Evidence for Malaria Medicines Policy

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

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Contents

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. Benin's first-line treatment for *Plasmodium falciparum* malaria is artemether-lumefantrine.

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. The absolute mark-up is the difference between the selling price and the purchase price per dose. The percentage mark-up is 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. Benin's second-line treatment for *Plasmodium falciparum* malaria is artesunate-amodiquine.

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

ABMS	*Association béninoise pour le marketing social* (PSI affiliate in Benin)
ACT	artemisinin-based combination therapy
AETD	adult equivalent treatment dose
AL	artemether lumefantrine
AMFm	Affordable Medicine Facility - malaria
AMT	artemisinin monotherapy
ASAQ	artesunate-amodiaquine
ASMQ	artesunate and mefloquine
CAME	*Centrale d'achat de médicament essentiels et des consommable médicaux* (central stores)
CQ	chloroquine
DHA	dihydroartemisinin
DHA+PP	dihydroartemisinin and piperaquine
DPAV	*Dépôt paiement après vente* (consignments only paid for once inventory is sold)
DPM	*Direction des pharmacies et médicaments* (drug regulatory agency)
GDP	Gross domestic product
IMCI	Integrated Management of Childhood Illnesses
INT	intermediate level (wholesaler of supply chain)
IPT	intermittent preventive treatment of malaria
IRS	indoor residual spraying
LLIN	long lasting insecticide treated net
LSHTM	London School of Hygiene & Tropical Medicine
MEC	mutually-exclusive category of wholesalers
MOH	Ministry of Health, Benin
MQ	mefloquine
nAT	non-artemisinin therapy
NGO	non-governmental organisation
OS	ACTwatch Outlet Survey
OTC	over-the-counter
Pf	*Plasmodium falciparum*
PGHT	manufacturer's price before taxes
PMI	US President's Malaria Initiative
PNLP	*Programme nationale de lutte contre le paludisme* (national malaria control programme)
POM	prescription only medicine
PSI	Population Services International
RDT	rapid diagnostic test
SP	sulphadoxine pyrimethamine
WHO	World Health Organization
WS	wholesaler
XOF	West African CFA franc

Executive Summary

In Benin, 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 (Benin, Cambodia, the Democratic Republic of Congo (DRC), Madagascar, Nigeria, Uganda and Zambia). This report presents the results from qualitative interviews with antimalarial drug wholesalers, retailers and other key stakeholders conducted in Benin in June 2009. 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 key findings from the qualitative interviews can be summarized as follows:

- The size of the antimalarial market in Benin was perceived to be relatively small, with very few products manufactured domestically; and as such, many antimalarials used in both the public and private sectors must be imported, including the recommended first-line treatment, AL, and other ACTs.
- Nevertheless, the sale of antimalarials was important to many pharmaceutical wholesalers and retailers, accounting for a substantial proportion of their overall sales.
- Antimalarials in the private commercial sector are distributed via two largely distinct chains: a more formal chain composed primarily of licensed pharmaceutical businesses, including a few importers and wholesalers, several hundred retail pharmacies and drug shops (known as pharmaceutical depots), and private clinics and health facilities; while the second chain running in parallel is composed of unlicensed businesses, of which the dominant type are specialised vendors operating within traditional open-air markets in commercial hubs throughout the country that engage in both wholesale and retail sales. Other unlicensed businesses that compose this more informal chain include general retailers and itinerant vendors.
- It was generally accepted that a large proportion of all antimalarial treatments obtained by private sector consumers in Benin are distributed through unregistered businesses.
- Both registered and unregistered businesses stocked a range of antimalarials, including the recommended first-line treatment for uncomplicated malaria, AL; however, stocking decisions were overwhelmingly driven by demand, which led some unregistered businesses to not stock comparatively unaffordable ACTs. Awareness of RDTs was very low and few businesses stocked them.
- Many respondents expressed concerns about the provenance and quality of the products being sold by unregistered businesses, citing issues with the sale of counterfeits and substandard products. It was widely accepted that most of these products enter the market over Benin's porous borders as illegal imports from neighbouring countries with more developed pharmaceutical markets, such as Nigeria; and

to a lesser degree, as a result of unauthorised purchases from registered private wholesalers and leakage from the public sector.

- Although most registered and unregistered businesses viewed the current regulations governing the pharmaceutical sector as necessary, most acknowledged that these regulations were only being enforced among registered businesses, while unregistered businesses operate in plain view with virtually no regulatory oversight. Because of this, and given the large role played by these unregistered businesses in the distribution of antimalarial treatment to the population, there was a common concern about the quality of pharmaceutical care that consumers receive from unregistered businesses.
- This dichotomy in the antimalarial distribution chain also extended to pharmaceutical pricing, where a fixed pricing regime determines wholesale and retail prices among registered businesses, and where price setting among unregistered businesses is primarily constrained by market forces. Many agreed that unregistered vendors, particularly those based within traditional open-air markets, typically offered antimalarials at lower prices compared to registered businesses, which is partly due to the differential application of pricing regulation across the two distribution chains, but may also be attributed to differences in costs (e.g. most market vendors do not deliver or pay licensing fees) and product mix (e.g. market vendors may tend to stock cheaper antimalarials, such as generics and older treatments like chloroquine).
- Although the formal and informal antimalarial distribution chains are distinct in many respects and often aim to capture different market segments, they do not operate in isolation from one another. Several accounts described transactions between the chains, such as instances of registered retailers and private health facilities purchasing their antimalarial stock from unlicensed market vendors. In addition, many respondents belonging to one chain often viewed businesses from the other chain as competitors because they targeted similar customers. For example, because registered businesses cannot compete on price due to pricing regulations, they must employ other strategies in order to differentiate themselves from registered and unregistered competitors, such as by maintaining regional warehouses and fleets of delivery vehicles to increase their geographic coverage and local presence.

1. Introduction & Objectives

Alongside the public and non-profit sectors, private commercial providers are important sources of malaria treatment in Benin. 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 Benin, Cambodia, the Democratic Republic of Congo (DRC), Madagascar, Nigeria, Uganda and Zambia. 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 *Association béninoise pour le marketing social* (ABMS) in Benin.

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, retailers and other related stakeholders conducted in Benin in June 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

Benin, located on the Gulf of Guinea, shares borders with Nigeria, Togo, Burkina Faso and Niger and has a population of 8.8 million. [2] Governed by a strict Marxist-Leninist government that enacted heavily interventionist economic policies in the 1970s and 1980s, Benin's annual gross domestic product (GDP) growth rate in that period was extremely volatile. However, following a transition to democratic governance in the early 1990s, annual GDP growth has remained positive, averaging 4.4%. [2]

Despite sustained growth over the last two decades, Benin remains a largely poor country. GDP per capita is estimated at US$1500 (constant 2008 US$, adjusted for purchasing power parity, PPP) [3], and about 39%[1] of the population lives under the national poverty line. [4] The percentage increases to over 47% when using the World Bank poverty line of US$1.25/day PPP-adjusted. [4] In terms of the Human Development Index, Benin is ranked 163rd out of a total of 177 countries. [5] The majority of the population, approximately 58%, lives in rural areas. [2] The agricultural sector accounts for 32% of GDP and provides a source of livelihood

[1] Most recent figure for 2003

for about 70% of the population. Cotton is Benin's main export commodity, comprising between 25% and 40% of the country's exports. [6] India and China are Benin's most important trade partners, jointly buying 47% of Benin's exports. [7]

Health System

Benin's health system is largely decentralised and is relatively easily accessible to the general population. For example, 77% of the population lives less than 5km away from a health facility; however, it is important to note that only 44% of the population use the health services offered at these facilities. [5] Although 11% of the national budget is allocated to the health sector (accounting for 4.7% of GDP and 8% of total public expenditure), households are the source of 52% of total health expenditure. [5] Public health facilities typically charge fees for consultation, medications and procedures; and the income raised from these fees, which accounts on average for 43% of the Ministry of Health (MOH) budget, is kept at facility level and allocated based on the community's needs in accordance with MOH policies. [8] The MOH subsidises fees for the poorest families, although there are reports that many at the bottom of the socio-economic ladder are unaware they are eligible for these benefits. [8]

