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A Qualitative Assessment of the Private Sector Antimalarial Distribution Chain in the Democratic Republic of Congo, 2010



December 2012

Country Program Coordinator

Dr. Louis Akulayi Tshisungu

Association de Sante
Familiale/DRC
232, Avenue Tombalbaye
Croisement Kasai
Kinshasa/Gombe
Democratic Republic of the
Congo Phone: + 243 998 23 96 80
Email: lakulayi@psicongo.org

Co-Investigators

Sarah Tougher
Benjamin Palafox
Edith Patouillard
Catherine Goodman

London School of Hygiene & Tropical Medicine
Department of Global Health & Development
Faculty of Public Health & Policy
15-17 Tavistock Place
London WC1H 9SH
Phone: +44 207 927 2389
Email: benjamin.palafox@lshtm.ac.uk

Principal Investigator

Kara Hanson

London School of Hygiene & Tropical Medicine
Department of Global Health & Development
Faculty of Public Health & Policy
15-17 Tavistock Place
London WC1H 9SH
Phone: +44 20 7927 2267
Email: kara.hanson@lshtm.ac.uk



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ACTwatch is a project of Population Services International (PSI), in collaboration with the London School of Hygiene & Tropical Medicine. The ACTwatch Group comprises of a number of individuals:

PSI ACTwatch Central:

Tanya Shewchuk, Project Director
 Dr Kathryn O’Connell, Principal Investigator
 Hellen Gatakaa, Senior Research Associate
 Stephen Poyer, Research Associate
 Illah Evans, Research Associate
 Julius Ngigi, Research Associate
 Erik Munroe, Research Associate
 Tsione Solomon, Research Associate

PSI ACTwatch Country Program Coordinators:

Cyprien Zinsou, PSI/Benin
 Sochea Phok, PSI/Cambodia
 Dr. Louis Akulayi, ASF/DRC
 Jacky Raharinjatovo, PSI/Madagascar
 Ekundayo Arogundade, SFH/Nigeria
 Peter Buyungo, PACE/Uganda
 Felton Mpasela, SFH/Zambia

London School of Hygiene & Tropical Medicine:

Dr. Kara Hanson, Principal Investigator
 Dr. Catherine Goodman, Co-investigator
 Dr. Edith Patouillard, Co-investigator
 Benjamin Palafox, Co-investigator
 Sergio Torres Rueda, Co-investigator
 Sarah Tougher, Co-investigator
 Dr. Immo Kleinschmidt, Co-investigator

Other individuals who contributed to ACTwatch research studies in DRC include:

| | |
|---------------------|---|
| Willy Mpwate | ACTwatch Assistant, Association de Santé Familiale/DRC |
| Dr Godé Mpanya | Research Manager, Association de Santé Familiale/DRC |
| Delphin Kayembe | Research Assistant, Association de Santé Familiale/DRC |
| Edouard Talnan | Regional Research Director, PSI/Benin |
| Sandra Le Fèvre | Pfizer Research Fellow, ACTwatch |
| Dr Jean A Angbalu | National Malaria Control Program, Ministry of Health, DRC |
| Séraphine K Kimwesa | National Malaria Control Program, Ministry of Health, DRC |

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A technical review of the ACTwatch supply chain study protocol was provided by the following ACTwatch advisory committee members:

| | |
|--------------------------|---|
| Mr. Suprotik Basu | Advisor to the United Nations Secretary General's Special Envoy for Malaria |
| Mr. Rik Bosman | Supply Chain Expert, Former Senior Vice President, Unilever |
| Ms. Renia Coghlan | Global Access Associate Director, Medicines for Malaria Venture |
| Dr. Thom Eisele | Assistant Professor, Tulane University |
| Mr. Louis Da Gama | Malaria Advocacy & Communications Director, Global Health Advocates |
| Dr. Paul Lalvani | Executive Director, RaPID Pharmacovigilance Program |
| Dr. Ramanan Laxminarayan | Senior Fellow, Resources for the Future |
| Dr. Matthew Lynch | Malaria Program Director, VOICES, Johns Hopkins University Centre for Communication Programs |
| Dr. Bernard Nahlen | Deputy Coordinator, President's Malaria Initiative (PMI) |
| Dr. Jayesh M. Pandit | Head, Pharmacovigilance Department, Pharmacy and Poisons Board–Kenya |
| Dr. Melanie Renshaw | Chief Technical Advisor, ALMA |
| Mr. Oliver Sabot | Vice President, Vaccines Clinton Foundation |
| Ms. Rima Shretta | Senior Program Associate, Strengthening Pharmaceutical Systems Program, Management Sciences for Health |
| Dr. Rick Steketee | Science Director, Malaria Control and Evaluation Partnership in Africa (MACEPA) |
| Dr. Warren Stevens | Health Economist |
| Dr. Gladys Tetteh | Deputy Director Country Programs, Systems for Improved Access to Pharmaceuticals and Services, Management Sciences for Health |
| Prof. Nick White, OBE | Professor of Tropical Medicine at Mahidol and Oxford Universities |
| Prof. Prashant Yadav | Director-Healthcare Delivery Research and Senior Research Fellow, William Davidson Institute, University of Michigan |
| Dr. Shunmay Yeung | Paediatrician & Senior Lecturer, LSHTM |

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Definitions

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

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

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

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

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

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

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

First-line treatment: The government recommended treatment for uncomplicated malaria. DRC's first-line treatment for *Plasmodium falciparum* malaria was artesunate-amodiaquine (4mg/10mg/kg).

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.

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

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

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

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

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

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

Abbreviations

| | |
|--------------------|--|
| ACT | artemisinin-based combination therapy |
| AL | artemether lumefantrine |
| AMFm | Affordable Medicine Facility - malaria |
| AMT | artemisinin monotherapy |
| ASAQ | artesunate-amodiaquine |
| ASF | <i>Association de Santé Familiale</i> (PSI affiliate in DRC) |
| ASRAMES | <i>Association Régionale pour Approvisionnement en Médicaments Essentiels</i> (Regional association for the supply of essential medicines) |
| BCAF | <i>Bureau de Coordination des Achats</i> (Office for the Coordination of Purchases) |
| BCZS | <i>Bureau Central de Zone de Santé</i> (Health Zone Central Office) |
| CDF | Congolese franc |
| CDR | <i>Centrale de Distribution Régionale</i> (Regional Distribution Centre) |
| CQ | chloroquine |
| DPM | <i>Direction des pharmacies et médicaments</i> (drug regulatory agency) |
| DRC | Democratic Republic of Congo |
| FBO | faith-based organisation |
| GDP | Gross domestic product |
| Global Fund | Global Fund to Fight AIDS, Tuberculosis and Malaria |
| IPT | intermittent preventive treatment of malaria |
| IRS | indoor residual spraying |
| LLIN | long lasting insecticide treated net |
| LSHTM | London School of Hygiene & Tropical Medicine |
| MOH | Ministry of Health, DRC |
| MSH | Management Sciences for Health |
| nAT | non-artemisinin therapy |
| NGO | non-governmental organisation |
| OCC | <i>Office congolais de contrôle</i> (national quality control laboratory) |
| OS | ACTwatch Outlet Survey |
| OTC | Over-the-counter |
| Pf | <i>Plasmodium falciparum</i> |
| PMI | US President's Malaria Initiative |
| PNLP | <i>Programme nationale de lutte contre le paludisme</i> (national malaria control programme) |
| PSI | Population Services International |
| RDT | rapid diagnostic test |
| SNAME | <i>Système National d'Approvisionnement en Médicaments Essentiels</i> (National System for Procurement of Essential Medicines) |
| SP | sulphadoxine pyrimethamine |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |
| WS | wholesaler |

Executive Summary

In Democratic Republic of Congo (DRC), 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, 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 DRC between January and March 2010. To provide a complete description of the supply chain for antimalarial drugs, this report should be read in conjunction with the report on the results of the quantitative supply chain survey also conducted as part of this study [1], available at www.actwatch.info.

The key findings from the qualitative interviews can be summarized as follows:

- Selling antimalarials is a key revenue generating activity for private sector wholesalers and retailers, and the private sector is an important source of antimalarials in the country.
- The private commercial sector market for antimalarials in DRC is composed of a number of domestic manufacturers, many importers, wholesalers and a range of different retailing outlets, primarily large and small retail pharmacies, and private clinics. Itinerant vendors and traders selling antimalarials in traditional open air markets were not perceived to be common.
- Vertically integrated businesses, where a single corporate entity owns and operates manufacturers, importers and wholesale distributors, were a common and distinct feature of the private sector antimalarial distribution chain in DRC. Several of these maintained production facilities in neighbouring countries or in India. This arrangement possibly reflects the challenges of importing and transporting medicines within the country, but also helps these companies to capture greater shares of the market and maximise profits through economies of scale.
- Although one would expect market power to be concentrated among vertically integrated businesses, other findings suggest that the wholesale market for antimalarials in DRC is competitive. When setting prices, competition was the primary consideration for most respondents, including those operating within vertically integrated companies. A range of different strategies were also used by suppliers to gain competitive advantages (e.g. exclusive distributorship agreements with manufacturers, the pervasive use of sales representatives for marketing), and to attract and retain customers (e.g. offering discounts, bonuses and gifts; maximising convenience for customers).
- However, delivery services or credit facilities were not commonly offered to customers by suppliers, and particularly not to retailers who typically collected orders themselves and relied on cash flow to finance restocking. Retailers also reported experiencing stock outs more frequently than wholesalers.
- Wholesaler and retailer stocking decisions were primarily driven by customer demand (i.e. business-to-business transactions for wholesalers, and consumer purchases for retailers), which was used to explain

the persistence of artemisinin monotherapies (AMTs) and older non-artemisinin therapies (nATs), such as chloroquine on the market, and also the low uptake of artemisinin-based combination therapies (ACTs) through the private sector. Alongside low levels of awareness, a key barrier to the wider use of ACTs suggested by respondents was their poor acceptability among the population, largely due to their comparative unaffordability and perceived side effects, in the case of artesunate-amodiaquine (ASAQ).

