all levels, respondents indicated that lower mark-ups would be applied to products that were close to the expiration date.

Price discrimination and variation

- Retailers frequently mentioned that they would reduce their price for an antimalarial if customers cited lower prices among their competitors, if a customer did not have the ability to pay (particularly poorer rural customers), or if a customer could not receive treatment at a public facility due to stock-outs. Typically, retailers would only reduce prices as low as cost price; however, several mentioned that they would give the drug away free of charge if affordability was an issue.
- Terminal wholesalers also considered their customers’ ability to pay when deciding prices, but prices were also reduced if there was an existing good relationship with the customer, and if the quantity purchased was large. Such discounts were also common among top-level wholesalers. Among all wholesalers, discounts ranged from 5% to 20%.
- In addition, some respondents indicated that they would lower the price for a given antimalarial if the product expiration date was approaching (e.g. within 3 months) to avoid losses from having to discard expired stock.
- There were some respondents at all levels of the chain who indicated that they did not vary prices for antimalarials.

4.2.4. Restocking practices

- Respondents commonly reported making advance orders with their suppliers. Orders were often taken by sales representatives visiting customers, as they tend to visit on a regular basis.
- Half of respondents reported collecting orders from suppliers themselves, while the remainder had their orders delivered by their suppliers, often through their sales representatives. One respondent indicated that orders were occasionally delivered via a private courier (ID 7).
- Whether or not a supplier delivered orders seemed to depend on location. A few terminal and top-level wholesalers stated that they would only deliver to customers in Lusaka and others would have to collect

their orders. One retailer explained that Lusaka-based suppliers had an additional charge if orders were delivered, while other suppliers did not apply an additional charge (ID 10).

- The frequency of making orders and receiving deliveries varied. Order frequency typically ranged from twice per week to once every few weeks; however, wholesalers operating at the top of the distribution chain placed orders less frequently. This was largely attributed to long lead times for importation, which were reported to range between 15-20 days up to 12 months.
- Several importers argued that long lead times combined with the large order volume required to make importing viable increased the risk of stock expiring and incurring losses.

4.2.5. Cooperation among businesses

- Most respondents mentioned belonging to commercial or professional associations. Such associations were often organised around certain professions (e.g. pharmacists), business types (e.g. wholesalers or importers), or by location; thus, association membership varied somewhat by supply chain level and region. However, some respondents said that they did not belong to any associations, and a few were not aware of their existence.
- The frequency of association meetings ranged from several times per month to annually, and the topics discussed also varied. Commonly mentioned topics included updates on regulatory requirements (e.g. registration, licensing), information on new products, development of drug resistance, poor availability of certain drugs, and more general discussions about operating a pharmaceutical business. Speakers from the PRA, medical and other commercial associations sometimes attended these meetings.
- Most respondents said that they did not discuss prices or price fixing with other similar businesses; however, two retailers operating in a remote area indicated that agreements on pricing levels were discussed in association meetings to ensure that there is not too much price variation (ID 13 & 14).

4.2.6. Repackaging

- Repackaging of antimalarials was not a common activity among wholesalers. Among those operating at the top of the chain, all respondents indicated that they did not repackage as it was prohibited either by regulations or by their suppliers.
- However, a few retailers reported deconditioning antimalarials purchased in bulk (e.g. in pots or tins of 1000 tablets) into individual doses for sale to customers, as such bulk purchases were often cheaper to procure or because smaller pack sizes were not available from their supplier (ID 7 & 13).

4.2.7. Sources of capital

- Most respondents reported using their own funds (i.e. business revenue) to finance their inventory.
- Alternatives to this were to use credit facilities offered by suppliers or to take a loan from the bank for large orders. However, respondents indicated that smaller businesses may experience difficulty securing such loans (ID 19) and that interest rates were high at approximately 20%. One wholesaler also described how suppliers providing credit impose limits that sometimes did not cover the entire value of the intended order (ID 19).
- One respondent operating as part of a vertically integrated enterprise explained that their stock was financed entirely through their sister company (ID 10).

4.3. Sales Revenue and Business 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, many 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 on furniture and fittings, purchase of initial stock, equipment and vehicles. Most respondents reported these in the local currency, which are reported here in US dollars¹; other importers estimated these values in US dollars.