Health service delivery in the public health sector was reorganised in 2010 and is structured as a pyramid with three levels. At the top are the Ministry of Health and Central Directorates, as well as a National Referral Hospital. The intermediate level is comprised of Departmental Directorates for Health and six referral hospitals. The bottom level is comprised of 34 health zones, which each cover an average population of 230,000[2]. In theory, each health zone contains zone hospitals, community health centres, private health facilities and village health units. [8] The private health sector in Benin includes licensed practitioners, private hospitals, and faith-based organizations, as well as unregistered clinics, drug providers and drug sellers. The number of unlicensed health facilities is difficult to determine, but it is widely accepted that a large number of patients acquire medication from informal sellers. A 2003 study by the *Fondation Pierre-Fabre* found that 40% of the 600 households interviewed in Cotonou acquired medicines from informal sellers. [9] Furthermore, many private health clinics are not registered with the MOH; a 2005 study of private health practices in four of the country's twelve departments showed that only 12% of private health practices were authorised by the MOH. [10]

Pharmaceutical Sector

The pharmaceutical sector in Benin is regulated by the *Direction des Pharmacies et Médicaments* (DPM), which is under the umbrella of the MOH, and is in charge of designing and ensuring the implementation of the national health policy in relation to the pharmaceutical sector, medications and traditional medicine. The DPM's tasks include creating and enforcing national pharmaceutical policies and requirements for opening and operating businesses that carry medical and pharmaceutical products. Additionally, the DPM is responsible for regulating the supply of medical and pharmaceutical goods for both the private and public sectors, creating and disseminating a list of authorised medications, and examining policies related to taxation and price setting of the aforementioned goods. Lastly, the DPM is also responsible for controlling the sale of illicit medications. [11]

[2] Although for health purposes the country is divided into health zones, administratively the country is divided into 12 departments, which are further subdivided into 77 communes. Each health zone covers between one and four communes.

Malaria Epidemiology and Control Strategies

Malaria is a leading cause of morbidity and mortality in Benin. In 2009, 4,537,600 suspected malaria cases were reported. [12] The disease burden is especially severe among children. One in 8 children in Benin die before their fifth birthday [13] and malaria is responsible for about 32% of those deaths. [14] The disease also places an enormous strain on the health infrastructure, accounting for 40% of outpatient consultations and 25% of hospital admissions. [14]

Malaria is endemic across the entire country. The predominant parasite is *Plasmodium falciparum* (*Pf*) and the predominant vector is *Anopheles gambiae.* [8] There are three distinct regions of malaria transmission: the coastal region in the south where malaria transmission is heterogeneous due to the presence of both *Anopheles gambiae* and *Anopheles melas* mosquito vector species, the inland area where transmission is holoendemic, and the north where malaria transmission is seasonal. Although malaria transmission occurs year round, malaria rates are highest during the rainy season. [8]

The government of Benin aimed to halve malaria morbidity and mortality by the year 2010. To meet this goal, the five-year National Malaria Control Strategy was developed for the period 2006 to 2010. The core interventions for malaria control in Benin include long lasting insecticide-treated net (LLIN) distribution through antenatal care clinics and immunisation visits, universal campaigns, and subsidised and at-cost sales in the private sector; intermittent preventive treatment for pregnant women (IPTp); case management (following diagnosis) at all levels of health care; and, to a more limited extent, indoor residual spaying (IRS). Benin has removed import tariffs on mosquito nets, antimalarials and RDTs; as of August 2010 tariffs still applied to pumps and insecticides used for IRS. [15]

National Treatment Policy

In 2005, the country adopted artemether-lumefantrine (AL) as the first-line treatment for uncomplicated malaria. Artesunate-amodiaquine (ASAQ) is recommended for patients under six months of age, for those who cannot tolerate AL, and when AL is not available. Parenteral quinine is recommended for severe malaria. Cases of malaria in pregnant women are defined as severe and, as such, should also be treated with quinine. Furthermore, Integrated Management of Childhood Illnesses (IMCI) guidelines recommend that children under the age of five with anaemia should also be treated with antimalarials. [8] Oral artemisinin monotherapy (AMT) has been banned since 2006. [13] At the time of data collection for this survey public facilities provided AL for a fee and are permitted to keep part of the proceeds from these sales. AL blister packs of 6, 12, 18, and 24 tablets were sold for 150 XOF (US$0.31), 300 XOF (US$0.63), 450 XOF (US$0.94) and 600 XOF (US$1.26), respectively[3]. [8]

According to the national policy, children under the age of five with a febrile illness should be treated presumptively for malaria. For patients aged five or older, the policy recommends that antimalarials be reserved for those whose malaria has been confirmed, either through RDTs or through microscopy. However, according to a report from the US President's Malarial Initiative (PMI) published in 2011, the government is considering changing the policy and requiring that all cases of malaria, regardless of age, be confirmed. Consequently, diagnostic testing is being scaled up alongside ACTs. Although microscopy should in theory be available in hospitals and large health facilities, equipment is not always functional and laboratory technician skills are often sub-optimal.

[3] The average exchange rate during the data collection period (4-29 June 2009) was 478.059 West African CFA francs (XOF) to US$1

The National Malaria Control Programme (*Programme nationale de lutte contre le paludisme*, PNLP), with help from PMI and the World Bank Booster Programme, is currently working to identify weaknesses in diagnostic services. It is estimated that Benin needs a total of 129 microscopes to cover departmental hospitals, health zones, and commune health centres through 2015. It is also estimated that approximately 648,000 RDTs are needed to cover the public sector in 2011. Because RDTs have been introduced recently, procurement is difficult as there is little data on consumption practices. [8]

Antimalarial Treatment Coverage and Access

According to the ACTwatch Baseline Outlet Survey completed in October 2008, first-line treatment (AL) was most frequently available in public health facilities (66%) or pharmacies and rural outpost pharmacies (77%). However, it was infrequently found in private health facilities (9%) and very rarely found in other types of informal outlets (1%). In total, only about 7% of all outlets surveyed carried AL. Non-artemisinin therapies, on the other hand, were carried by a total of 67% of outlets surveyed, with chloroquine, quinine and SP the kinds of medication that were most frequently in stock. [16]

In terms of treatment seeking behaviour, the ACTwatch household survey conducted in April and May 2009, found that only 41% of children under five with fever were treated with antimalarials, and only 7% with first-line treatment. Approximately 40% of those treated with an antimalarial received it from a public health facility, while 17% sourced antimalarials from informal outlet types, such as kiosks, market stalls and mobile vendors. Public health facilities were by far the most common source of ACT treatment; 73% of those seeking ACT obtained it from this source.[13]

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. [17] 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 (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 organizations such as associations of wholesale pharmacists. 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, from various trading environments (e.g. inside and outside of traditional markets), 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. pharmacies, pharmaceutical depots, clinics, market vendors).

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 French, piloted by trained data collectors, and further revisions were made to adapt the tools to the specificities of the Beninese 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 emphasised 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, 6 key informant and 27 in-depth interviews were conducted in Benin (Table 3.1). Of the 27 in-depth interviews, 12 were with market vendors distributed across all levels of the distribution chain. Respondents at two retailers and one top-level wholesaler refused to participate.

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

Business type/Distribution chain level	Number of interviews
Retailer[1]	9
Terminal wholesaler[2]	6
Intermediate wholesaler[3]	6
Top-level wholesaler[4]	6
Total	27

1: Retailers interviewed included 3 pharmaceutical depots, 2 market vendors, 2 private clinics, 1 health centre selling medicines, and 1 public hospital selling medicines; several registered retail pharmacies were also interviewed, but were included among terminal and intermediate wholesaler categories because these businesses were observed to wholesale at these levels. 2: Of these, 3 were registered retail pharmacies and 3 were market vendors. 3: Of these, 2 were registered retail pharmacies and 4 were market vendors. 4: Of these, 3 were registered wholesale pharmacies and 3 were market vendors.