- Potential strategies to improve ACT use through the private sector suggested by respondents included reducing import taxes and tariffs on antimalarials to decrease end-user prices, increasing public awareness of ACTs, and improving retailer knowledge and opinions of ACTs and the treatment guidelines, to leverage their influence over consumer treatment choices.
- Unlike wholesalers who reported having multiple sources of information on antimalarials, retailers relied heavily on private sector sources of information to learn about new products and even about the changes to the malaria treatment guidelines following the adoption of ACTs. As such, improving retailer knowledge and opinions of ACTs could involve increasing communication to this group from public sector sources and improving the knowledge and opinions of ACTs among the suppliers of retailers at higher levels of the distribution chain.
- The pharmaceutical regulatory system is perceived to be weak and cannot adequately ensure the quality of products or pharmacy practice in the private sector across the country. Confidence in the regulatory system is further undermined by corruption that many respondents believe occurs at multiple levels of the private sector distribution chain. Regulatory issues of common concern include the high prevalence of counterfeit and substandard antimalarials in the private sector and the proliferation of unlicensed retail outlets that provide poor pharmaceutical care to consumers.
- Rapid diagnostic tests for malaria were not available in the private sector at the time of data collection.

1. Introduction & Objectives

Alongside the public and non-profit sectors, private commercial providers are important sources of malaria treatment in the Democratic Republic of Congo (DRC). 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, 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 de Santé Familiale* (ASF) in DRC.

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 DRC between January and March 2010. 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 quantitative supply chain survey also conducted as part of this study [1], available at www.actwatch.info.

2. Country Background

Social and Economic Profile

DRC is located in central Africa and is the second largest country by area on the continent. The first Republic of Congo was formed in 1960 upon gaining independence from Belgium; however since then, the country has experienced several name changes and incarnations of the republic – the current being the 3rd Republic. The centre of DRC is a vast low-lying river basin exhibiting a hot and humid tropical climate. The basin experiences a long rainy season that lasts 8 to 10 months per year, with around 2m of rainfall per year and an average temperature of 26°C. In the east of DRC mountains rise up from the river valley and the climate is cooler and wetter. In 2009 the population was estimated at 71.7 million, making it the fourth most populous country in Africa. [2] Approximately 20% of the population is under five years of age [3], and 40% of households are located in urban areas. [4] Administratively DRC is divided into 11 provinces and 45 districts. The official language is French, with Kikongo, Lingala, Tshiluba and Swahili recognised as national languages. The country's modern history has been turbulent and in 2003 DRC emerged from nearly a decade of civil war; however, there is continuing violence in the east of the country and an estimated 2 million people remain displaced by the conflict. [5]

Although more than 70% of economic activity in DRC is in the agriculture and service sectors, economic growth has largely been driven by industrial activity, particularly in mining. In 2009, the economy grew by 2.9% compared to 7.2% in 2010 and 6.5% in 2011, partly due to the global recession but also to fluctuations in global market prices for DRC's key mineral exports in 2009. [2] But despite the vast natural wealth, the country remains poor with 2009 per capita gross domestic product (GDP, adjusted for purchasing power parity) estimated at US\$ 300 – although this is based on a GDP value that excludes exchanges in the substantial informal economy – and a high degree of income inequality, with more than a third of the nation's wealth belonging to the richest 10% of households. [2] An estimated 80% of the population live on less than US\$1 a day and the country was ranked 176 out of 182 countries according to the 2009 Human Development Index. [6] Life expectancy in 2009 was under 55 years [2], and it is estimated that one in seven children die before reaching their fifth birthday. [4] These poor social conditions are exacerbated by the poor state of public infrastructure, particularly in transport and communication. Some parts of the country are considered to be unreachable, and transport in many rural areas is provided solely through private services. [7]

Health System

The health system has suffered from years of civil war and chronic underinvestment, and the government currently has limited capacity to rebuild the social sector. The health sector is largely unregulated and scant up-to-date information exists regarding the public and private sectors. The public sector is built around the health zone (*zone de santé*), an administrative area that typically covers a population of 100,000 in rural areas and 150,000 in urban areas. Each health zone is organized around a central office (*bureau central de zone de santé*, BCZS), which includes a general referral hospital, and is further divided into health areas (*aires de santé*) where health centres operate. There are currently more than 6000 health centres offering a basic package of services scattered across 515 health zones across the country. [8] In 2009, government expenditure on health was estimated at 2% of GDP. [9] Public sector patients are charged user fees for almost all aspects of their health visit, from consultation and diagnostic tests to medicines, and the revenues generated are used to fund the day-to-day operations of health providers, which may include procuring out-of-stock medicines from private sector suppliers. There is no regulation of the amounts charged and fees are set at the level of the health centre or hospital.

The public health sector is characterized by low utilisation rates (providing care for as little as 30% of reported illnesses [10]); while the private sector, including private not-for-profit services provided by non-governmental organisations (NGOs) and faith-based organisation (FBOs), is estimated to provide 60% of the health services used by the population. [11] The majority of the NGO and FBO services are provided with external donor support, creating a fragmented system as each donor and partner works in specified health zones. Under this model, 391 of the 515 health zones are reported to have a partner providing malaria services, leaving 24% of health zones unsupported. [11]

Pharmaceutical Sector

There are several legislative and regulatory instruments governing the pharmaceutical sector in DRC, with the earliest remaining in effect since 1933; although there have been several revisions and updates to regulations, most recently in 2009 with the assistance of Management Sciences for Health (MSH), the US Agency for International Development (USAID) and the WHO. The pharmaceutical regulatory authority in DRC is the *Direction de la pharmacie, médicaments et plantes médicinales* (DPM), a section within the national Ministry of Health (MOH), which is responsible for the registration of pharmaceutical products for

sale on the market; inspection of premises; granting of licenses to pharmaceutical enterprises; promotion of generic medicines and local manufacturing; oversight of the marketing of pharmaceutical products; regulation of controlled substances, veterinary, cosmetic and dietary products; pharmacovigilance, quality assurance and control; maintenance of the national formulary and pharmacopoeia; and regulation of prices at manufacturing, wholesale and retail levels. [12] The DPM issues different licenses and authorisations to enterprises for the manufacture, import, wholesale, and retail of pharmaceuticals, which do not have an expiration date. Each type of pharmaceutical business must employ a full-time pharmacist with current registration and must also possess a trading license (*registre de commerce*). Within retailing, regulations define two types of enterprises: private pharmacies (*officines*), and facility/hospital pharmacies (*pharmacies internes/ hospitalières*); and within wholesaling, there are wholesalers (*établissements de vente en gros*), distribution centres (*centrales de distribution*) and centralised purchasers (*centrales d'achats*), the last two typically functioning as state-run or parastatal agencies. Registration of pharmacists is overseen by the Order of Pharmacists (*L'Ordre des Pharmaciens*), of which there were 1144 in 2008. [13]

Malaria Epidemiology

Malaria is one of the leading causes of mortality, and DRC has one of the highest malaria burdens in Africa: suspected malaria accounts for an estimated 40% of outpatient visits by children under five, and 40% of all-cause under-five mortality. [11] Nearly 8 million suspected malaria cases were reported in 2009 [14], and estimated annual deaths from malaria are on the order of 140,000¹. [15] Given reporting completeness of less than 70% for outpatient health facilities, coupled with the fact that many people do not seek care for illness at a formal health facility or receive parasitological confirmation, there is some uncertainty about the true burden of malaria-related morbidity and mortality.

Virtually all of the population (97%) live in areas with stable, perennial malaria transmission (with seasonal peaks in the country's tropical zone) while the remaining 3% live in areas with unstable malaria. The mountainous regions in the east of the country, including parts of Katanga, the Kivus and Ituri, are generally considered unstable and at risk of malaria epidemics. *Plasmodium falciparum* is the predominant parasite species, responsible for 95% of infections. [8] In mid-2007, the country adopted a new national malaria control plan (*Faire Reculer le Paludisme Plan Strategique 2007–2011*) that encompasses the main WHO-recommended malaria control interventions. The challenge is to operationalise the plan across the country's 11 provinces given the large distances involved, poor infrastructure, limited capacity and financial resource constraints.

Malaria Control, Treatment and Diagnosis

The core interventions for malaria control in DRC 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 of malaria (IPT) for pregnant women; and case management at all levels of health care. Indoor residual spraying (IRS) plays a very minor role in malaria control and is currently only practised by mining companies in select health areas in Katanga. As of August 2010 tariffs still applied to all antimalarial commodities imported into DRC (bednets, antimalarials, RDTs, IRS insecticides and pumps). [16]

¹ Based on an estimated 193 malaria deaths per 100,000 population (2008 estimate).