4.3.1. Revenue from antimalarial sales and fluctuations in sales

- When asked for the proportion of revenues from antimalarial sales relative to total revenue, responses varied both within and across distribution chain levels. But in general, respondents indicated that sales of antimalarials constitute a sizeable proportion of their overall sales.
- Among top-level wholesalers, revenues from antimalarials accounted for between 5% and 20% of total revenues; and between 5% and 15% among terminal wholesalers.
- The greatest variation was observed among retailers, where antimalarial sales comprised between 5% and 75% of total revenues, and differences were not noted across outlet type or location.
- Fluctuations in sales revenue (and profit) from antimalarials were reported to be mainly associated with the rainy season from November to April. Several respondents described that revenues during the rainy season were approximately 20% higher than during the dry season.
- However, other respondents reported a consistent and high demand for antimalarials throughout the year.

4.3.2. Start-up costs

- As expected, estimated costs to start-up pharmaceutical businesses varied across distribution chain level, but tended to be higher for those operating higher in the chain.
- For most retailers, the key costs were for purchasing furniture and fittings, ranging from US\$ 4.40 to US\$ 526.90, as well as purchase of initial stock, ranging from US\$ 878.16 to US\$ 2634.49. Very few retail respondents reported start-up costs for equipment and vehicles.
- Terminal wholesalers estimated start-up costs to range between US\$ 1756.32 to US\$ 8781.62 for furniture and fittings, between US\$ 526.90 and US\$ 35,126.48 for initial stock purchases, between US\$ 526.90 and US\$ 3512.65 for equipment (e.g. for air conditioning, refrigeration) and between US\$ 4390.81 and US\$ 17,563.24 for vehicles.
- Top-level wholesaler estimates ranged from US\$ 526.90 to US\$ 20,000 furniture and fittings, from US\$ 8781.62 and US\$ 120,000 to purchase initial stock, from US\$ 3512.65 and US\$ 20,000 for equipment (with several respondents mentioning the high costs to install air conditioning in warehouses), and from US\$ 6000 to US\$ 150,000 for vehicles. Those reporting very high vehicle costs at this level attributed this to the need to initially purchase several vans and trucks.

¹ The average exchange rate during the data collection period (28 February to 6 May 2009) was 5693.71 Zambia Kwacha (ZMK) to US\$1 (www.oanda.com).

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 cited sales representatives and suppliers as their main source of information on antimalarials. One respondent described how some suppliers send sales representatives to provide product information to health professionals at health facilities in order to generate demand (ID 21). This practice is generally known as product detailing. No respondent described having supplier representatives embedded within their own staff.
- Respondents who were members of commercial and professional associations (see section 4.2.5) also described these as important sources of information on antimalarials.
- Respondents also learned of policy changes or government announcements (e.g. about the ban on oral AMTs) through television and radio, or occasionally directly from government, regulatory and other agencies (meetings with the district health board and the Malaria Consortium, an NGO, were specifically named); the internet was only rarely mentioned as an information source.
- Other sources of information included books, journals, customers (from prescriptions and demand), colleagues with professional qualifications (e.g. pharmacists) and the information leaflets including in medication packaging.

4.4.2. Training of private providers

- Several respondents criticised the Ministry of Health for implementing programme and policy changes without providing sufficient training or information to private providers.
- When new products and devices enter the market, some respondents felt that training should be provided by their suppliers. According to one respondent, this happened only occasionally (ID 19).
- Several respondents also felt that the training that was currently being provided by government and regulatory authorities favoured public sector providers, and requested that private providers be given equal opportunity and more training, guidance and information in general. One respondent added that this would require meetings and workshops to be scheduled at “private sector-friendly” hours (ID 18).

4.4.3. Other suggestions for non-regulatory interventions

- Regarding ACTs, one respondent suggested that these antimalarials needed to be promoted more widely with messages focussing on why ACTs are more effective than older, more familiar drugs (ID 2).
- Coartem’s relative unaffordability was viewed by several respondents as a barrier to its wider use, particularly for the poor. Suggestions to improve the affordability and availability of Coartem in the private sector included increasing the number of distributors to intensify competition, and also to consider domestic Coartem production to avoid the high costs of importing.
- The need to improve diagnosis and treatment alternatives was also mentioned. A few respondents viewed rising treatment resistance as a major future challenge and stressed continued progress in the development of new antimalarial treatments, novel dosage forms and better treatment schedules. Respondents also highlighted how RDTs were rarely being used to diagnose malaria, even in public clinics, because of poor availability and high prices (see section 4.7).

- More generally, some respondents felt that future widespread availability of antimalarials will continue to be challenged by the poor state of transportation infrastructure and the long distances between customers in the provinces and suppliers in Lusaka.