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. Composition of the distribution chain for antimalarials

Antimalarial wholesalers

- The overall size of the antimalarial market in Benin was perceived to be relatively small with few top-level wholesalers. At the time of data collection, there were 3 importing wholesalers registered with the pharmaceuticals regulatory authority (DPM) actively supplying antimalarials in the private sector.[4] These wholesalers reported importing antimalarials from international manufacturers based mainly in Western Europe, India and China, but also mentioned importing products from other West African countries, including Nigeria, Togo, and Ghana. In order to clear customs, importing wholesalers need to present authorisation from the DPM and pay a clearance tax totalling 2.5%.
- A domestic manufacturer was also producing unbranded generic formulations of quinine and SP, but there was no domestic manufacturing capacity for ACTs.[5]
- Respondents at the top of the distribution chain also reported supplying wholesalers outside of Benin, specifically in Cameroon and Nigeria.
- Alongside the procurement of generic medicines on the National Essential Medicines List for public sector use, Benin's public sector procurement and distribution agent, the *Centrale d'Achat des Médicaments Essentiels et des Consommables médicaux* (CAME), has also been selling antimalarial products to private sector buyers since 1994. However, stock that is funded by donors, such as products intended for vertical disease control programs, cannot be purchased by private sector buyers. For example, CAME is responsible for storing and managing large volumes of Coartem financed by the World Bank and other donors on behalf of the National Malaria Control Program (PNLP). Private sector buyers cannot purchase these stocks of Coartem.[6]

Antimalarial retailers

- Patients in Benin access treatment for malaria in a diverse range of outlets in the public and private sectors, including registered pharmacies, pharmaceutical depots and private clinics. Unregistered outlets are also believed to be a significant source of antimalarial treatment in Benin.
- Registered pharmacies are owned and managed by a pharmacist, and tend to be concentrated in urban centres. For example in 2009, 48% of registered pharmacies were based in Cotonou, and 8.3% in Porto

[4] A fourth wholesaler was inactive due to financial difficulties, and a fifth wholesaler had submitted an application for registration.
[5] Only one of the two domestic pharmaceutical manufacturers registered with the DPM produces antimalarial treatments.
[6] At the time of data collection, a significant portion of the stock of Coartem currently being stored by CAME was at risk of expiry. To prevent these supplies from being wasted, the PNLP was considering distributing this stock to non-profit private health centres, particularly faith-based organisations.

Novo, the two largest cities. They sell a variety of prescription and over-the-counter medicines, as well as nutritional supplements and cosmetic products. In 2009, there were 180 registered pharmacies in Benin.

- To increase the geographical accessibility of pharmaceuticals beyond the areas covered by registered pharmacies, a type of registered outlet category similar to drug shops, called pharmaceutical depots, was introduced by the DPM. As of 2008, there were 279 depots registered in Benin. These outlets must be located at least 10km away from a registered pharmacy, and must close if a pharmacy opens in the area. Depots must sign a memorandum of understanding with a registered pharmacy from which it must purchase all pharmaceuticals[7] directly, rather than purchase supplies from public or private sector wholesalers; however in practice, depots often procure antimalarials from multiple sources. For example, to take advantage of lower purchase prices, depots sometimes buy antimalarials directly from private wholesalers or CAME. Since depots are not authorised to purchase supplies from either private or public wholesalers, the depots interviewed explained these purchases were facilitated by personal connections. Depots may also purchase supplies from registered pharmacies with which they have not signed a memorandum of understanding.
- Antimalarials are also available in private sector health facilities, which include both private for-profit clinics and non-profit religious health centres. Many clinics in the private sector are not registered with the Ministry of Health. A 2005 study of private health practices in Borgou, Alibori, Mono, and Couffou found that only 12% were authorised by the MOH.[8] Private clinics are not supposed to sell pharmaceuticals to patients, but rather charge patients for medicines used during hospitalisation. For outpatient visits, the clinic should write a prescription to be filled at a registered pharmacy or pharmaceutical depot. However, there is a widespread perception that some private clinics, particularly those that are unregistered, do not follow this rule and supply pharmaceuticals directly to patients. In terms of supply, larger private clinics typically procure antimalarials from CAME. Some private clinics also buy supplies from private wholesalers.[9] Trading among private clinics is common as small clinics that do not have access to a public or private wholesaler may buy their antimalarials from larger clinics. This is particularly true for small faith-based health centres. Private clinics also purchase antimalarials from registered pharmacies or pharmaceutical depots.
- As such, although businesses may be assumed to operate only at a single level of the chain (i.e. importers operating at top-level; pharmacies at retail level), many often operate simultaneously across several levels. For example, many wholesalers categorised as 'intermediate' because they were observed to purchase from wholesalers and supply other wholesalers, also retailed antimalarials directly to consumers. In addition, several retailers stated that they not only sold to consumers, but to informal retailers as well, such as itinerant drug vendors.

Unregistered wholesalers and retailers and the informal sector

- As previously mentioned, respondents widely believed that the informal sector played a considerable role in the distribution of antimalarials in Benin. While the exact size of the informal sector in Benin is unknown, one pharmacy respondent from Cotonou asserted that the informal sector handled around 60% of total pharmaceutical trade [ID 18]. Many respondents also believed that a large proportion of antimalarial treatments were dispensed to patients through the informal sector, largely composed of unregistered drug sellers. This is supported by a 2003 study in Cotonou conducted by the *Fondation Pierre-Fabre* which found that 40% of the 600 households interviewed had purchased medicines from

[7] Depots are not permitted to sell all registered pharmaceutical products, such as narcotic and psychoactive drugs.
[8] Cited in Adeya, G. et al. 2007. *Évaluation rapide du système de santé du Bénin.* Arlington, VA: Management Sciences for Health.
[9] Private wholesalers are not authorised to sell medicines to private health facilities.

informal sellers. [9] Unregistered outlet types include itinerant drug sellers, stalls and stores in markets, and stalls and stores outside of markets. These types of outlets often sell fast moving consumer goods, as well as some medicines (primarily antipyretics).

- In terms of the distribution channels that supply medicines sold by unregistered outlets, data collected from each outlet about their two most important antimalarial supply sources during the first round of the ACTwatch Outlet Survey by PSI/Benin in 2008 revealed that, of the 524 unregistered retail outlets providing this information,[10] 85% identified one of Benin's traditional open-air markets as their top supply source, while the *Marché Dantokpa* located in Cotonou was named the most frequently. [16] Results from the ACTwatch supply chain survey [1] also underscored the considerable role that these traditional open-air markets play in Benin's private pharmaceutical sector overall. This survey found that 67% of all supplier mentions gathered from a representative sample of private sector outlets referred to markets located in both large cities and small towns. At wholesale level, 76% of all wholesalers interviewed as part of the supply chain survey were located in markets, and 60.2% of all wholesalers surveyed reported at least one market-based supplier as their top supply source of antimalarials. See section 4.5.2 for additional discussion on unlicensed businesses in the antimalarial distribution chain.

4.1.2. Range of antimalarial products

- All three registered wholesalers that supply antimalarials reported regularly stocking a large proportion of registered antimalarials, including many different ACTs, AMTs and non-artemisinin therapies (nATs) in a range of dosage forms, and under a variety of brand and generic names. This may be explained by the fact that regulatory requirements oblige wholesalers to stock 90% of the pharmaceuticals registered in Benin.[11] Consequently, manufacturers do not have sole distributorship agreements for registered pharmaceuticals, or other special relationships with particular importers. The manufacturers also do not have rules pertaining to sale prices, order volumes or embedded sales teams.

Figure 4.1: (left) Registered pharmacy in urban area, and (right) typical traditional open air market selling antimalarials

[10] In the 19 sub-districts visited during Round 1 of the ACTwatch Outlet Survey, 653 informal retail outlets were identified that either had antimalarials in stock at the time of the visit or stocked antimalarials in the past 3 months. Of the 653 outlets, 20% either did not know their top supplier for antimalarials or refused to answer the question.