In 2005, the national malaria control plan adopted artesunate-amodiaquine (ASAQ) as the first-line treatment for uncomplicated malaria. Quinine is the recommended treatment should the first-line treatment fail, and for the treatment of severe malaria. Sulfadoxine-pyrimethamine (SP) is used for IPT in pregnancy. The MOH introduced community case management guidelines in 2007, which included deployment of ACTs through trained community health workers. [17] As indicated above, the public health system relies on a cost-recovery model and antimalarial treatment is available to patients for a fee that varies across public health facilities. In the private sector, PSI and ASF introduced a socially marketed, pre-packaged ASAQ product for children, called SérénaDose, in 2007 which was distributed in 9 urban centres through NGO partners, with the aim of increasing access to quality, effective treatment. However, recent studies suggest that ACT use continues to be rare. According to the 2007 Demographic & Health Survey, less than one percent (0.6%) of children under five with suspected malaria were treated with ACT. [4] By 2010, the ACTwatch Household Survey found that this had only risen to 4.5%. [18]

Although the policy change to ACT occurred in 2005, it was not until 2006 that implementation began and scale-up has been slow. It was expected that ACTs would be available and in use in the 395 health zones supported by an external partner during 2009. [11] The 2009 ACTwatch Outlet Survey found that ACTs were available in 85.3% of public health facilities, 72.2% of private not-for-profit health facilities and 100% of registered pharmacies; however, availability of ACTs in other types of private for-profit outlets was considerably lower: 30.2% in for-profit health facilities and 56.1% in drug stores (i.e. unlicensed pharmacies). [19] In terms of ACT use, the 2010 ACTwatch Household survey found that although 42.7% of children under five with fever were treated with an antimalarial, only 3.0% took ASAQ. [18]

A law banning the distribution and sale of oral artemisinin monotherapies (AMTs) was passed in 2007 [20]; however, anecdotal evidence suggests that enforcement of the ban did not begin nationwide until June 2009. The ACTwatch Outlet Survey conducted between August and October 2009 found that oral AMTs were stocked by 10.3% of public facilities, 13.8% of private for-profit facilities, 74.0% of pharmacies and 47.4% of informal drug stores. [19]

Regarding diagnosis, the 2007 policy is quite narrow, restricting its focus to treatment failure and complicated malaria. At the peripheral level there is generally no diagnostic capacity and suspected malaria cases are treated based on clinical signs. At the referral level, the guidelines state that laboratory confirmation is obligatory where there is no response to first-line treatment of clinically diagnosed malaria and for complicated malaria cases. The 2009 ACTwatch Outlet Survey found that 81% of public and not-for-profit health facilities had any diagnostic blood testing available, and a similar proportion (80%) of private for-profit facilities also had such testing facilities available; however, it was more common to find microscopy services than RDTs in each type of facility. Almost none of the other types of private sector outlets were found to have diagnostic testing services available. [19]

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. [19] 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; and (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. A member of the research team conducted interviews 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. Due to safety-related travel restrictions, in-depth interviews were conducted in three urban locations only: Lubumbashi in the south, the capital city Kinshasa, and the main seaport of Matadi. To include a diverse mix of businesses types, respondents in each location were purposively sampled from different levels of the supply chain, from retail level to the top of the supply chain. Wholesalers were then classified into three categories for analysis: (i) primary wholesalers at the top of the supply chain (i.e. importers or those who are supplied directly by manufacturers); (ii) intermediate wholesalers (i.e. wholesalers that supply other wholesalers); and (iii) terminal wholesalers (i.e. wholesalers that supply retailers). Retailers were also selected to ensure some variation in outlet type (e.g. pharmacies, pharmaceutical depots/wholesalers, clinics, drug shops/unlicensed pharmacies).

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 Congolese 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. Interviews conducted

In total, 13 key informant and 23 in-depth interviews were conducted in DRC (Table 3.1). Due to security-related travel restrictions, in-depth interviews were limited to three urban locations: 8 in Kinshasa, 9 in Lubumbashi, and 6 in Matadi.

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 | 5 |
| Intermediate wholesaler | 5 |
| Top-level wholesaler | 4 |
| Total | 23 |

1: Retailers interviewed included 3 clinics/health facilities (2 non-profit, 1 for-profit), and 6 retail pharmacies/dispensaries (1 licensed, 3 unlicensed, 2 unable to confirm status). 2: Of these, 1 was a licensed retail pharmacy and 3 were licensed wholesalers.

3.3.2. Analytical approach

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

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

4. Results

4.1. Market Structure

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

4.1.1. Composition of the distribution chain for antimalarials

Pharmaceutical manufacturers

- In 2008, there were 22 domestic pharmaceutical manufacturers registered with the DPM, of which most were producing antimalarial products. [13] Quinine is one of DRC's main agriculturally derived products, much of which is exported [2], but a broad range of antimalarials are domestically produced, including several AMT and ACT products.
- Some domestic manufacturers grant distribution rights to approved wholesalers. One wholesaler in Matadi that was an approved distributor explained that this agreement granted them access to credit facilities and discounts of 10% on all tablet products from the manufacturer [ID 18]. This respondent also said that in order to be an approved distributor, wholesalers must operate solvent businesses, agree to carry the manufacturer's entire product range, and ensure that resale prices were competitive.
- Other domestic manufacturers operate within vertically integrated business models where a single corporate entity owns and operates both a pharmaceutical manufacturing plant (or plants) and multiple wholesale depots situated across the country (see section 4.1.3 for more discussion on business integration). According to one respondent, independent wholesalers wishing to stock products from such companies must purchase from the wholesales depots, rather than directly from the production facility [ID 2].
- Some domestic manufacturers also import other antimalarial products or wholesale antimalarials produced by other domestic manufacturers; while others do not [ID 8].
- One manufacturer respondent described their company as the only Congolese production unit pre-qualified to supply a number of NGOs operating within the country and also supplied customers in neighbouring countries [ID 8].

Importers

- Importing of antimalarials is a common activity. One respondent involved in pharmaceutical sector regulation estimated that there were more than 30 importers in Kinshasa, but could not estimate the number of importers in other parts of the country due to incomplete registers [ID 27].
- Several importers functioned as part of vertically integrated enterprises and were supplied by foreign production units operating under the same umbrella company (see section 4.1.3 for more discussion on business integration).

- Some of these vertically integrated businesses also functioned as exclusive distributors for other foreign manufacturers, as did several independent businesses. One respondent felt that these exclusive arrangements were beneficial as it gave him access to preferred pricing [ID 2]. In some cases, these importers are required to register the foreign manufacturer's products with the regulatory authorities (e.g. conduct product analyses and obtain certificates of compliance) [ID 8]; and most distributor agreements require the importer to house local sales and/or medical representatives (i.e. embedded sales force) who actively promote the manufacturer's products to prescribers, pharmacists and pharmaceutical businesses (see section 4.4.1 for additional information on sales representatives, and section 4.1.2 for additional discussion on market concentration).
- Several importers were also selling domestically manufactured products [ID 9, 10].
- Importers, particularly those with exclusive distributorships [ID 2], typically supplied wholesalers; and those in vertically integrated enterprises used their distribution network to sell to customers in different parts of the country and from neighbouring countries [ID 7].
- Importers tended to be larger businesses than smaller wholesalers, employing pharmacists, managers, accountants and administrators. See additional discussion on barriers to entry in section 4.1.4.

Wholesalers

- Pharmaceutical wholesalers are also common in DRC. The official register of authorised wholesalers in DRC from March 2010 listed a total of 113 wholesaling establishments, 76 of which were located in Kinshasa. [21]
- The wholesalers interviewed tended to be small, employing only a few individuals such as the pharmacist, owner, manager and technicians; though some larger wholesalers also employed nurses, marketing staff, cashiers, assistants and casual workers.
- Supply sources for wholesalers appeared to be based in the same region. For example, in the east of DRC, suppliers for wholesalers in Butembo were typically in Goma [ID 26]; and wholesalers in the southern city of Lubumbashi and the port city of Matadi were supplied by manufacturers, importers [ID 6, 18, 22] and other wholesalers in Kinshasa [ID 14] (see section 4.2.1 for discussion on supplier choice).
- For wholesalers based in Kinshasa, their customers were from both Kinshasa and other parts of the country. One larger wholesaler said that his clients 'come from everywhere' [ID 2]. Another respondent described how many customers used to come from 'the interior' or rural areas of the country, but that the number of these clients had declined over the past few years [ID 6]. One wholesaler in Lubumbashi described his customer base as 'local' [ID 14].
- There was also some horizontal trading between wholesalers, with one respondent saying that a large proportion of his sales went to other wholesalers and that wholesalers were 'interdependent' [ID 2, 23].

Retailers and other private outlets

- Many believed that the number of private retail outlets dispensing antimalarials in DRC was high. For example, one respondent from the east of the country estimated that there were nearly 1000 private outlets in the province of North Kivu, with most of these located in the major urban areas of Goma, Butembo and Beni [ID 26].
- It was also widely held that many retail outlets operated informally without the necessary authorisation from the regulatory agency [ID 21, 26]. Many were said to operate as 'small pharmacies' or drug shops, with some operating in traditional markets in Kinshasa and Lubumbashi [ID 8, 9]. Itinerant medicine vendors were also mentioned as antimalarial outlets by a few respondents in Lubumbashi [ID 9, 10]. When asked why unlicensed retailers were perceived to be so common in DRC, one respondent said that

these types of businesses started to appear in the 1990s (from the advent of the Third Republic) when many untrained people needed to pursue a livelihood in order to survive [ID 14]. See section 4.5.3 for additional discussion on unlicensed pharmaceutical outlets.