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 licencing, 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. Pharmaceutical business licensing

- Respondents typically listed the various types of licences that needed to be obtained to operate a pharmaceutical business. These included licenses from the Pharmaceutical Regulatory Authority, local government, and the fire department license, and also certification following successful business and health inspections.
- Most respondents did not express issues with licensing requirements; however, a few felt it was unreasonable that all types of businesses are required to employ a pharmacist. This was viewed as a particular issue for small retailers, such as drug shops, causing many to operate illegally without a registered pharmacist. One respondent explained how this requirement limited access to ACTs as customers first need a prescription, which could only then be filled by shops employing a pharmacist.
- Similarly, licensing restrictions that limited small retailers, such as drug shops, to selling only OTC medicines were also criticised because a limited variety of drugs offered was perceived to reduce the attractiveness of shops to customers.
- To address these issues, it was suggested that the government should introduce ACT dispensing courses for drug shops and allow them to sell ACTs, so that they may be more widely accessible to the community.

4.5.2. Inspections and regulatory enforcement

- In general, respondents described two different types of inspections: those conducted by health inspectors required to obtain a business license and those routinely conducted by the PRA for regulatory compliance and enforcement.
- Most of the experiences and opinions elicited from respondents related to inspections conducted by the PRA. These visits were typically unannounced, during which time inspectors examined the registration of products being sold, product expiration dates, the vendor's knowledge of the regulations, the overall state of the premises (including storage conditions), and the possession of required documentation. One respondent also described being able to call the regulatory authorities to have them collect and dispose of any expired drugs (ID 2). Businesses must pay for this service.
- Most respondents indicated that these inspections happened once or twice a year, primarily in conjunction with license renewal; however, one large importer based in Lusaka said that their business had been inspected as many as six times in a year (ID 30), while a small drug shop respondent also based in Lusaka stated that they had not been inspected or had any experiences with regulators (ID 3). This last experience may be related to a perceived lack of capacity to regulate and inspect the whole market, as noted by one respondent (ID 10).

- There was some variation in the experiences and opinions of respondents regarding inspections. While some described inspections to be more participatory and constructive with inspectors making suggestions for improvement and causing little disruption to business by imposing strict sanctions, others described their impression that sanctions would be applied immediately through warnings, fines or forced closures should any deficiencies be found. One respondent described how inspections caused all regular business operations to cease during an inspection (ID 18); and some described how inspectors would confiscate expired products or products found to be stocked without the appropriate licence (e.g. drug shops stocking POMs).
- In general, respondents believed that businesses complied with regulations and that regulations were being enforced by the authorities. As such, no respondent was personally aware of any businesses that had been closed down or taken to court due to non-compliance. However, one respondent described how some businesses appear to close down just prior to an impending inspection in order to avoid scrutiny (ID 7).
- To improve the effectiveness of inspections, respondents provided several commonly mentioned suggestions, including conducting more regular inspections, changing the focus of inspections to be more constructive rather than punitive, and amending the requirements to obtain a pharmaceutical business licence and the list of OTC medicines to better reflect real market conditions and to improve accessibility to ACTs.

4.5.3. Importation and drug registration

- Most discussion on the topic of drug registration was critical. Wholesalers generally felt that the fees charged by the PRA for product registration and retention were too high for businesses wishing to enter the import market, leading some to suggest fee decreases. One importer also described how high product registration fees acted as a disincentive to changing foreign suppliers (ID 32); while another indicated how the registration process could take up to two years, but that this could be completed more quickly for a much higher fee (ID 27), and that this practice favoured the formation of sole distributorship arrangements. See section 4.1.3 for more information on barriers to entry.
- To cope with the high fees associated with product registration and retention, some respondents described how importers and manufacturers would sometimes split these expenses between them, or have them covered completely by the manufacturer.
- Several respondents also suggested that more rigorous implementation of quality assurance measures needed to be conducted (e.g. better screening at ports of entry and laboratory testing) to reduce the prevalence of counterfeit and substandard products.
- Among the more positive comments elicited, one respondent felt that the current drug registration regime, in particular the requirement to have product registration numbers printed on exterior packaging, has made it more difficult to sell unregistered and smuggled drugs (ID 16). Several others agreed that import controls had contributed to the successful reduction of oral AMTs, counterfeit and substandard drugs available on the market.

4.5.4. Counterfeit and substandard drugs

- Respondents expressed concern over fake and substandard antimalarials. Several described that counterfeit drugs were being sold in traditional markets, and described the difficulty in distinguishing genuine products from counterfeit and substandard products.