[11] All imported and domestically manufactured antimalarials must be registered by the *Service d'Enregistrement, de Statistique et de Controle de Qualité* (SESCQ) of the DPM. Each dosage form and presentation of an antimalarial product must be registered individually. Moreover, if a manufacturer would like to register an antimalarial that is essentially identical to one that is already registered, it must be at least 15% less expensive than the antimalarial already registered. The fee for registering a new product is 250 000 XOF (US$ 522.95). Registrations must be renewed every 5 years for a fee of 100 000 XOF (US$209.18). Décret n^{o} 97-632 du 31 December 1997. *Recueil des textes législatifs et réglementaires du secteur pharmaceutique.* 2^{e} édition. Decembre 2007.

- By comparison, the range of antimalarials available for purchase by private sector buyers from CAME was more limited, but included ACT tablets and suspensions, AMT injectables, and quinine and SP tablets and injectables. While all ACT and AMT products carried by CAME for private sector sale were imported, several nAT tablet products were manufactured domestically. The recommended first-line treatment, AL, was available for private sector purchase in unbranded generic form, and the Coartem brand of AL stocked by CAME on behalf of the PNLP could only be distributed in the public sector.
- The registered pharmacies visited stocked a wide range of antimalarial products, including ACTs, AMTs and nATs in multiple brands, strengths and dosage forms for most compounds.
- Pharmaceutical depots stocked fewer antimalarials and hold much smaller inventories relative to registered pharmacies.
- Many vendors operating in traditional open-air markets also stocked different brands of the first-line treatment, AL, alongside mainly nATs such as chloroquine and quinine, but a number of these vendors did not stock AL.

4.1.3. Competition

- The large wholesalers registered with the DPM perceived each other as their principal competitors. Some of these respondents also considered the pharmaceutical wholesalers operating in the large traditional open-air markets as competitors, but others did not. One respondent did not perceive these market vendors as competitors because he believed that the products being sold by these vendors were of dubious quality and provenance [ID 22], and another respondent said that these market-based wholesalers targeted a different market segment [ID 24].
- Wholesalers operating within traditional open-air markets located in the national commercial hubs of Cotonou and Porto Novo only described the multitude of other market vendors as competitors. Apart from being based in the same locality, several respondents also perceived these other wholesalers to be competitors because they tended to sell the same or similar products.
- The scope of perceived competitors was broader among market-based wholesalers located in the various regional commercial hubs visited as part of this study (e.g. Bohicon, Parakou, Lissezoun). In addition to other market vendors operating within the same locality, several respondents included registered pharmacies among their list of competitors; while one respondent also mentioned government health centres [ID 12], and another mentioned CAME [ID 5]. Yet another one of these respondents indicated not having any real competitors due to the range of strategies that they used to retain customers [ID 3].
- Similarly, retail pharmacies considered a broad range of businesses as competitors, including health centres, private hospitals and clinics. Some pharmacy respondents also considered market vendors operating in the 'parallel market' to be competitors because such market vendors also supplied other wholesalers, retailers, health centres and hospitals [ID 2]. It was interesting to note that registered pharmacies did not mention other pharmacies among the list of perceived competitors. One respondent believed that this reflects the regulations which prevent the density of pharmacies in a given locality from rising above a set ratio of pharmacies per population [ID 18].
- In one moderately accessible market location in the north, retailer types other than pharmacies (i.e. private clinics and pharmaceutical depots) considered the *'bonne dames'* operating small medicines vending stalls to be particularly shrewd competitors as they typically sold products at comparatively lower prices; these respondents also believed that the medicines being sold by these small businesses were of inferior quality [ID 10, ID 11].

- Vertical or horizontal integration was not commonly used by pharmaceutical businesses as a strategy to compete more vigorously and increase market share; however, several of the large registered wholesalers have established regional warehouses to facilitate distribution across the country. See section 4.2.5 for more information on restocking and distribution practices.

4.1.4. Barriers to entry

- Respondents identified several factors limiting the number of formal registered wholesalers in Benin.
- First, Benin's relatively small population (and consequently small market) was perceived to limit the number of importers that could be profitable. Existing wholesalers have well-established distribution networks and relationships both with their customers and suppliers, most of which are located outside of Benin. This was perceived to constrain a new entrant's ability to compete
- Second, the segmentation of the private commercial sector for pharmaceuticals between the formal and informal sectors was perceived to further limit the number of registered importers and wholesalers. Respondents at all levels of the distribution chain cited the informal sector as a significant competitor for antimalarial drug sales and was perceived as taking potential customers from the formal sector, and consequently reducing the demand for the products procured by registered importers and wholesalers.
- Third, while regulations requiring wholesalers to maintain a minimum operating capital of 100,000,000 XOF (US$ 209,179) and also stock three months' inventory of 90% of all registered pharmaceuticals make an important contribution to ensuring availability of medicines for the private sector, these same requirements discourage the formation of smaller wholesalers.
- Other factors associated with wholesaler registration identified as barriers include the requirement that 70% of the business' capital must be owned and operated by registered pharmacists and several steps of the registration processes required by the *Registre de Commerce et du Credit*, such as the completion of a technical feasibility study, and the registration fee of 550,000 XOF (US$ 1150).

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

- Most respondents, regardless of distribution chain level, considered *supplier selling prices* as the key factor in choosing a supplier. For example, one retailer located in a moderately accessible town in the south of Benin described his preference to bypass retail pharmacies located nearby to purchase new stock directly from wholesalers because the cheaper prices offered by wholesalers allow him to apply higher mark-ups of 25%, rather than 10% if supplied by pharmacies [ID 14]. Despite being mandated to purchase all supplies from the registered pharmacy with which they have signed a memorandum of understanding, respondents also described that in practice pharmaceutical depots often procured antimalarials from private wholesalers, CAME or even from market vendors [ID 15] in order to take advantage of lower purchase prices. Because depots are not authorised to purchase supplies from either private or public wholesalers, respondents from depots explained that these purchases were facilitated by personal connections.

- Such *personal and business relations* were also mentioned as an important factor by other businesses operating at lower levels of the distribution chain. For example, because importers and wholesalers typically have minimum bulk order values, some respondents described being able to bypass these restrictions by using personal contacts within suppliers in Benin and Nigeria. A pharmacist in Cotonou mentioned that because he owned shares in one of Benin's registered importing wholesalers, he tried to purchase as much new stock as possible from that wholesaler [ID 2].
- *Product promotions and discounts* also influenced choice of supplier. The most commonly cited type of promotion offered by suppliers was small discounts for customers paying in cash or purchasing in large quantities (see section on 4.2.7 on sources of capital). Several respondents also described a now defunct scheme where customers would receive free units from wholesalers if purchasing in large quantities. To qualify for these promotions, pharmacies would often pool orders together (also see section 4.2.6 on cooperation among businesses). While this type of promotion is now prohibited in Benin, it continues in neighbouring countries acting as an incentive for some businesses to purchase clandestinely abroad.
- A *provider's expertise, knowledge or qualification* was cited by intermediate and terminal wholesalers as an attractive supplier characteristic for potential customers. This was mentioned as being relevant during shortages or stock outs of particular antimalarials, when knowledgeable suppliers could recommend appropriate alternatives.
- *Reputation* was brought up as an important factor by some respondents in both choosing a supplier and in attracting and retaining clients; although this was not as important among top-level wholesalers, likely because these wholesalers purchase directly from manufacturers abroad that have been pre-approved by the DPM. Fear of counterfeit drugs and the ubiquity of the informal sector seemed to augment the importance of purchasing from a reputable source, as reputation and reliability were closely associated with effectiveness and quality of the medications. The quality of a wholesaler's customer service and the speed of filling orders were also mentioned as important factors that influence the selection of supply sources. Beyond this, there also seemed to be a temporal dimension to reputation. For example, one market-based terminal wholesaler mentioned that he attracted clients because his business was widely regarded as being the first to start selling medications in the market [ID 19].
- Because prices are regulated among top-level suppliers (see section 4.2.4 on price setting), supplier differentiation relied on other characteristics, such as by *offering credit*. While private wholesalers offered credit, CAME required payment at the time of purchase; some respondents mentioned this as a reason why they prefer to buy from private wholesalers in certain situations (see also section 4.2.7 for more discussion on credit and other sources of financing).
- *Location* was also a factor influencing choice of supplier for some, particularly for businesses purchasing from foreign suppliers. Many of these respondents preferred suppliers in Nigeria due to the favourable exchange rate between the Naira and the West African CFA franc, as well as the abundance of manufacturers in Nigeria which tends to drive down prices. This preference was particularly strong among respondents in Porto Novo, which is very close in proximity to Lagos.
- In terms of changing suppliers, several respondents in remote and semi-accessible areas mentioned that they typically purchased from their regular suppliers partially out of habit. Registered pharmacists indicated that they typically purchased most of their antimalarials from one preferred registered wholesaler, but would buy stock from other wholesalers in cases of stock outs. This preference reflects the situation described above in which owners of registered pharmacies are often shareholders in a private wholesaler, and consequently prefer to purchase supplies from that wholesaler (see section 4.2.6 on cooperation among businesses).

