The private commercial sector distribution chain for antimalarial drugs in Nigeria

Findings from a rapid survey

November 2009

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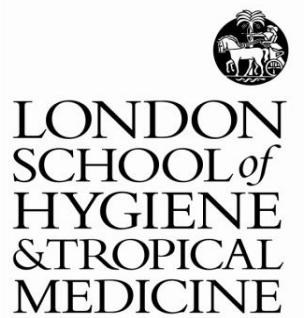


Executive Summary

In November of 2008, the Global Fund to Fight HIV/AIDS, TB and Malaria announced that it would administer the first phase of an ambitious scheme to increase the availability of effective treatment for malaria, the Affordable Medicines Facility-malaria (AMFm). Artemisinin-based combination therapies (ACTs) are highly effective, but remain prohibitively expensive for those who are most vulnerable to malaria infection.[1] The AMFm aims to significantly reduce the price of ACTs by offering a co-payment for ACTs purchased by eligible buyers at the top of the supply chain.

Recognizing that the public and private sectors are important sources of antimalarials in most endemic countries, both public and private sector buyers will be entitled to purchase subsidised ACTs. The involvement of the private sector is an innovative element of AMFm, as many countries already have experience distributing ACTs in the public sector. To ensure that subsidised ACTs reach patients at the lowest possible cost, it is necessary to gain a better understanding of the private sector supply chains for antimalarials in each country participating in the AMFm.

The objective of the rapid supply chain survey was therefore to assist Nigeria, which is one of the 11 countries invited to apply to the first phase of the AMFm, in the development of an effective implementation plan by providing an understanding of the current supply chain for antimalarials, and the way in which subsidised ACTs are likely to travel through this chain to reach patients. This report presents the findings of a series of semi-structured interviews conducted with government officials and private suppliers of malaria treatment operating at the various levels of the chain. Supplemental sections include brief discussions on the Nigerian drug monitoring system, on the proposed tax exemption for subsidised ACTs under the AMFm, and also on the private sector capacity to repackage and re-label imported subsidised ACTs. In addition, data from the December 2008 report on the first round of the ACTwatch Outlet Survey in Nigeria were used to estimate key variables, such as antimalarial market shares.

In 2008, over 100 Nigerian manufacturers were registered to produce an antimalarial, while 10 of these were registered to produce an ACT product. There were also 286 registered drug importers in Nigeria in 2008; however, there was insufficient data to determine how many of these businesses were importing antimalarials. In terms of drug distribution and wholesaling, there were 616 businesses licensed to do so in 2008; although it is widely accepted that unlicensed wholesalers play a very significant role in drug distribution at this level of the supply chain. In terms of retailing and dispensing, the December 2008 ACTwatch Outlet Survey revealed that the most common source of antimalarials were Proprietary Patent Medicine Vendors (68%), followed by public (13%) then private (10%) health facilities. Registered pharmacies, which numbered 1526 in 2008, were the least common formal source of antimalarials at 9%.

Manufacturers and importers of antimalarials are concentrated mainly in the South-West region of the country in and around Lagos State, and to a lesser degree in Onitsha, Anambra State; while antimalarial wholesaling activity is typically concentrated within commercial hubs at the regional or state level, with notable pharmaceutical markets located in Kano, Aba and Ibadan (in addition to Lagos and Onitsha).

[1] Nicholas White, "Malaria – Time to Act," *The New England Journal of Medicine.* 355 (2006): 1956-1957.

Distribution practices vary, but are well established. The use of vertically integrated distribution infrastructure and third-party logistics service providers is common among manufacturers and importers to achieve wide geographic coverage of their products. This is enhanced through the pervasive use of sales representatives deployed, not only for product detailing, but also for order taking and delivery. Authorised distributorship arrangements between top-level suppliers and wholesalers, which use a variety of incentives to increase product volume flowing through the supply chain, are also a prominent feature of distribution practices.