- Both licensed and unlicensed pharmacies tended to be small, with 2 to 3 staff members, including the owner, a sales person, the pharmacist (if licensed), and sometimes a nurse (if unlicensed). Private clinics tended to have doctors and nurses on staff.
- Retailers typically purchased supplies from wholesale depots and not directly from manufacturers [ID 12, 19, 20, 21]; however, a few respondents in Kinshasa described bypassing wholesalers to purchase from manufacturers and importers [ID 5, 6]. Outside Kinshasa, one respondent said that they did not purchase from manufacturers or importers due to limited financial capacity, suggesting that these types of suppliers impose minimum wholesale purchase sizes or values [ID 20]. Another respondent from Matadi said that they typically purchased from local suppliers, but also from wholesalers in Kinshasa [ID 23].
- Most retailers described their customers generally as ‘sick people’. Some said their clients come only from their own commune [ID 5, 13] and others mentioned clients coming from both within and outside of their commune [ID 11].

4.1.2. Competition

- Retail pharmacies viewed similar [ID 4, 20, 21] and neighbouring businesses [ID 3] as competitors. By contrast, private clinics either cast a wider net by counting retail pharmacies as competitors [ID 5], or did not perceive any competition because they viewed the clinic as providing a vital public service [ID 19].
- Wholesalers in Kinshasa generally viewed other Congolese wholesalers as competitors, but particularly those based in the commercial pharmaceutical district in Gombe [ID 2, 6]. In addition to local competitors, some wholesalers outside of the capital also viewed Kinshasa-based wholesalers as competitors [ID 18]. Those operating within vertically integrated business models [ID 9] or with exclusivity rights [ID 2] felt that such arrangements provided them with a competitive advantage by reducing the number of businesses selling the same products and by granting them access to preferred pricing.
- It was interesting to note that in Lubumbashi, wholesalers believed that they faced serious competition from informal and/or unlicensed retailers [ID 9, 10, 14]. Wholesalers in Lubumbashi also indicated that product-level competition was intensifying as new lower priced antimalarials continued to be introduced from an increasing number of manufacturers [ID 15, 17].

4.1.3. Integration

- Of the 14 in-depth interviews conducted with wholesalers operating at various levels of the distribution chain, 9 were businesses operating as part of an integrated business model (5 vertically integrated and 1 horizontally integrated).
- Among the vertically integrated businesses encountered, the clear advantage of this model was that it allowed companies to expand their geographic coverage across the country and increase market share, and it gave more latitude to make strategic decisions and take advantage of economies of scale to reduce unit costs (particularly costs associated with importation) and enhance competitiveness.
- In terms of supply sources, vertically integrated businesses either manufactured domestically [ID 9], imported [ID 7, 10, 15], or used a combination of the two [ID 8]. Companies with domestic manufacturing capacity had plants in Kinshasa [ID 1, 8], while those importing brought in antimalarials from manufacturers either subcontracted to produce own-branded products [ID 10] or operating under the same umbrella company [ID 8] based in neighbouring Tanzania and in India. One respondent said

that the key advantage of maintaining manufacturing plants outside DRC were the considerably lower production costs [ID 8].

- To overcome the difficulties and minimise the expenses of transporting goods within DRC, those companies that imported or had multiple supply sources divided the country into two or more distribution arms. For example, the two companies with supply sources in Tanzania distributed those products in the east and south-east, and products from other supply sources in the remaining parts of the country [ID 8, 10]. Another company that manufactured all its medicines at its sister plant in India operated several importing businesses to take advantage of various ports of entry across the country [ID 7]. The branch in Kinshasa served sub-branches in the west; products destined for the Goma branch arrived via Kenya and Uganda to supply sub-branches in the east; products headed for the Lubumbashi branch in the south passed via Zambia and entered at Katanga; while products bound for Gemena sometimes entered via Cameroon and passed through the Central African Republic. These branches and sub-branches then distributed to other wholesalers and retailers [ID 7].
- Regarding administrative control, the head offices of these vertically integrated companies were either maintained in Kinshasa or in India. Product pricing for branches and sub-branches was largely determined centrally to ensure consistency of pricing across the country. However, branches were often permitted to add small margins to account for transport and other costs [IDI 1, 8], but sometimes were required to report any such price changes to managers in Kinshasa and India [IDI 8]. Decisions on product selection and order volume, on the other hand, were primarily the purview of branches.
- One instance of horizontal integration was observed where a chain of retail pharmacies was operating under the same business name and in the same metropolitan area [ID 23]. In this business model, one of the pharmacies functioned as a central procurer by pooling orders across the retail chain.

4.1.4. Barriers to entry

- Most of the market entry barriers mentioned by respondents related to the importation process, including the high costs associated with customs clearance, import duties, and transport of goods within the country. Because of these costs, one terminal wholesaler who sometimes engaged in importing said that it was not a profitable endeavour [ID 22], and several other respondents who expressed a desire to import said they lacked the necessary capital to do so.
- The prohibitive cost of operating a retail pharmacy, specifically the cost of employing a pharmacist, was the key reason why one retailer chose to operate without the proper authorisation/license [ID 13]. A wholesaler cited the overly bureaucratic process required to obtain authorisation to open a wholesale business as another barrier to entry, noting that documentation must be sought from several different government ministries [ID 18]. See section 4.5.3 for additional discussion on licensing.

4.1.5. Links between private and public sectors

Public sector distribution chain

- In the public sector the procurement and distribution of most medicines is coordinated through SNAME (*Système National d'Approvisionnement en Médicaments Essentiels*), where two national-level procurement agencies, BCAF (*Bureau de Coordination des Achats*) in Kinshasa and ASRAMES² (*Association Régionale pour Approvisionnement en Médicaments Essentiels*) in Goma, purchase according to the national pharmaceutical policy and distribute to provincial-level via 15 regional distribution centres.

² ASRAMES is a private not-for-profit procurement and distribution agent of essential medicines and medical supplies for a range of faith-based, non-governmental, humanitarian and development organisations operating in eastern DRC.

- Medicines then flow through the existing hierarchy of public health facilities (i.e. general referral hospitals and central offices to health centres) to finally reach patients. [7] A number of bilateral, multilateral, non-governmental, and faith-based organisations also procure and distribute pharmaceuticals in DRC. Some of these pharmaceuticals are distributed through the existing public system; however, much of these are distributed through verticalised programme- or organisation-specific channels, creating a highly fragmented system. To demonstrate, one detailed study of the pharmaceutical supply system in DRC conducted in 2009 identified 52 non-state organisations involved in the medicine supply system, of which 17 were procuring and 38 were stocking/distributing medicines using structures running parallel to the existing public system. [7]
- Public sector malaria control activities are largely financed by external donors, and the level of financing has grown substantially since 2005, including funding for ACTs. Key donors are the World Bank, the US President’s Malaria Initiative (PMI), and the Global Fund to Fight AIDS, Tuberculosis and Malaria.
- Despite this, coverage under the public system is not complete and it is widely accepted that the private sector still plays a major role in the distribution of antimalarials [ID 16, 32]. This is substantiated by findings from the 2009 ACTwatch Outlet Survey, which estimated that 70% of all antimalarials in the country were distributed via private for-profit outlets. [19]

Inter-sectoral transactions

- Because domestic manufacturers do not produce a WHO-prequalified ACT, instances of private sector providers supplying public and NGO sector buyers is limited; but there are several notable exceptions regarding the supply of non-ACT antimalarials. For example, quinine is supplied to state and parastatal agencies delivering health services by Pharmakina, DRC’s largest producer of quinine, and several other domestic manufacturers and importers [ID 28, 30]. One of these private sector suppliers indicated that public and NGO buyers are given lower prices [ID 8]. When producing antimalarials, such as SP, for public sector use, this respondent also said that special public sector packaging is used to differentiate it from commercial versions and to reduce the likelihood of leakage to the private sector. Another inter-sectoral link outside the health sector was noted by one large private wholesaler who listed the SNCC (National Railways) as a customer [ID 15].
- The other major area of public-private interaction noted during interviews occurred at service delivery level, where NGO agencies using donor funds to operate the public primary health care system subcontract private clinics in selected areas of intervention to deliver an agreed package of services [ID 30, 33]. Private clinics involved in this way receive antimalarials through the established public sector distribution chain, and may also undergo inspection or receive training provided by the implementing agencies (e.g. health zone or NGO) [ID 19].
- For more information on public-private links, see section 4.4.2 on sources of information, section 4.4.3 on changes to the national treatment policy, section 4.5 on regulation, and section 4.6 on RDTs.