- To attract and keep customers, registered wholesalers reported occasionally sending staff to verify that their customers were satisfied with the service provided, such as to check if orders were filled accurately and delivered promptly; but these staff were not considered to be sales representatives (see section 4.4.1 for more discussion on the use of sales representatives). To preserve customer loyalty, registered wholesalers sometimes offered rebates to customers that pay in cash, repay credit on time, or purchase large volumes. Rebates of approximately 3% to 10% of the total value of an order or the total value of orders over a defined period of time (such as orders placed over the past year) are offered to these customers, since the unit costs of pharmaceuticals are fixed in Benin (see section 4.2.4 for discussion on price setting).
- Although regulations restrict the types of suppliers from which different outlet types may purchase (e.g. health facilities may only purchase from CAME) in practice, these restrictions are not always adhered to.

4.2.2. Drug Availability

- All respondents described having problems with drug availability, and that both the large registered wholesalers and CAME experienced stock outs. However, respondents' perceptions of the frequency of stock outs varied, with only a few top-level wholesalers stating that stock outs occurred frequently [ID 25, ID 26, ID 27]. One pharmacy respondent attributed these stock outs to the lack of domestic manufacturing capacity, and drew comparison with Morocco where the pharmaceutical manufacturing sector grew as a result of political intervention, which helped to alleviate availability issues in that country [ID 2].
- There were also contrasting opinions about the availability of ACTs. One retailer in a remote area mentioned that he could not find ACTs among his usual suppliers, as he would otherwise stock them [ID 10]. On the other hand, a terminal wholesaler in Cotonou mentioned that the growing diversity of available ACT types and brands reduced the likelihood of a complete stock out of all ACTs [ID 18].
- Access to sufficient capital also impacted drug availability. For example, several retailers explained that stock outs of antimalarials resulted from not being able to maintain larger inventories as they did not have access to credit [ID 14]. See section 4.2.7 for more discussion on credit.

4.2.3. Product selection and stocking decisions

- Customer demand was mentioned by nearly all respondents at all levels of the chain as one of the key factors in deciding what products to stock and in what quantities. According to some respondents, prescribers often specify the brand name of the product (as opposed to the generic name) when writing prescriptions, and therefore play a key role in creating demand for a specific product. In addition, respondents from pharmacies explained that consumer and individual pharmacist preferences also played a role in their businesses' stocking decisions.
- Perceived drug quality and/or effectiveness were also mentioned. However, several respondents (two intermediate-level and one terminal wholesaler) revealed that there was a trade-off between affordability and quality because it was sometimes challenging to sell antimalarials of the highest quality as these often more expensive products were much less affordable to consumers, limiting demand and the profit from their sale.

4.2.4. Price setting

Price regulation in CAME and among registered private wholesalers and retailers

- The prices of pharmaceutical products in the formal private sector are regulated to ensure that the entire population can buy medicines for the same price regardless of where they live. The basis for calculating the prices of antimalarials bought from private wholesalers is the manufacturer's price before

taxes (PGHT). This price excludes all taxes, transportation and insurance costs. The wholesaler's selling price is calculated by multiplying the PGHT by a coefficient of 1.36. Similarly, the retail price is calculated by multiplying the PGHT by a coefficient of 1.78. Pharmaceutical depots are able to purchase products from registered pharmacies at a discount of 8% from the retail price (effectively allowing them a mark-up of 8% when reselling at the fixed retail price). Public health facilities are able to purchase products from wholesalers at a discount of 13% from the retail price.[12] To ensure that prices are stable, at the time a pharmaceutical is registered the manufacturer must provide a detailed explanation of a product's cost structure and set the PGHT for a period of five years.[13] After five years, the manufacturer can apply to the *Commission Tarifaire des medicaments et spécialités pharmaceutiques* to adjust the PGHT.[14]

- Products bought from CAME have a different pricing structure. CAME's selling price is calculated by multiplying the total price of the product once it reaches the central warehouse (including freight, insurance, clearance, and other charges) by a coefficient of 1.2. The retail price is calculated by multiplying CAME's selling price by a coefficient of 1.5. If this is higher than the price that is obtained by multiplying the identical product's PGHT x 1.78, the final price must be reduced to this level. Table 4.1 compares the price structures for products purchased from CAME with products purchased from private wholesalers.
- The pricing structure created for CAME's products is not applied uniformly. The regulation that established the pricing structure applies to public and private health facilities only.[15] There is ambiguity on how registered pharmacies and pharmaceutical depots should price products procured from CAME.
- There were also contrasting views on whether these fixed price structures were well respected by private wholesalers, registered pharmacies, and pharmaceutical depots. For example, several respondents suggested that the price structure differed between generic and branded products, and others said that established prices were not respected during periods of product shortage.
- Some respondents also believed that the fixed mark-up prescribed by the *Commission Tarifaire* was too low to generate an acceptable level of income. For example, one respondent from a pharmaceutical depot suggested that the permitted mark-ups for this business type be increased from 8% to 15%, as the current pricing regime incentivises depots to seek alternative suppliers, including the parallel market, with prices that are lower than those of the pharmacy to which they are tied [ID 15].

Table 4.1: Price and mark-up structures for antimalarials purchased from CAME and private wholesalers

	Medicines bought from private wholesalers	**Medicines bought from CAME**
Wholesale price	PGHT X 1.36	Price after taxes, international and local transport X 1.2
Retail price	PGHT X 1.78	Wholesale price X 1.5
Wholesaler mark-up	36%	20%
Pharmacist's mark-up	31%	50%

[12] Arrêté Interministériel n^{0} 006/MICPE/MSP/MFE/DC/DCCI du février 2002 *Recueil des textes législatifs et réglementaires du secteur pharmaceutique.* 2^{e} édition. Décembre 2007.
[13] Décret n^{o} 97-632 du 31 December 1997
[14] Arrêté Interministériel année 2003 n^{0} du 029/MICPE/MSP/DC/SG/DC/DCCI/DPED 18 juin 2003. *Recueil des textes législatifs et réglementaires du secteur pharmaceutique.* 2^{e} édition. Décembre 2007.
[15] Arrêté Interministériel n^{0}11063/MS/MDEF/DC/SGM/CTJ/DPM/SA du 26 octobre 2006. *Recueil des textes législatifs et réglementaires du secteur pharmaceutique.* 2^{e} édition. Décembre 2007.