Price mark-ups among manufacturers were reported to be between 15 and 40%, while importers indicated that their mark-ups depended on the costs of product and importation, exchange rate and competition. Reported wholesaler mark-ups ranged from 1-15%, while those among retail pharmacies were estimated to be between 20% and 30%. Credit facilities may be offered, but were reported to be less available at lower levels of the supply chain.

The antimalarial product market in Nigeria is very diverse and includes 177 registered ACT products. The December 2008 ACTwatch Outlet Survey also showed that, in terms of volumes, the product market continues to be dominated by non-artemisinin therapies such as chloroquine and sulphadoxine pyrimethamine (SP), accounting for approximately 83% of the total number of adult treatment courses sold or dispensed, followed by artemisinin monotherapies (approximately 10% of the total volume). On the whole, ACTs constituted approximately 6% of the total volume of adult antimalarial treatment courses dispensed. This pattern of volumes was common across all types of antimalarial source, including public health facilities; although PPMVs appear to be a major driver behind the dispensing of non-artemisinin therapies, as they are the source for more than 60% of all antimalarials dispensed, of which more than 90% are of this type.

When asked about the proposed AMFm mechanism, respondents generally reacted positively and agreed that this initiative could help to improve access to effective treatment for malaria. They were also asked about any existing or potential barriers to the widespread distribution of ACTs in the private sector and identified a number of supply- and demand-side factors. These included leakage of products to the informal sector, unpredictable top-level availability of product, poor acceptance of ACTs among consumers, opposition to the AMFm from local manufacturers of antimalarials, the role of PPMVs in improving accessibility to ACTs, and geographical accessibility of ACTs.

Contents

Acknowledgements

This report was commissioned by the Clinton Foundation as part of their support to countries preparing proposals for funding under the AMFm. We are grateful for the advice and input from Clinton Foundation staff in the development of data collection instruments and facilitation of data collection, and also for their valuable feedback on the content of the reports.

Thanks also to the staff of Population Services International and the Society for Family Health – Nigeria for providing administrative and logistical support, advice and feedback during the implementation of this rapid survey.

We acknowledge the important contributions from our interviewees from the National Malaria Control Programme, the Pharmacists Council of Nigeria, the National Agency for Food and Drug Administration and Control, the Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria, manufacturers, importers, wholesalers and retailers who all gave a share of their valuable time to participate in the interviews.

This study was undertaken as part of ACTwatch, a collaboration between Population Services International (PSI) and the London School of Hygiene & Tropical Medicine (LSHTM), and funded by the Bill & Melinda Gates Foundation (www.actwatch.info). It draws on data collected by PSI for the first round of the Outlet Survey, conducted in December 2008. We are grateful to Kate O'Connell, ACTwatch Principal Investigator, and Mrs. Arogundade Ekundayo, the Nigeria Country Programme Coordinator, for facilitating use of these data.

The views expressed in the report remain those of the authors. Any questions, comments or data requests should be directed to the research team based at the London School of Hygiene & Tropical Medicine by contacting Benjamin Palafox (benjamin.palafox@lshtm.ac.uk).

Abbreviations

ACT	Artemisinin-based Combination Therapy
AETD	Adult Equivalent Treatment Doses
AL	Artemether Lumefantrine
AM	Antimalarial drugs
AMFm	Affordable Medicine Facility For malaria
AMT	Artemisinin Monotherapy
CF	Clinton Foundation
CMS	Central Medical Stores
CQ	Chloroquine
DDIC	Drug Distribution Inspection Committee of the PCN
DHA	Dihydroartemisinin
IPT	Intermittent Preventive Treatment of malaria
LSHTM	London School of Hygiene and Tropical Medicine
NAFDAC	National Agency for Food and Drug Administration and Control
NGO	Non-Governmental Organisation
NMCP	National Malaria Control Programme
OS	ACTwatch Outlet Survey
OTC	Over the counter
PCN	Pharmacists Council of Nigeria
PMG-MAN	Pharmaceutical Manufacturers Group of the Manufac. Assoc. of Nigeria
POM	Prescription only medicine
PPMV	Proprietary Patent Medicine Vendor
PSI	Population Services International
SFH	Society for Family Health, Nigeria
SP	Sulphadoxine Pyrimethamine
VAT	Value Added Tax
WHO	World Health Organization