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

- Both wholesalers and retailers often mentioned that they used a single supply source, particularly wholesalers in vertically integrated businesses [ID 9, 15] and retailers [ID 4, 5, 11, 21]; although, others had several regular supply sources. A few respondents expressed feelings of loyalty or faithfulness to their habitual suppliers [ID 3, 6, 21], with one saying that, even if other suppliers were available, they still tried to buy from their usual supplier as it was more convenient to have one main supply source [ID 21]. This respondent also said that, although credit was not typically offered by suppliers, one advantage of using a single supplier was that they may sometimes extend credit for a period of time.
- However, many retailers sometimes changed suppliers for specific reasons, such as if a supplier was stocked out of a particular product [ID 3, 4, 14]; if a rival supplier were to offer a good discount [ID 11]; or if a highly demanded product arrived on the market and was only carried by a rival supplier [ID 4, 12].
- For most wholesalers and retailers, product pricing was a key consideration when choosing suppliers, and an important strategy to attract and retain customers. For some, price was the primary criteria for supplier choice [ID 6, 17] and was viewed by some as a reason to change suppliers [ID 11, 12, 13].
- Many respondents also mentioned supplier promotions, gifts and discounts as important strategies for attracting and retaining customers. Wholesalers often mentioned giving gifts to customers at the end of the year, which were typically related to the total annual value of a customer's purchases. For example, one terminal wholesaler described giving calendars, free samples and small consumer appliances [ID 6]; and a few larger wholesalers gave freezers, televisions, DVD players and free orders to their highest value and most loyal customers [ID 10, 15]. Small gifts, such as pens, key chains, notebooks, calendars, and free products samples were given on a more regular basis by some wholesalers [ID 7, 10]. Discounts were sometimes extended to loyal customers [ID 6, 10, 15], but were more frequently given as a function of a customer's order value or volume. See section 4.2.4 on price setting.
- Stocking a wide range of products was another factor impacting choice of supplier. For a number of respondents, it was important to be able to provide all of the products sought by customers. Two wholesalers described going to rival suppliers to purchase out-of-stock items when requested by a customer [ID 1, 9]. Similarly, several wholesalers and retailers also believed that customers valued convenient locations when selecting suppliers, helping them to save time and other resources.
- Also, given that certain products are only stocked by particular suppliers, the choice of supplier for both wholesalers and retailers was often constrained by the products demanded by their customers.
- Various dimensions of a supplier's reputation were considered by many respondents. Chief among these was a supplier's reputation for selling quality products (particularly given the perceived high prevalence of counterfeit medicines circulating in the DRC market, see section 4.5.4); followed by their reputation for providing reliable customer service.

- In addition, minimum purchase order conditions were enforced by some larger suppliers such as manufacturers and importers, which restricted the supplier choice set of some respondents [ID 4, 20]. One large importer said that the minimum invoice value at their business was US\$ 10 [ID 7].

4.2.2. Drug Availability

- Across all levels of the distribution chain, nearly all respondents had experienced stock outs.
- Among retailers, the reported frequency of stock outs ranged considerably from occurring rarely among some based in Kinshasa [ID 3, 5] to every month for a retailer in Lubumbashi [ID 12].
- Among wholesalers, the frequency of stock outs ranged from ‘never’ [ID 17] to occasionally or several times a year; and in terms of stock out duration, one wholesaler described waiting between one week and up to one month to receive new stock from their sole supplier [ID 9].
- The causes of stock outs suggested by respondents were varied and applied to different levels of the chain, from manufacturing, to import, to distribution within the country; although for many, the consistent high demand for antimalarials in the private sector was a key co-contributing factor.
- At the production level, several manufacturers occasionally experienced difficulties obtaining good quality raw materials [ID 1, 7, 8]. Factors relating to import included delays with customs clearance [ID 9, 11, 23], longer than expected sea freight [ID 11], and problems conducting sample analyses of consignments [ID 7]. A few respondents attributed stock outs to difficulties with transporting goods within the country, which were exacerbated during times of bad weather and by the need to deliver to remote locations [ID 8, 18]. One retailer said that they experienced stock outs due to limited funds that could be used for restocking [ID 5].
- Several respondents also described strategies used to reduce instances of stock outs. One importer said that placing larger orders for consignment helped to improve product availability [ID 7], and two wholesalers in Lubumbashi described stocking a wide range of antimalarial types and brands in order to offer customers alternatives or make substitutions as necessary [ID 14, 15]. In Kinshasa, one respondent suggested that the existence of many different wholesalers and importers has helped to reduce the likelihood of experiencing stock outs as it was very easy to find alternative suppliers [ID 6], and this sentiment was echoed by another respondent from nearby Matadi who said that he sometimes changed suppliers when restocking in Kinshasa to find all of the products he was seeking to procure [ID 23].

4.2.3. Product selection and stocking decisions

- For most respondents at all levels of the distribution chain, the primary consideration when selecting products to stock was customer demand. For a number of respondents demand was the only consideration. For example, two wholesalers in Matadi said they could not stop selling AMTs and nATs despite the ban on their use because many of their customers from Angola still demanded them [ID 18, 22]. A retailer also said that they stopped stocking the socially-marketed brand of ASAQ, SérénaDose, simply because it was not selling well [ID 21]. See more discussion on customer demand in section 4.4.1 on demand generation, section 4.4.2 on provision of information, and section 4.4.3 on changes to the treatment guidelines.
- Stocking decisions for several retailers and one terminal wholesaler [ID 22] were based on price and their own perceptions of product efficacy. One respondent from a private clinic said that it was important to stop stocking a product if it was no longer an effective treatment [ID 5], and another retailer considered a product’s affordability in relation to the type of consumers they served [ID 13]. This respondent also described proposing cheaper treatment alternatives to patients, even if they had come with a prescription in hand.

- A few wholesalers in Lubumbashi said their decision on what products to stock was influenced by the updated malaria treatment guidelines, and so were stocking ACTs and ASAQ in particular [ID 9, 17]. Changes to the treatment guidelines prompted another wholesaler to stop stocking certain products, such as AMTs and nATs [ID 14]. See section 4.4.3 for more discussion on changes to the national treatment guidelines.
- While most respondents said that suppliers did not restrict or place any conditions on which products they could purchase from them, those operating within vertically integrated businesses were sometimes required to stock the full range of antimalarials produced by their parent company [ID 16].

4.2.4. Price setting

Price regulation and typical mark-ups

- In DRC, national regulation limits the maximum pharmaceutical price mark-ups that may be added by wholesalers and retailers, and the pricing regime is overseen by the Ministry of Economic Affairs. [13] However, it was widely accepted that wholesalers and retailers do not adhere to these price regulations, and several respondents were not aware that medicine prices were regulated [ID 6, 18].
- When describing mark-ups, nearly all of the respondents who provided these details used percentages rather than currency terms. Top-level respondents found it difficult to estimate typical mark-ups, but one of these respondents said that their average mark-up was 20% on top of the cost price [ID 17]; terminal and intermediate wholesaler mark-ups ranged from 2% to 20%; while retailer mark-ups ranged from 20% to 50%. Both wholesalers and retailers said that the mark-up applied to a given product often varied depending on a wide range of factors described below.

Factors influencing price and mark-up

- Competition was the most frequently mentioned consideration when setting prices, and in all three locations where interviews were conducted, competition was perceived to be intense and businesses were described as price-takers. For example, several respondents said that it was important to ‘account for the reality on the ground’ [ID 1, 8] and to gather information on the prices of their competitors either themselves or from suppliers [ID 12, 14]. Even wholesalers with exclusive distribution rights who may have a supplier price advantage still considered the prices of their competitor when setting prices [ID 1] and would adjust their prices depending on degree of competition [ID 17].
- Another important consideration when setting prices was the various types of costs incurred. In addition to the typical costs of operating a pharmaceutical business, respondents highlighted costs associated with the transport of goods, importation [ID 10, 17], and any unexpected costs that may be related to fines [ID 18] or political instability in certain areas [ID 8].
- Changes in supplier purchase price affected the size of mark-up that could be applied, particularly because consumers were widely viewed as very price-sensitive. Consequently, many respondents were mindful of affordability when setting prices. To demonstrate, one retailer described his process of testing customers’ willingness to pay for a new product by initially procuring small quantities and selling it at a test price, and then raising the price if the product sold well [ID 21]. A wholesaler also said that when setting prices, it was important to ensure that businesses further down the chain (e.g. retailers) could still add a sufficient mark-up so that the end-user price was still acceptable [ID 10].
- A few respondents also said that product scarcity often led to dramatic increases in prices, particularly because demand for antimalarials was always high. Conversely, one retailer said that a product’s retail price could go below the wholesale purchase price if it was abundant in the market [ID 21].