Factors influencing price and mark-up

- Purchase price was the main determinant of selling price and was mentioned by nearly half of all respondents, followed by a range of different operating costs. Of these, expenditure on transport (e.g. for collecting and delivering orders) was most frequently mentioned, and other significant costs included rent, taxes and customs charges (mentioned by importers). One market-based intermediate wholesaler also mentioned several costs related to "being part of the black market", but did not elaborate on what these costs were [ID 3].
- Several other factors affecting price or mark-up were mentioned only by single market-based respondents. One retailer described how product scarcity caused by disruptions in supply or instances where only one or two distributors carry a particular product led to price increases that force buyers to seek alternatives [ID 9]; an intermediate wholesaler indicated that she reduces the price of a product if its expiration date is approaching in order to quickly sell off remaining stock and minimise loss from wastage [ID 3]; and another intermediate wholesaler said that the mark-up applied depended on the type of antimalarial: quinine had the highest mark-ups and Nivaquine, a foreign brand of chloroquine, had the lowest [ID 4].
- Offering discounts when customers purchased large volumes (i.e. second degree price discrimination) was commonly mentioned by respondents, particularly among intermediate-level wholesalers; but respondents described several other situations in which they would offer discounts to customers, including loyal/repeat customers and if customers paid in cash rather than with credit. For example, one retailer described applying a mark-up that was 15 percentage points higher to purchases made by specific clinics because they were given credit terms of several months [ID 14], and some respondents said that they apply lower mark-ups when selling directly to patients as opposed to other wholesalers or retailers. However, one large health facility in Cotonou described being unable to apply any mark-up when selling medicines to smaller faith-based health centres because they were supplied by CAME only and could not access the cheaper products offered by private wholesalers [ID 8].

4.2.5. Restocking and distribution practices

CAME

- According to CAME's standard operating procedures, competitive tendering (opened or closed) should be the standard method for procuring supplies. However, CAME's antimalarial stocks that can be purchased by private sector buyers, in particular ACTs, are procured through consignment (*Dépôt paiement après vente,* DPAV). Under this practice, manufacturers deliver antimalarials or other pharmaceuticals to CAME's storage facilities. Supplies are not paid for until after they are sold, and unsold inventories are the property of the manufacturer, not CAME.
- Pharmaceuticals procured by CAME are stored at the central level warehouse located in Cotonou. Medicines are delivered directly from the central warehouse to two major public health facilities located in Cotonou and two regional warehouses located in Parakou and Natitingou. CAME does not normally distribute pharmaceutical products beyond its regional depots, but on request can make its vehicular fleet available on a cost-recovery basis to buyers that place large orders.
- Private sector buyers typically collect orders directly from the central or regional warehouses. Orders must be paid for in cash, as credit is not available. Customers must pay for any costs incurred to transport pharmaceuticals from the warehouse to their facilities.

Registered wholesalers

- All three wholesalers use their own fleet of vehicles to deliver antimalarials to registered pharmacies, while one wholesaler reported having contracts with inter-city public taxis to reach certain remote pharmacies, but the private wholesalers do not deliver orders to private clinics [ID 22]. Supplies are delivered free of charge to all registered pharmacies regardless of where they are located. The frequency of deliveries ranges from 4 times per day in Cotonou and Porto Novo to three times per week for pharmacies located in more remote areas. Two wholesalers have regional warehouses (in Bohicon and Parakou) to facilitate distribution to pharmacies located outside of Cotonou and Porto Novo.
- Each wholesaler reported employing a logistician responsible for quantifying purchase volumes. Orders for antimalarials are not placed at specific intervals, but instead are based on sales volumes over the past 15 days to three months. All three wholesalers endeavoured to maintain an inventory sufficient to cover sales for three months, in accordance with regulatory requirements. One wholesaler stated that they adjust their order volumes so that they have a larger inventory of antimalarials in July and August to account for the high transmission period [ID 17].
- The lead time between placing an order and the receipt of antimalarials ranges from one to three months, depending on how quickly the manufacturer can fill the order and the type of transportation used (i.e. air vs. sea). To clear imported antimalarials through customs, the wholesaler must present authorisation from the DPM, and pay clearance taxes totalling 2.5%.[16]

Pharmacies

- Pharmacies reported maintaining a small inventory of antimalarials that is sufficient to cover their sales for one week to one month, and indicated that quantification of orders was based on recent sales volumes (sales of the past day to the past two weeks).
- The frequency of placing orders depended on the business practices of each individual pharmacy, but ranged from twice per day to two times per month. For orders placed with private wholesalers, lead times ranged from two hours (for pharmacies located in Cotonou or Porto Novo) to two days (for pharmacies further north). Pharmacies located in Cotonou indicated that most orders are filled the same day or early the next morning if the order was placed late in the afternoon. Orders placed with CAME were also often ready for pick-up the same day.
- Pharmacies purchasing stocks from CAME must pay cash for their orders, and cover transportation costs. In contrast, private wholesalers provide credit for 15-30 days on all orders, and do not charge pharmacies for deliveries.

Market vendors

- Restocking frequency among these respondents varied greatly, with larger businesses in Cotonou placing orders anywhere from once per month to once every three months, and wholesalers in smaller towns tending to restock more frequently, up to two times per day.
- Respondents at the top of the chain and terminal level wholesalers reported a mix of both having orders delivered and collecting orders from their suppliers, while most businesses operating at the intermediate wholesale and retail levels mentioned that suppliers did not deliver and they had to collect orders themselves.

[16] The clearance tax is broken down as follows: *Redevance Statistique*: 1%, *Prélèvement Communitaire de Solidarité*: 1%; *Prélèvement Communitaire*: 0.5%. Medicines are exempt from the following taxes : *Droit de Douane, Taxes sur Valeur Ajoutée, Droit fiscal*, and *Commission CNCB*.

- Decisions on the size and scope of orders for most respondents were based primarily on previous sales; however, one large vendor in Porto Novo who admitted to selling mostly illegally imported medicines indicated that he did not stock large quantities in order to minimise potential loss if apprehended and his stock confiscated by the authorities [ID 27].
- It was less common for market vendors to deliver orders to their customers, although this varied somewhat by supply chain level. More of those operating at the top and intermediate levels of the chain reported delivering, sometimes using their own vehicles and in one case, only if the customer paid for their order up front [ID 1]. One large vendor based in Cotonou also described using taxis to deliver orders, where the customer covered the cost of delivery [ID 23]. No terminal wholesalers or retailers reported delivering orders.

4.2.6. Cooperation among businesses

- Most respondents stated that they were not aware or were members of any trade or professional associations. However, several respondents at all levels of the chain described a variety of ways in which businesses and professionals collaborated both formally and informally.
- Most examples of collaboration regarded practicing pharmacists and registered pharmacy retailers. One intermediate-level respondent described that the benefits of belonging to the professional union of pharmacists, the *Syndicat des Pharmaciens du Bénin,* included the sharing of information and collective representation for political lobbying, such as demanding a clear policy from the government on the prices of generic medications [ID 1]. Given the regulatory requirement that at least 70% of pharmaceutical wholesale businesses must be owned by pharmacists and the high operating capital involved (see section 4.1.4), groups of pharmacists have pooled their resources to establish registered wholesalers in Benin. Because many of these pharmacist-shareholders also own and operate their own retail pharmacies, these wholesale businesses are often the sole or major suppliers of these retail pharmacies [ID 2].
- Private clinics purchasing pharmaceuticals from CAME also cooperated by pooling orders through the Association of Private Clinics of Benin, which also organises meetings and conferences for members [ID 13].
- Several market-based respondents described cooperating informally by borrowing units of stocked out products from neighbouring businesses or friends. However, one retailer originally from Nigeria indicated that he was often excluded from participating in such informal collaboration due to his nationality [ID 9].
- In one of the large traditional markets in Cotonou, a large wholesaler reported belonging to an association of market vendors that played a quasi-regulatory function within the market by conducting surveys of vendors for expired, banned and other substandard products, and imposing penalties on offending businesses, such as by forcing shops to close for periods of one to three months [ID 23].

4.2.7. Sources of capital

- At the higher levels of the chain, businesses reported using mainly a combination of bank loans/credit and revenues from sales to finance their inventory, and several others at this level also mentioned using capital from microcredit and semi-formal group saving schemes (sometimes collectively referred to as *tontines*); while retailers and terminal wholesalers relied almost exclusively on their savings and revenues, with one retailer located in a remote location believing that there was no possibility of accessing credit facilities from banks or other types of lenders [ID 10].