1. Context

In November 2008, the Global Fund to Fight AIDS, Tuberculosis and Malaria launched the first phase of a new global subsidy on ACTs, known as the Affordable Medicines Facility-malaria (AMFm). The primary objectives of the AMFm are to make ACTs available and affordable to all patients through both the public and private sectors, and to delay the onset of artemisinin resistance by displacing artemisinin monotherapies from the market.

Through a co-payment applied at the manufacturer level, the AMFm will enable public and private (both for profit and not-for-profit) suppliers in approved countries to purchase high-quality ACTs at a fraction of current prices. As a result, it is expected that ACTs will be sold through private shops at a similar price to that of older and less effective drugs, thereby dramatically increasing patients' access to ACTs. The AMFm has been designed to ensure that first-line buyers, who operate at the top of the supply chain and are the first point of entry for drugs into the country, maintain any pre-existing purchasing relationships with manufacturers, and to minimise disruption to the operation of the supply chain. Gaining a comprehensive understanding of public and private sector ACT distribution channels is therefore needed to ensure successful implementation of the AMFm, and ultimately maximise ACT access in each country.

Nigeria is one of the 11 countries eligible to apply for the first phase of the AMFm that will operate for 18 months. The AMFm country application form requests a description of the current supply chain for antimalarials across public and private sectors. The description will serve as a key input into the selection and design of supporting interventions to ensure safe and effective distribution of subsidised ACTs under the AMFm.

This report presents the findings of a rapid assessment of the private sector supply chain for antimalarials in Nigeria. It seeks to identify the strengths and weaknesses of Nigeria's supply chain, and describe how the private sector would respond to subsidised ACTs. The results of the rapid analysis are presented in several sections. First, the report describes the structure of the private sector supply chain for antimalarials in Nigeria, including a description of the business practices of key actors along the distribution chain. Second, it identifies potential barriers that could inhibit the distribution of subsidised ACTs in the private sector. Three supplemental sections include brief discussions on the Nigerian drug monitoring system, the proposed tax exemption for subsidised ACTs under the AMFm, and the private sector capacity to repackage and re-label imported subsidised ACTs.

This assessment was undertaken within the broader set of activities of ACTwatch, a collaboration between Population Services International (PSI) and the London School of Hygiene & Tropical Medicine (LSHTM), which aims to provide and promote evidence and recommendations for policy makers on methods to increase availability and decrease the consumer price of quality assured artemisinin-based combination therapies through the private sector. ACTwatch involves 3 main data collection activities: national level household and outlet surveys, both led by PSI; and a supply chain analysis which is led by LSHTM. The analysis presented below draws on data collected in the first round of the Outlet Survey, and on the sampling methods and data collection instruments developed for the supply chain analysis.

2. Methods

The rapid analysis of the private sector antimalarial supply chain in Nigeria used a mix of qualitative and quantitative methods.

First, primary data were collected during 24 semi-structured qualitative interviews with stakeholders operating at different levels of the supply chain. Of the 24 interviews, 7 were conducted with key informants from governmental, non-governmental and private sector organisations that play an important role in the supply chain (Table 1). Key informants were asked questions about the overall supply chain for antimalarials in Nigeria; their perceptions of the effectiveness of regulations and other factors affecting the price and availability of antimalarials; and their view on the impact of the AMFm on the market for antimalarials in Nigeria.