- Mark-ups were also said to vary by product type. For example, higher mark-ups were applied to imported antimalarials compared to domestically produced antimalarial (10-15% vs. 6-10%) [ID 1, 10, 15], and to products in high demand compared to those in low demand (e.g. quinine and Coartem vs. amodiaquine) [ID 12].
- Approaching product expiration dates also led some respondents to reduce prices in the hope of selling off remaining stock and minimising incurred losses [ID 15, 20].
- Several respondents also cited how fluctuations in the Congolese franc-US dollar exchange rate and rapid inflation led to changes in medicine prices [ID 3, 6, 12].
- The effect of supplier restraints on price setting was largely limited to wholesalers operating within vertically integrated companies as prices were often set centrally; although there were instances where branches were accorded some latitude in terms of pricing, such as allowing branches outside of Kinshasa to apply slightly higher mark-ups to account for additional transport costs and variation in state taxes [ID 1, 17]. In two instances, similar restraints on pricing were enforced by other suppliers on independent customers, such as the recommended retail price for the socially-marketed brand of ASAQ, SérénaDose, distributed by ASF/PSI [ID 14]; however, one retail respondent viewed these conditions as suggestions, and asserted that ‘suppliers generally had little interest in what was done with the medicines afterwards’ [ID 21]. Otherwise, vertical restraints on pricing were not typically imposed.
- Discounts that varied either by purchase volume or value were commonly offered to retailers and wholesalers, and the size of reported discounts ranged from 1% up to 30%. The minimum order value at which suppliers granted access to these discounts was reported to be US\$ 100 by one respondent [ID 10] and US\$ 1000 by another [ID 20].
- Discounts were also offered to certain customers. For wholesale customers, this sometime depended on the length of the client relationship [ID 6]; and for retail customers, prices could be lowered if the consumer was disabled or could not afford to pay the full price [ID 21].

4.2.5. Restocking and distribution practices

Importers

- Order frequency for antimalarials among importers ranged from 2-3 times per year up to two times a month [ID 16]. Order volumes were based on 6-month forecasts using sales data from the previous year. One importer included additional ‘buffer stock’ to their projected needs, and also mentioned considering the dates of important religious holidays in India when planning orders from their Indian suppliers to avoid delays [ID 8].
- Lead times for consignments were 3-4 months by sea and ground freight, but could take longer because of industrial action or holidays in the country of origin [ID 8]. For one importer, urgent orders for smaller quantities could be sent from their supplier via air cargo [ID 8].
- Customers of importers typically came themselves to collect orders. One importer sometimes delivered to customers placing large orders and made several delivery runs per week [ID 17]; and another importer sometimes used medical representatives to deliver orders to customers, if possible [ID 16].

Wholesalers

- Among wholesalers, order frequency ranged considerably from 4-6 times per year to monthly to several times per week. A few respondents in Lubumbashi said that antimalarial order frequency changed according to the season with more orders placed during the rainy season and fewer during the dry season [ID 10, 14]. Order volumes were determined on average daily [ID 1] or monthly [ID 2] sales

volumes; and for one terminal wholesaler, order sizes also depended on cash flow and were sometimes reduced regardless of projected need [ID 15].

- Orders could be placed via telephone [ID 18], the internet (e.g. email) [ID 2] or through supplier sales representatives during visits [ID 22]; and one wholesaler in Matadi engaged an agent who made orders in person at suppliers in Kinshasa and who also arranged shipping [ID 18].
- While one wholesaler based in Kinshasa did not have orders delivered [ID 6], most respondents did have orders delivered, with lead times ranging from one week [ID 17] to the same or next day [ID 22]. Some deliveries were made by visiting sales representatives [ID 22], while others were shipped via air or ground transportation services. Several respondents described issues related to suppliers and couriers not being able to handle the quantities ordered [ID 15], the high cost of transporting goods by air [ID 2, 8], and also the political instability in some areas that sometimes incurred extra security-related expenses or rendered some areas inaccessible for transport [ID 8].
- Customers of most wholesalers collected orders themselves, but some wholesalers did deliver to selected customers, such as hospitals [ID 14] and public sector buyers [ID 15], making several trips per week. One wholesaler used to provide a delivery service for customers but had recently stopped due to the high costs of operating the service [ID 9].

Retailers

- Retailers restocked antimalarials 1-8 times per month [ID 3, 4, 11], and purchase volumes for most respondents were primarily determined by their cash flow.
- Purchases were typically made in person. One respondent from Matadi sometimes travelled to Kinshasa to take advantage of the wider selection of suppliers and products [ID 23].

4.2.6. Cooperation among businesses

- Retailers in Kinshasa and Lubumbashi did not perceive there to be any collaboration between businesses [ID 3, 4, 11, 12, 13]. One respondent noted that an association of pharmacists used to exist but was no longer active [ID 3]. However, one respondent from a private clinic in Kinshasa believed there to be 'genuine collaboration' between other clinics operating in the area [ID 3]. In Matadi, there was an active association of pharmacy owners, APROPHAR, that engaged in lobbying activities to advance members' interests [ID 23], but not all respondents believed that membership of this association would benefit their business [ID 20].
- Other commercial organisations were also mentioned by wholesalers, including an association of pharmaceutical wholesalers and importers in DRC, AFEC, based in Kinshasa. The 36 members of this association hold monthly meetings to share information, develop strategies for solving common problems, and collectively lobby the government. AFEC also engages 'forwarding agents' that oversee order delivery for members, from handling customs clearance in Matadi to arranging transport from Matadi to warehouses in Kinshasa. [ID 2]. In Goma, a respondent involved in pharmaceutical sector regulation said that pharmacy owners there have formed associations to discourage any would-be itinerant vendors or vendors in traditional market [ID 26].
- Other types of collaboration mentioned by wholesalers were more informal in nature. For example, a number of respondents described supplying other wholesalers in case of stock outs, sometimes selling to them at cost price [ID 2], giving discounts [ID 14, 22] or even allowing them to purchase on credit [ID 22]. Another respondent said that trading among wholesalers supervised by registered pharmacists helped to ensure the quality of the products being supplied [ID 10]. Because many of the pharmaceutical wholesalers are either owned or operated by members of the South Asian ethnic community, several

respondents commented that, although these businesses were competitors, these ethnic links facilitated collaboration among them [ID 9, 15].

4.2.7. Sources of capital

- Retailers reported using mostly cash generated from sales to purchase new stock. Although some respondents said that none of their suppliers offered credit facilities [ID 20], there were a few instances where retailers used credit to finance restocking. For example, one retailer said that their longstanding supplier sometimes allowed them to make purchases on credit for short periods of time [ID 21].
- Wholesalers described using a mix of cash and supplier credit when restocking. However, credit facilities were not available from all suppliers [ID 8, 19] and were sometimes extended to wholesale customers only after establishing a relationship with the supplier [ID 10]. One wholesaler operating as part of a vertically integrated business with a domestic manufacturer said orders were purchased using credit.
- Respondents did not provide details on credit terms.

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 or did not know this information, and others preferred to speak in general terms rather than give specific figures. In nearly all cases where respondents provided details on revenues and costs, these were reported using US dollars.³ No respondents provided estimates of start-up costs.

4.3.1. Revenue from antimalarial sales and fluctuations in sales

- For most respondents, antimalarials were key revenue generators. One terminal wholesaler said that antimalarial sales contributed 50% of their total revenue [ID 6], and many other respondents ranked them as either their top selling category of medicines [ID 14, 18] or among the best selling product categories alongside antibiotic, anti-inflammatory, anti-parasitic and anti-fungal products.
- A few respondents were also able to identify individual antimalarial products that were selling well. Two wholesalers mentioned AMTs among their top selling antimalarials. For one wholesaler, the top sellers were artemether and quinine [ID 9], and for the other wholesaler it was the brand of dihydroartemisinin, Malaxin, that was particularly popular because of its perceived lack of side effects [ID 14]. Only one respondent identified ACT products as top selling antimalarials: the Coartem branded artemether-lumefantrine (AL) and Co-arinat branded artesunate+sulphamethoxy-pyrazine-pyrimethamine [ID 15].
- In Lubumbashi where malaria incidence is more seasonal, antimalarial sales volumes and revenues were reported to be high during the rainy season (November-April) and low during the dry season when other products such as cough medications [ID 9, 10, 13] were the top-selling drug. One retailer remarked that remaining antimalarial stock at the end of the rainy season often expires during the dry season, resulting in considerable losses [ID 12]. In Kinshasa and Matadi, antimalarial sales were reported to be consistent throughout the year as malaria is less seasonal in these areas [ID 7, 8, 18, 20].

³ The average exchange rate during the data collection period (11 Jan-17 Mar 2010) was US\$1 to 899 Congolese francs (CDF). Historical exchange rates averaged over the specified periods were obtained from <http://www.oanda.com/currency/historical-rates>.

4.3.2. Cost structure⁴

- Respondents at all levels of the distribution chain mentioned employee salaries, domestic transport, building rental/maintenance fees and state taxes as their major operating expenses. As expected, wholesalers engaged in importing mentioned costs associated with this particular activity (e.g. customs clearance) as notable expenses. See section 4.5.6 for additional discussion on import taxes and tariffs.
- Some detailed expense data was provided by two wholesalers (one each in Kinshasa and Lubumbashi). Rent ranged from US\$ 2000 to US\$ 3000 per month; for one wholesaler, staff salaries cost US\$ 3000 per month, and taxes and unofficial payments cost US\$ 5000 per month [ID 6]. See section 4.5 for more information on unofficial payments and corruption.
- Respondents also listed a range of different taxes and fees that they paid regularly (e.g. either monthly or annually), including business tax, hygiene service tax, local government (commune) tax, authorisation/licensing fees paid to different jurisdictions (e.g. Ministry of Health, the commune), and one manufacturer also mentioned contributing to an 'industry promotion fund' [ID 8].
- While all respondents refused or could not provide estimates of start-up costs, one terminal wholesaler asserted that such costs 'would not be very expensive' [ID 6].