- A few retailers and wholesalers did have access to credit facilities from their suppliers, who typically provided credit terms of 15 to 30 days; although, several retailers described that the value of credit and the terms provided could vary depending on past repayment performance. In addition, while the large registered wholesalers provided credit to customers, CAME required all qualifying customers, such as pharmacies, to pay for their orders in cash.
- Respondents at all levels of the chain expressed concerns about a lack of capital necessary to run businesses in the long term. Due to insufficient capital, some respondents said they were often unable to order buffer stock to minimise the chances of stock-outs due to supply disruptions, and one upcountry retailer said that he sometimes did not have sufficient revenues to restock at all [ID 14]. Lack of capital also prevented several respondents from delivering merchandise to their clients, a service they believed would allow them to be more competitive.

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, many respondents refused to answer and others preferred to speak in general terms rather than give specific figures. Where detailed, these costs are reported in both the local currency and US dollars.[17] Nearly all respondents were unable or refused to provide estimates of start-up costs.

4.3.1. Revenue from antimalarial sales and fluctuations in sales

- Of the 15 respondents who discussed revenues, most considered antimalarial sales to be important to their overall business. For example, when estimating relative to total sales volumes and revenues, antimalarials typically accounted for between 10% and 25%, and most respondents ranked antimalarial sales volumes as either first or second among different types of medication. However, several respondents clarified that, although sales of antimalarials may be very high in terms of volume, this did not necessarily mean they were as high in terms of revenue generation.
- There were some deviants from these general patterns: one large market vendor based in Cotonou indicated that antimalarial sales accounted for half of total volumes sold [ID 23]; while a respondent working at a health centre indicated that antimalarial sales only generated a very small proportion of total revenues, as consultation fees generated much more revenues in comparison [ID 7].
- Most respondents, regardless of supply chain level, reported fluctuations in antimalarial sales, with peaks coinciding with the rainy season that runs roughly from May through September; although, some respondents mentioned that antimalarial sales remain high year round.

4.3.2. Cost structure

- When asked about their typical expenditure on a number of recurrent expenses, including rent, electricity, inventory, water, telephone, regular and casual employment salaries, stationary, transport, marketing, fees to DPM and associations (e.g. professional or trade), licences, insurance, transportation (e.g. vehicles for deliveries), security, taxes and tariffs, only 11 respondents provided information, of which 9 were market-based vendors operating across all levels of the distribution chain and the remaining 2 were rural pharmaceutical depots. In several cases, respondents did not know the typical expenses for all categories, and some of the data collected was incomplete or more qualitative (e.g. 'our important expenses are...').

[17] The average exchange rate during the data collection period (4-29 June 2009) was 478.059 West African CFA francs (XOF) to US$1

- Rent was considered an important recurrent expense for most market-based vendors, and ranged from 5000 XOF to 11,500 XOF per month (US$ 10.45-24.05) at retail, terminal and intermediate levels of the chain, and up to 30,000 XOF per month (US$ 62.75) among market vendors operating at the top of the chain. Among the pharmaceutical depots that provided rental expense data, one spent 15,000 XOF per month (US$ 31.38) and the other owned the premises and did not pay rent.
- Other important expenses mentioned by several respondents included employee salaries (18,000-70,000 XOF per month, US$ 37.65-146.42), telephone costs (1500-6000 XOF per month, US$ 3.14-12.55), and transport costs. Regarding transport costs, one market-based vendor described paying up to 500 XOF per transaction (US$ 1.05) to the men who transport his stock in carts; while a large vendor based in a Cotonou market said that he spent 150,000 XOF per month (US$ 313.77) on transport.
- It was also noted that market vendors reported not having any expenses related to pharmaceutical licences, professional memberships, insurance or marketing.
- Most respondents also indicated that they paid some type of tax, including business and local taxes. Many respondents also considered the annual fees associated with maintaining a business licence (‘*patente*’) as a type of tax, which ranged from 8000-25,000 XOF per year (US$ 16.73-52.29).

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 and demand generation

- Market-based wholesalers and retailers identified their suppliers and other vendors as their main sources of information about antimalarials, but also mentioned learning about products from product packaging and inserts, through the media, and from prescriptions presented by customers.
- On the other hand, more formal types of businesses, such as registered wholesalers, pharmacies, pharmaceutical depots and health facilities, mentioned a wider range of information sources, including their suppliers, medical representatives, the DPM, professional bodies, unions, media and other health facilities or colleagues who were health professionals. Individual respondents from this group also mentioned the PNLP, medical literature and the internet as sources of information.
- Both wholesalers and retailers reported receiving sales or medical representatives; however, most of these businesses were of the more formal type and were located in the two major cities of Cotonou and Porto Novo. These representatives were not sent by wholesalers themselves to promote specific products; instead, they are employed by pharmaceutical manufacturers either directly or through a third-party agency. Representatives are typically responsible for a specific territory and visit health facilities and other retail outlets (such as registered pharmacies) to promote the manufacturer’s products. Several respondents postulated that the representatives have a significant impact on doctors’ prescription practices and consequently, demand for certain products.

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 parallel/black market, counterfeits, substandard products, and suggestions to improve regulation of the pharmaceutical sector.

4.5.1. General views on regulation and enforcement

- Many respondents from registered businesses, such as pharmacies, pharmaceutical depots, clinics and registered wholesalers, believed that the regulatory instruments governing the pharmaceutical sector in Benin were appropriate; and several market-based vendors even acknowledged the need for and value of these instruments.
- Most respondents from registered businesses also believed that registered businesses generally complied with the regulations and that the level of enforcement among these businesses was acceptable. Respondents described being inspected by agents of the DPM once or twice per year, during which inspectors would verify storage conditions, recordkeeping, the range of products in stock, and their expiration dates. One depot also described receiving impromptu inspections [ID 14].
- However, there was widespread consensus among both registered and market-based businesses that regulations were not being effectively enforced, and that businesses operating within traditional open-air markets did so without any or very little regulatory oversight. For example, one market vendor admitted to having had no previous dealings with agents of the DPM [ID 3], while another vendor described how several years prior, after the authorities had confiscated her stock and forced her business to close, she reopened a few days later and had continued to operate since [ID 6]. Other respondents echoed these experiences, stating that although fines were imposed on unregistered market vendors from time to time, the sale of medications in markets has continued.
- For the most part, respondents perceived the lack of regulatory enforcement as a symptom of limited capacity within the DPM, rather than as a result of corruption. For example, one respondent from Cotonou sympathetically confided that the "DPM inspectors do what they can" [ID 1].
- Perhaps as a reflection of the regulatory vacuum that persists in traditional markets, one large market vendor in Cotonou indicated that he was a member of an association that surveys market vendors for expired and banned products [ID 23]. See section 4.2.6 for more related discussion on cooperation among businesses.

4.5.2. Unlicensed businesses & the black/parallel market

- The black or parallel market was generally perceived to include any type of unlicensed medicine outlet (e.g. market stalls, itinerant vendors, unauthorised clinics); but when discussing the parallel market, most respondents referred to vendors in traditional open air markets.
- Virtually all respondents acknowledged that the black market existed and operated in plain view, and many respondents – particularly from registered businesses – believed it to be significant, using terms such as *omnipresent*, *enormous* and *everywhere* when describing it. A few estimated that the parallel market accounted for between 40% [ID 17] to 60% [ID 18] of total pharmaceutical trade in Benin, and a number of registered businesses viewed black market vendors as competitors because they supplied similar customers, such as retail pharmacies [ID 21] and hospitals [ID 22].
- Several different sources of drugs sold in the black market were identified by respondents. Some speculated that drugs were leaked from registered wholesalers through illicit transactions [ID 21] or

purchased from these wholesalers or CAME by market vendors using falsified documents or through personal connections [ID 22, ID 7]. There were many who also believed that black market products were imported from neighbouring countries (Nigeria, Togo, Ghana), where prices are often lower. In relation to this, one retailer in the north said that much of the black market chloroquine was being sourced in neighbouring countries where its sale had not yet been banned [ID 10]. A large market vendor in Porto Novo cited the ease of accessing comparatively cheaper suppliers in Lagos as the main reason why many vendors in Porto Novo imported illegally [ID 27]. This respondent went on to describe making smaller purchases more frequently when restocking in order to minimise losses if caught importing illegally; and also transporting his stock in a separate vehicle when returning from Lagos to avoid getting apprehended with the illegal goods.