- One respondent was concerned about the quality of products imported from India and China, particularly because product information leaflets included with the packaging were not available in a relevant local language, which could lead to problems with drug administration (ID 7).
- Opinions varied on the effect that high importation costs were having on the prevalence of counterfeit and substandard drugs on the market, with some believing that high import costs ensured that only those importers and producers of quality antimalarials would be able to afford to import, while others felt that high import fees led to higher end-user prices, which in turn, creates conditions where the selling of counterfeit or substandard products is more lucrative.
- To improve the quality of antimalarials in the distribution chain, respondents suggested conducting additional quality control tests at points of entry (ID 19), and more frequent 'spot checks' at different points in the distribution chain.

4.5.5. Black market/Parallel market

- Many respondents said that they were unaware of a black market for smuggled drugs or believed it only to be small, with several suggesting that this may be the result of improvements in product registration and enforcement of quality control measure at ports of entry. However, a few respondents were convinced that a black market does exist in Zambia and that it was the source of large volumes of antimalarials.
- The hypothesised origins of smuggled drugs being sold on the black market varied, with some suggesting that drugs primarily came from the DRC, and others citing Malawi and Zimbabwe as the source of these drugs. One respondent believed that RDTs from Asia were being smuggled into Zambia though Tanzania (ID 18). It was also suggested that Zambia may be the source of antimalarials smuggled into other countries, such as Malawi where the sale of SP and chloroquine had already been banned.
- As for the reasons contributing to the existence of the black market in Zambia, respondents suggested that some businesses may try to avoid the high fees charged by the PRA for product registration and retention, while another asserted that the high demand for low cost drugs was a major incentive to sell smuggled antimalarials, which are typically cheaper than their genuine counterparts (ID 19).

4.5.6. Leakage of public sector drugs to the private sector

- Most respondents had heard stories of leaked public sector ACTs available for sale in the private sector, particularly in rural areas and among particular provider types (e.g. unregistered outlets). However, some respondents who had not heard of such drug leakages or believed that this was a common problem in the past which had since been resolved.
- These respondents suggested that the distinct packaging of the public sector Coartem served as an effective deterrent, making the public sector product very easy to distinguish from the commercially packaged version. A few respondents believed that shops found to be selling leaked public sector Coartem would be closed down by regulators and the leaked products confiscated. Believing that Coartem could only be distributed from public facilities, one respondent expressed no interest in stocking Coartem out of fear from being reprimanded (ID 4); while others highlighted the importance of purchasing antimalarials only from registered suppliers (see section 4.2.1).
- When discussing the scope and causes of drug leakage, several described it as a problem limited to the retail sector, and one respondent attributed leakage to relatively low public sector wages, implying that to supplement their income employees at public facilities would take Coartem stock from their workplace and supply it to small private outlets (ID 19).

4.5.7. Ban on AMT

- Most respondents had heard about the ban on the sale of oral artemisinin monotherapies that had been in place since 2003; and most reported learning of this ban passively through the media, rather than directly from government or regulatory authorities (see section 4.4). A few respondents were unclear of the purpose of the ban, and one respondent (ID 30) criticised that the wording of the ban was unclear on whether all AMTs were banned or just oral dosage forms (i.e. not injectables). Another respondent had not heard of the ban at all (ID 28).
- Respondents also described how learning about the ban through mass media led to uncertainty on what private sector suppliers were to do with their unsold stocks of oral AMTs, which prompted several respondents to contact the authorities for more information on the ban, specifically on when the ban would come into effect.
- They also described how most customers were uninformed about the ban of oral AMT sales and continued to demand these products. This caused a degree of dissatisfaction among customers seeking to buy oral AMTs as their availability dwindled, raising concern for both wholesale and retail suppliers fearing a loss of custom.

4.6. Subsidy for ACTs

Although Zambia was not one of the countries selected to participate in the first phase of the AMFm, respondents were asked a range of questions related to their opinions of the proposed subsidy mechanism and about any potential barriers that could inhibit the distribution of subsidised ACTs in the private sector.

- Many private wholesale and retail respondents welcomed the idea of a subsidy on ACTs, particularly Coartem, in the private sector.
- One respondent believed that such a subsidy could help to increase their ACT sales by making these drugs more affordable, particularly because stock outs of ACT were common in the public sector.
- Others were more cautious: one importer indicated that he would be supportive of the idea so long as sufficient margins, estimated at around 40%, could still be gained (ID 28). Another said that its success would depend on who is selected to distribute the subsidised drugs, as some existing distributors, such as the NGO Society for Family Health (SFH), already have well-established delivery channels (ID 18).
- There were also a few who were critical of the subsidy idea. One respondent was concerned that only manufacturers “from the West” producing patented antimalarials would benefit from the subsidy (ID 25). There was also concern that the subsidy would only be applied to Coartem in Zambia and exclude ACTs produced by other manufacturers. Another respondent felt uneasy about the proposed subsidy, saying that poor implementation could lead to losses from surplus supply or that he may lose customers if the subsidy does not go ahead (ID 26).