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. Demand generation

- The use of sales representatives was a common strategy used by manufacturers to generate demand for their products. Representatives of domestic manufacturers were typically attached to the plant itself or to the chief branch in the case vertically integrated companies [ID 9], and those of foreign manufacturers were typically attached to the importer acting as an exclusive distributor [ID 8, 15]. In these cases, the sales representatives remained the employees of the foreign manufacturer. Where a supplier was promoting both their own domestic products alongside imported products, separate sales teams were maintained for each type [ID 8].
- The key activity of sales representatives was to detail prescribers by visiting them at health facilities to provide them with product information and samples with the aim of generating prescriptions. They also visited wholesalers and retailers to do much of the same, but might also take and deliver customer orders (see section 4.2.5 on restocking practices). One wholesaler, however, did not feel that this marketing activity was particularly effective as it was not sufficient to influence his stocking decisions [ID 14]. Sales representatives also collected market intelligence on product sales volumes and trends from wholesalers and retailers [ID 9, 16, 18].
- In addition to sending representatives, suppliers also tried to influence the product choices and order volumes of wholesalers and retailers with various types of promotions (see section 4.2.3 on product selection and section 4.2.4 on price setting). One terminal wholesaler commented that this type of strategy is not always effective as customers often arrive already knowing which particular products they wish to purchase [ID 6].

⁴ No respondents from Matadi provided information related to business costs or operating expenses.

- One top-level supplier also described making considerable donations to NGOs with political connections and also to university academics to conduct research on agreed topics [ID 7].
- At retail level, pharmacies provided advice to patients and consumers, and many of these believed that they were providing an essential public service, particularly when patients could not afford to see a doctor [ID 21].

4.4.2. Sources of information about antimalarials

- The most common sources of information about antimalarials mentioned by wholesalers and retailers were supplier sales representatives or the suppliers themselves (i.e. when purchasing in person).
- Other sources of information included meetings and workshops organised by suppliers [ID 14], the media (e.g. television, radio) [IDI 5, 18], and from customers asking about new products [ID 22] or coming to the pharmacy with a particular prescription [ID 20].
- Only one respondent mentioned the Ministry of Health and NGOs as a source of information on new antimalarial products [ID 18].

4.4.3. Changes to the malaria treatment guidelines and improving private sector uptake of ACTs

- When respondents were asked how they thought the adoption of ASAQ as the recommended first-line treatment for uncomplicated malaria had affected their business, the wholesalers who responded had mixed feelings. For one wholesaler, the policy change came as a surprise and he recounted feeling unprepared on how to deal with the large remaining stocks of antimalarials that were no longer recommended [ID 2]. Another respondent from a large vertically integrated company who had been involved in discussions on the policy change said that his business did not suffer as they were able to introduce a new low-priced ACT for sale in the private sector by the time the change was implemented [ID 7]. For other respondents, the shift toward ACTs was said to have simply prompted them to adapt their product range by stocking products that were in line with the new recommendations and discontinue stocking other drugs [ID 14, 17].
- One sentiment expressed by several respondents was that the policy change was poorly disseminated within the private sector. Criticisms mentioned were that certain stakeholders were not adequately engaged in the decision making process [ID 9, 16]; the government did not communicate information on the change in a timely way [ID 2, 3]; and that retailers were largely overlooked during dissemination, with many of them only learning of the policy change when they began to notice that certain products were no longer available on the market [ID 14]. Perhaps as an extension of these observations, one retailer said she was not aware of the updated treatment policy [ID 12] and two others said that they learnt of it through their private sector suppliers [ID 11, 13]. By contrast, wholesalers reported learning about the policy change from a number of different sources, including during conferences and meetings organised by the MOH and PNLP, from the *Ordre des pharmaciens*, and through various media channels. A respondent from the PNLP also admitted that when the policy changed, they initially met only with importers and local manufacturers for the first two years of implementation, and only began disseminating among a wider audience from 2007 with the cooperation of the NGO MSH [ID 35]. This respondent also acknowledged that behaviour change among private sector providers would take time.
- While some respondents hypothesised that poor dissemination of the policy change among private providers was one reason for the persistently low use of ACTs [ID 16, 25], several other factors were suggested as barriers to their more widespread use. These included low levels of awareness and unfamiliarity of ACTs among the general population [ID 23, 26]; poor levels of ACT acceptance by patients, which is exacerbated by their relatively high price [ID 13, 17] and side effects associated with

the amodiaquine component of ASAQ [ID 10, 16, 19]; issues related to transport and political instability [ID 26] that limit availability of ACTs in some areas; and the persistent availability of older more familiar drugs, such as chloroquine and quinine, which some still perceived as effective treatments [ID 9].

- Given all these barriers, respondents offered a range of different suggestions to improve private sector uptake of ACTs, including awareness generating campaigns targeting the general population [ID 9, 23]; increased product promotion of ACTs and SérénaDose in particular among wholesalers and retailers [ID 14]; information campaigns targeting healthcare providers to encourage them to promote ACTs to patients when prescribing [ID 25]; training of private sector pharmacists on the updated treatment guidelines and on using SérénaDose [ID 35]; developing an ASAQ/SérénaDose product in oral liquid form [ID 16]; and expanding the guidelines to encompass better tolerated ACTs, such as AL and artesunate+SP, both of which were already perceived and promoted as viable alternatives to ASAQ by wholesalers in Lubumbashi and Goma [ID 10, 25]. See section 4.5.6 for discussion on the contribution of import taxes and tariffs to high ACT prices.

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. See section 4.2.4 for discussion on price regulation.

4.5.1. General views on regulation and enforcement

- While some wholesale and retail respondents expressed that regulation of the pharmaceutical sector was necessary, normal and expected, and felt that the current regulations applicable to their type of business were reasonable or satisfactory, many believed that change to the pharmaceutical regulatory system was required.
- Two top-level wholesalers felt that the current legislative texts governing pharmaceutical sector regulation were out-dated and no longer reflected the contemporary pharmaceutical trade or pharmacy practice [ID 8, 17].
- Many more believed that the current regulations were not being effectively enforced by the responsible agencies, resulting in low levels of regulatory compliance among wholesalers and retailers. For example, one retailer said that only large pharmacies possessed the necessary authorisations to operate from regulators and admitted that she herself did not [ID 21]; and two respondents from Lubumbashi believed that if all the regulations were to be fully enforced, there would only be one wholesaler [ID 14] and a handful of retailers found to be fully compliant [ID 9].
- Some of the more general reasons for poor compliance suggested by respondents were that the DPM lacked funding and capacity [ID 16, 31]; many businesses did not respect the regulations or fear the repercussions of non-compliance [ID 14]. Supervising pharmacists in wholesale businesses were said to generally be employees rather than owners, and consequently did not have enough say in how businesses were run, while owners were motivated more by profits [ID 6].
- Widespread corruption was also viewed as an important factor contributing to low levels of compliance (see further discussion on corruption in section 4.5.2 on inspections, section 4.5.3 on unlicensed businesses and section 4.5.4 on counterfeit and substandard drugs).

4.5.2. Inspections

- Visits from regulators were reported to occur regularly: 2-4 times per year for one wholesaler [ID 1] and at least once per quarter for another [ID 8].
- A retailer said that multiple agencies, including the DPM, Ministry of Commerce, and Hygiene Service, each conducted their own inspection [ID 4]. A private clinic integrated into the public health system said that agents from the health zone conducted inspections of the clinic pharmacy during supervisory visits, as did agents from the provincial bureau of the DPM from time to time [ID 19].
- Reacting to the frequency of inspections, one wholesaler complained that with each visit there was always ‘something to pay’ [ID 18]. Another wholesaler described in greater detail his experience with corruption, saying that regulators use their position to extract unofficial payments by threatening to impose fines for things out of their control (e.g. when a refrigerator is not working during a power outage), and that ‘paying makes life easier’ [ID 6].

4.5.3. Unlicensed wholesalers and retailers

- By far the most common regulatory issue mentioned by respondents related to the prevalence of unlicensed businesses operating within the pharmaceutical sector, including wholesale and retail pharmacies, drug shops, vendors in traditional markets and itinerant vendors (see section 4.1.1 for descriptions of the types of unlicensed businesses).
- The main concern expressed by respondents was that unlicensed businesses rarely employed dispensers with the necessary training to properly diagnose and treat health conditions, or even differentiate between good and poor quality products. Combined with the popular practice of self-medication, many felt that allowing such businesses to proliferate unchecked compounded the risk of patients receiving poor, if not dangerous, pharmaceutical care.
- However, one respondent who admitted operating without the proper authorisation said that it was not feasible to operate a small retail pharmacy like her own while employing a registered pharmacist as they did not generate sufficient revenue to cover a pharmacist’s salary [ID 13]. Unlike some other countries, the current regulations do not permit a tier of official retail pharmacies that do not require the involvement of a registered pharmacist, such as the Class C drug shop in Uganda, Part II pharmacy in Tanzania or Patent Proprietary Medicines Vendor in Nigeria.
- Others criticised the overly bureaucratic process required to set up a pharmaceutical business as it required several different authorisations (e.g. from the Ministries of Health/DPM, Environment, Small and Medium Business) [ID 18] and was inefficient. To demonstrate, the central office of the DPM in Kinshasa issues authorisations once a dossier has been approved and forwarded to them by the provincial DPM bureau, which is then sent to the Ministry of Health for signature. Because these multiple transactions may cause lengthy delays in issuing authorisations, some provincial bureaux have opted to issue interim authorisations (*autorisations direct de fonctionner*) pending response from the central office [ID 26].
- Corruption was described as another means to circumvent licensing regulations. A few respondents described how unlicensed wholesalers and retailers threatened with forced closure were permitted to continue operating following unofficial payments to regulatory agents [ID 18, 21]. These observations are supported by findings from the quantitative ACTwatch supply chain survey that, although only 20% of all wholesalers interviewed were observed to have any authorisation from the DPM, nearly all (94%) reported being recently visited by a pharmaceutical inspector. [1]
- Given the scope of the problem, several respondents suggested that unlicensed business operators could be given training to help them to improve their business and dispensing practices [ID 3, 13].