- Respondents from both registered businesses and market vendors expressed a number of ways in which the trade of antimalarials in the black market compromised the quality of pharmaceutical care provided to consumers. Although the sale of chloroquine in the private sector was forbidden, several respondents said that consumer demand for chloroquine persisted and was consequently widely available among market vendors [ID 10]. Others described how market vendors dispensed as they saw fit, even if customers presented prescriptions [ID 5]. But there were still a number of respondents from both registered businesses and market vendors who believed that the black market served the population by helping consumers to access antimalarials because antimalarials could always be purchased from market vendors (although this was not always the first-line treatment) [ID 7] and at much more affordable prices when compared to registered pharmacies and other more formal types of outlets [ID 3].
- With this in mind, several market vendors felt that more effort should be made to integrate market vendors into the more formal pharmaceutical sector. Providing vendors with training on stock management [ID 23] and appropriate medicine use [ID 26] were suggested as one way to do this; while others felt that given the important public service that market vendors provide, the authorities should stop 'persecuting' market vendors [ID 9] and create avenues for those already providing high quality pharmaceutical services to operate within the law [ID 5] by simplifying regulatory requirements and reducing barriers to entry (see section 4.1.4).

4.5.3. Counterfeit, substandard and expired drugs

- Respondents from registered businesses and market vendors believed that counterfeit and poor quality drugs were widely available in markets across the country, due in large part to the porous borders that facilitate the illegal import of drugs from neighbouring countries, prompting one market vendor to suggest more regulatory enforcement at points of entry to curb the sales of these drugs [ID 6].
- But some market vendors stressed that not all businesses participating in the parallel market sold counterfeit and substandard products, and that some exercised good storage practices in order to preserve product quality. Some also emphasised that there were many market vendors who consciously chose reliable suppliers selling quality genuine medicines.
- Because inspectors checked for expired stock during inspections, registered businesses did not feel that expired drugs were a problem [ID 7], but believed that expired products could be found in markets.
- In terms of drug quality monitoring, most respondents were critical of the status quo. Although, there previously existed a means to collect adverse event data from consumer reports through points of sale and passed up to manufacturers [ID 21], most respondents were unaware if a pharmacovigilance system was currently in place, and several confided that despite pharmacists imploring government to operationalise such as system for nearly a decade [ID 2], plans were still at the 'embryonic' stage.

- A few respondents indicated that lot quality testing was occasionally done, but that most batches and consignments avoided this testing [ID 8], and one respondent also mentioned that samples were sometimes drawn from retail pharmacies for quality testing [ID 24].

4.5.4. Licenses

- In addition to the concerns and suggestions regarding unlicensed businesses described in section 4.5.2, several respondents from registered businesses voiced other issues.
- A respondent from one of the large registered wholesalers expressed concern about issuing too many licenses to wholesalers, as this may lead to overcrowding within the wholesale market [ID 22].
- Pharmacies, on the other hand, felt more secure about their position and share of the market. One respondent said that this was largely the result of the regulations that cap the number of pharmacies operating in a particular locality according to a population-based ratio [ID 18]. However, another pharmacist insisted that the requirements for new entrants did not go far enough, and suggested that pharmacists should be required to have some experience before being permitted to establish a new pharmacy [ID 17].
- One respondent from a rural pharmaceutical depot took issue with the rule whereby pharmacies were legally allowed to displace depots. This respondent believed that pharmacies used depots to do the groundwork of creating demand in rural areas, and that once market conditions were favourable, only then would pharmacies open, consequently forcing the depot to close [ID 14].

4.5.5. Leakage of public sector drugs to the private sector

- Respondents at all levels of the chain from both registered businesses and market vendors stated that it was common to find public sector drugs for sale in traditional markets. For example, a 2009 study found that ACTs designated for the public sector were being sold in markets [18], and one vendor who admitted to sometimes selling these leaked drugs expressed a preference for them, believing them to be of good quality [ID 4].
- When speculating about the source of these leaked public sector drugs, another vendor suspected them to come from 'fraudulent transactions' at health centres [ID 26].

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, only a few respondents discussed these topics.

- Only two top-level wholesalers briefly discussed issues related to RDTs.
- Although both believed that RDT use needed to increase to reduce the practice of presumptive treatment and self-medication, they advised that their use should be restricted to health professionals. Furthermore, one of these respondents felt that RDTs should be restricted to health centres and not distributed through retail pharmacies [ID 24].

5. Summary of Key Findings

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

- The size of the antimalarial market in Benin was perceived to be relatively small, with very few products manufactured domestically; and as such, many antimalarials used in both the public and private sectors must be imported, including the recommended first-line treatment, AL, and other ACTs.
- Nevertheless, the sale of antimalarials was important to many pharmaceutical wholesalers and retailers, accounting for a substantial proportion of their overall sales.
- Antimalarials in the private commercial sector are distributed via two largely distinct chains: a more formal chain composed primarily of licensed pharmaceutical businesses, including a few importers and wholesalers, several hundred retail pharmacies and drug shops (known as pharmaceutical depots), and private clinics and health facilities; while the second chain running in parallel is composed of unlicensed businesses, of which the dominant type are specialised vendors operating within traditional open-air markets in commercial hubs throughout the country that engage in both wholesale and retail sales. Other unlicensed businesses that compose this more informal chain include general retailers and itinerant vendors.
- It was generally accepted that a large proportion of all antimalarial treatments obtained by private sector consumers in Benin are distributed through unregistered businesses.
- Both registered and unregistered businesses stocked a range of antimalarials, including the recommended first-line treatment for uncomplicated malaria, AL; however, stocking decisions were overwhelmingly driven by demand, which led some unregistered businesses to not stock comparatively unaffordable ACTs. Awareness of RDTs was very low and few businesses stocked them.
- Many respondents expressed concerns about the provenance and quality of the products being sold by unregistered businesses, citing issues with the sale of counterfeits and substandard products. It was widely accepted that most of these products enter the market over Benin's porous borders as illegal imports from neighbouring countries with more developed pharmaceutical markets, such as Nigeria; and to a lesser degree, as a result of unauthorised purchases from registered private wholesalers and leakage from the public sector.
- Although most registered and unregistered businesses viewed the current regulations governing the pharmaceutical sector as necessary, most acknowledged that these regulations were only being enforced among registered businesses, while unregistered businesses operate in plain view with virtually no regulatory oversight. Because of this, and given the large role played by these unregistered businesses in the distribution of antimalarial treatment to the population, there was a common concern about the quality of pharmaceutical care that consumers receive from unregistered businesses.
- This dichotomy in the antimalarial distribution chain also extended to pharmaceutical pricing, where a fixed pricing regime determines wholesale and retail prices among registered businesses, and where price setting among unregistered businesses is primarily constrained by market forces. Many agreed that unregistered vendors, particularly those based within traditional open-air markets, typically offered antimalarials at lower prices compared to registered businesses, which is partly due to the differential application of pricing regulation across the two distribution chains, but may also be attributed to differences in costs (e.g. most market vendors do not deliver or pay licensing fees) and product mix (e.g.

market vendors may tend to stock cheaper antimalarials, such as generics and older treatments like chloroquine).

- Although the formal and informal antimalarial distribution chains are distinct in many respects and often aim to capture different market segments, they do not operate in isolation from one another. Several accounts described transactions between the chains, such as instances of registered retailers and private health facilities purchasing their antimalarial stock from unlicensed market vendors. In addition, many respondents belonging to one chain often viewed businesses from the other chain as competitors because they targeted similar customers. For example, because registered businesses cannot compete on price due to pricing regulations, they must employ other strategies in order to differentiate themselves from registered and unregistered competitors, such as by maintaining regional warehouses and fleets of delivery vehicles to increase their geographic coverage and local presence.

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 are likely to have occurred since then.

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