4.7. 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, only a few respondents discussed these topics.

- According to most respondents who discussed RDTs, microscopy continues to be the main tool used for confirming malaria diagnoses. Even when RDTs are available, one respondent indicated that in clinics microscopy was still preferred (ID 5). The high price for RDTs was given as one reason for this, leading some to use RDTs only in emergencies, such as during power cuts. One respondent chose not to stock RDTs because he preferred selling “faster moving” products (ID 29); while another stated that their current PRA license did not permit them to sell RDTs (ID 13).
- Those stocking RDTs typically purchased them from their antimalarial supplier, if available; although a few respondents purchased RDTs from suppliers other than those supplying them with antimalarials. As such, the factors affecting choice of RDT supplier were similar to those related to the choice of antimalarial supplier (see section 4.2.1).
- Customers purchasing RDTs were more likely to be health facilities (e.g. private and mining hospitals), than retail stores or patients (IDI 21). One respondent commented that many customers from the provinces come to Lusaka to procure RDTs, and described that mark-ups on RDTs were similar to those applied to antimalarials (ID 2).
- In terms of RDTs sales volumes, those stocking RDTs described that they were able to sell their stock; however compared to those operating elsewhere, respondents in Lusaka spoke more confidently about their ability sell RDTs, as customers from across the country come to Lusaka to purchase them (ID 2).

5. Summary of key findings

Viewed alongside the findings from the quantitative survey of the private commercial distribution chain for antimalarials in Zambia (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 Zambia.

- The hub of the private commercial distribution chain for antimalarials is Lusaka, and most wholesalers and retailers operate as independent businesses, rather than franchises or vertically integrated models. Private sector businesses generally view the public sector as competitors, particularly as public facilities provide the first-line treatment, artemether-lumefantrine (AL) predominantly branded as Coartem, free of charge to patients. However, public sector stock outs continue to make it viable to sell ACTs in the private sector, including alternative brands of AL to Coartem, which is unaffordable for many Zambians.
- Because most antimalarials must be imported into Zambia, many respondents operating at all levels of the distribution chain had opinions regarding importation. Overall, the import market was perceived as difficult to enter, mainly due to the high transaction costs involved, including the fees charged by the Pharmaceutical Regulatory Authority to register products. Sole distributorship arrangements between foreign suppliers and Zambian importers were also perceived to be common. These factors work to create a high degree of market concentration at importer level.

- Choice of antimalarial supplier was influenced by many factors related both to the products stocked (e.g. product variety stocked, availability and price) and to business practices (e.g. established relationship, availability of credit, reputation, discounts and added value services offered); while the choice to stock certain products was primarily driven by demand.
- Selling prices were largely determined by the price paid to purchase the antimalarial from the supplier, but other factors affecting selling prices included operating costs (e.g. transport and delivery), competition, and product expiration dates. Price discrimination was common among retailers and wholesalers, who considered their customers' ability to pay and also existing relationships. Volume discounts were often also commonly given to customers.
- Suppliers were more inclined to deliver orders to customers located in the same vicinity, which was often one of the responsibilities of supplier sales representatives.
- Respondents also considered supplier sales representatives as important sources of information on antimalarials. Other important sources of information included the commercial and professional pharmaceutical associations to which many businesses belonged. However, respondents expressed the desire for more targeted information and training directly from government and regulatory authorities, particularly regarding policy and programme changes relevant to malaria treatment.
- Overall, respondents viewed current regulations as reasonable and well complied with, but raised several issues. Regarding licensing, smaller retailers (e.g. drugs shops) viewed the requirement to employ a pharmacist as a barrier that led many businesses to operate without a proper license. Respondents also acknowledged the presence of counterfeit antimalarials, the existence of a black market for antimalarials, and the problem of public sector ACTs leaking into the private market, although these problems were perceived to be small. The ban on the sale of oral AMT was widely perceived as effective.
- Although the recommended first-line treatment for uncomplicated malaria, predominantly branded as Coartem, was being provided free of charge in public facilities, respondents felt that frequent public sector stock outs forced many patients to seek treatment from private outlets. Because Coartem was widely viewed as unaffordable for most Zambians, some respondents chose to stock cheaper alternatives, such as generic ACTs and non-ACTs. RDTs were not commonly sold by private sector wholesalers and retailers, as many felt that RDTs were too expensive and that microscopy continued to be the preferred method of confirming diagnoses.

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 validity 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 market since then are likely to have occurred.

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