Another respondent from the regulatory authority described how they were working to identify and classify unlicensed outlets as either viable or not, and then provide assistance to viable outlets and close the rest [ID 26].

4.5.4. Counterfeit, substandard and expired drugs

- Many respondents at all levels of the distribution chain acknowledged the existence of counterfeit antimalarials, though only a few mentioned issues related to substandard [ID 15, 22] and expired [ID 26] products being sold on the market.
- Because poor quality antimalarials were perceived to be so common and differentiating between high and low quality products was difficult [ID 6], several respondents said that a key strategy to avoid these types of products was to select reliable suppliers [ID 3, 6, 23].
- Although instances were noted where regulators closed shops found to be stocking substandard goods [ID 6], several knowledgeable respondents highlighted the government's limited capacity to test the quality of drugs arriving at ports and in national circulation, and cited the lack of sufficient equipment and reagents to analyse all submitted samples at the national quality control laboratory (*Office congolais de contrôle*, OCC) as the key limiting step [ID 7, 8, 26, 31]. One of these respondents, an importer, quipped that he was rather more likely to learn about counterfeits identified by their sales representatives and customers [ID 8]. Another of these respondents added that it was possible to import at certain land border crossings and circumvent all quality control measures with a small payment made to the authorities [ID 7].

4.5.5. Stocking prohibited or leaked products

- During an interview at the PNLP, the respondent acknowledged that oral AMTs were still widely available despite the ban that had been in place since 2007 and that nATs, particularly chloroquine, continued to be used to treat malaria despite the shift to ACTs in the national treatment guidelines. In their continuing efforts to eliminate these antimalarials from the market, the respondent said that a new ban on AMTs and certain nAT (i.e. chloroquine) was planned for implementation from June 2010, and that a national public awareness campaign about this new ban would be launched on World Malaria Day of that year [ID 35]. As part of the ban, a grace period to sell off remaining stock of banned antimalarials was negotiated between the PNLP, DPM and a commercial organisation representing manufacturers, wholesalers and retailers (*Fédération des Entreprises du Congo*).
- In terms of leakage, antimalarials donated for use in the public sector were sometimes said to be found for sale in private outlets [ID 4, 6], and drugs leaked from the public sectors in neighbouring countries were said to be found in North and South Kivu [ID 26] and in Lubumbashi [ID 15].

4.5.6. Import issues

- In addition to the issues related to importing discussed above (i.e. delays due to sea freight, customs clearance, batch quality described in section 4.2.2 on availability and stock outs; high costs of importing described in section 4.1.4 on barriers to entry and section 4.3.2 on cost structure), import taxes and tariffs were another issue mentioned by a number of respondents [ID 25, 26, 27, 32, 35].
- Existing taxes and tariffs applied to imported private sector antimalarials were widely acknowledged as critical contributors to high private sector ACT prices, preventing their more widespread use.
- The types of taxes and tariffs mentioned by respondents included clearance fees paid to the MOH at a rate of 2% of the cost, insurance and freight price (a quarter of which covered administrative fees), a batch quality testing fee paid to the OCC of US\$ 250, and various other taxes applied to all importing

businesses by national and provincial authorities, such as the Ministry of Finance and the Provincial Health Division [ID 26]. For comparison, the Malaria Taxes and Tariffs Advocacy Project estimated that import tariffs on antimalarials in DRC ranged between 1% and 9%. [16]

- At the time of data collection, negotiations between the Ministry of Finance and the PNLP were ongoing seeking tariff exemptions for recommended antimalarials imported into DRC to help reduce private sector ACT prices [ID 25, 32].
- Several respondents also described tariff evasion tactics used by importers by underreporting the total value or volumes of consignments to port authorities.

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.

- While RDTs were rarely observed in the private sector, several respondents remarked that RDTs had been circulating within the public health system for at least a year prior to data collection using donor funds and were being distributed through the existing supply infrastructure for medications and other health commodities [ID 24, 28]. However, due to the high degree of fragmentation in the delivery of public health services, other respondents highlighted that not all health zones in the country were being supplied with RDTs as this depended the source of donor funding and the implementing partner (for example, only health zones in the east supported by Global Fund grants through *Médecins sans frontières* were using RDTs at primary care level) [ID 25, 32].
- At the time of data collection, only one private sector RDT distributor based in Kinshasa was identified who was supplying only public and NGO sector customers, and who had not yet received any enquiries from private sector wholesalers or retailers [ID 29]. This respondent noted that RDT sales volumes had increased considerably since the national policy change began promoting testing in public health facilities.
- Several other respondents identified challenges to the more widespread use of RDTs in the private sector. These included their relatively high cost compared to the purchasing power of the population [ID 26], the common practice of self-medication among a population with low levels of education and awareness [ID 35], and the need to identify and appropriately treat co-infections with multiple *Plasmodium* strains (including *vivax* and *malariae*) as the current RDTs were specific for *falciparum* only [ID 26].

5. Summary of Key Findings

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

- Selling antimalarials is a key revenue generating activity for private sector wholesalers and retailers, and the private sector is an important source of antimalarials in the country.
- The private commercial sector market for antimalarials in DRC is composed of a number of domestic manufacturers, many importers, wholesalers and a range of different retailing outlets, primarily large and small retail pharmacies, and private clinics. Itinerant vendors and traders selling antimalarials in traditional open air markets were not perceived to be common.
- Vertically integrated businesses, where a single corporate entity owns and operates manufacturers, importers and wholesale distributors, were a common and distinct feature of the private sector antimalarial distribution chain in DRC. Several of these maintained production facilities in neighbouring countries or in India. This arrangement possibly reflects the challenges of importing and transporting medicines within the country, but also helps these companies to capture greater shares of the market and maximise profits through economies of scale.
- Although one would expect market power to be concentrated among vertically integrated businesses, other findings suggest that the wholesale market for antimalarials in DRC is competitive. When setting prices, competition was the primary consideration for most respondents, including those operating within vertically integrated companies. Suppliers also used a range of different strategies to gain competitive advantages (e.g. exclusive distributorship agreements with manufacturers, the pervasive use of sales representatives for marketing), and to attract and retain customers (e.g. offering discounts, bonuses and gifts; maximising convenience for customers).
- However, delivery services or credit facilities were not commonly offered to customers by suppliers, and particularly not to retailers who typically collected orders themselves and relied on cash flow to finance restocking. Retailers also reported experiencing stock outs more frequently than wholesalers.
- Wholesaler and retailer stocking decisions were primarily driven by customer demand (i.e. business-to-business transactions for wholesalers, and consumer purchases for retailers), which was used to explain the persistence of AMTs and older nATs, such as chloroquine on the market, and also the low uptake of ACTs through the private sector. Alongside low levels of awareness, a key barrier to the wider use of ACTs suggested by respondents was their poor acceptability among the population, largely due to their comparative unaffordability and perceived side effects, in the case of ASAQ.
- Potential strategies to improve ACT use through the private sector suggested by respondents included reducing import taxes and tariffs on antimalarials to decrease end-user prices, increasing public awareness of ACTs, and improving retailer knowledge and opinions of ACTs and the treatment guidelines, to leverage their influence over consumer treatment choices.
- Unlike wholesalers who reported having multiple sources of information on antimalarials, retailers relied heavily on private sector sources of information to learn about new products and even about the changes to the malaria treatment guidelines following the adoption of ACTs. As such, improving retailer knowledge and opinions of ACTs could involve increasing communication to this group from public sector sources and improving the knowledge and opinions of ACTs among the suppliers of retailers at higher levels of the distribution chain.

- The pharmaceutical regulatory system is perceived to be weak and cannot adequately ensure the quality of products or pharmacy practice in the private sector across the country. Confidence in the regulatory system is further undermined by corruption that many respondents believe occurs at multiple levels of the private sector distribution chain. Regulatory issues of common concern include the high prevalence of counterfeit and substandard antimalarials in the private sector and the proliferation of unlicensed retail outlets that provide poor pharmaceutical care to consumers.
- RDTs were not available in the private sector at the time of data collection.

When interpreting the findings of this study, there are a number of issues that need to be considered. First is that, due to travel restrictions, the sample selected for interview was limited to three urban locations. This is unlikely to have had a major impact on the findings for wholesalers, which tend to be concentrated in large cities and towns, such as the ones visited. [1] However, retail antimalarial markets in more rural and remote areas are likely to be less competitive; may experience more frequent or longer stock outs; order new stock less frequently; have a more limited supplier choice set; be less likely to bypass wholesalers to purchase directly from manufacturers; or interact more with public, NGO and FBO sector as sources of supply or information. 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 2010 and changes to the market are likely to have occurred since then.

6. References

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