Table 1: Interviews with Government, NGOs and Private Sector Key Informants

Organisation	Type
Society for Family Health	NGO
Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN)	Private
Pharmacists Council of Nigeria – Headquarters	Government
National Malaria Control Programme	Government
Pharmacists Council of Nigeria – Enugu	Government
National Agency for Food and Drug Administration and Control (NAFDAC)	Government
Pharmacists Council of Nigeria – Kano	Government

The remaining 17 in-depth interviews were conducted with private sector wholesalers and retailers operating at all levels of the pharmaceutical supply chain (Table 2). These respondents were asked questions about the structure of the market for antimalarials and their business practices, including their relationships with their suppliers and customers, stocking decisions, the level of competition and collusion in the market for antimalarials, and their perception of the appropriateness of regulations. In addition, respondents were questioned about how their businesses and the market for antimalarials would respond to subsidised antimalarials through the AMFm.

The interviewees were selected purposively through discussions with Society for Family Health (SFH) and Clinton Foundation (CF) staff working in Nigeria and were interviewed by a LSHTM researcher accompanied by a trained note taker using a prepared semi-structured interview guide. These primary data were supplemented with quantitative analysis of other data where possible. In particular, data from the December 2008 report on the first round of the ACTwatch Outlet Survey in Nigeria were used to estimate key variables, such as antimalarial market shares.

Table 2: Interviews of Private Sector Supply Chain Businesses

Business Type (Location)	Identified by:[2]
Importer (Lagos)	ACTwatch Outlet Survey (OS)
Manufacturer/Importer (Lagos)	Society for Family Health (SFH)
Manufacturer/Importer (Lagos)	SFH, ACTwatch OS
Wholesaler/Importer (Onitsha)	SFH
Wholesaler (Abuja)	SFH
Wholesaler (Abuja)	SFH, ACTwatch OS
Wholesaler (Abuja)	SFH, ACTwatch OS
Wholesaler (Enugu)	SFH
Wholesaler (Enugu)	SFH
Wholesaler (Kano)	SFH
Wholesaler (Kano)	SFH
Wholesaler (Kano)	SFH
Wholesaler (Kano)	SFH
Wholesaler (Lagos)	SFH
Wholesaler (Onitsha)	SFH, ACTwatch OS
Wholesaler/Retailer (Enugu)	SFH
Wholesaler/Retailer (Kano)	SFH

3. Antimalarials in the private sector in Nigeria

3.1. The structure of the antimalarial supply chain

A simplified schematic that describes the flow of antimalarials through the private commercial sector supply chain in Nigeria is provided in Appendix 1.

Several pieces of Nigerian legislation and related regulations define how pharmaceuticals should be distributed from wholesalers to the private sector outlets located at the bottom of the chain. The solid arrows in Appendix 1 demarcate the distribution relationships permitted by legislative texts. Evidence suggests that these regulations are not adhered to in practice. The alternating dash-and-dotted arrows in Appendix 1 show the unauthorised distribution relationships identified during the rapid analysis. Respondents strongly believe that Nigeria has a large informal private sector that plays a significant role in the distribution of medicines. In addition, pharmaceuticals flow between the private and public sectors at different points along the supply chain; these flows are represented in the diagram with the dashed line.

3.1.1. The sources of antimalarials in the private sector

Antimalarial products sold to private sector wholesalers are procured from domestic manufacturers or from international manufacturers by private sector importers. Local manufacturers may also import antimalarial products to complement domestically manufactured product lines.

[2] Businesses interviewed for the rapid survey were identified either as suppliers of antimalarial retail outlets surveyed for the first round of the ACTwatch Outlet Survey (OS) in December 2008, or selected from a list of antimalarial wholesalers operating in the study area recommended by Society for Family Health (SFH) product detailers. This latter strategy was used in order to reach the target number of interviews in the constrained period of data collection.

All antimalarial products must be registered by the National Agency for Food and Drug Administration and Control (NAFDAC) before they may be either manufactured in or imported into Nigeria. In addition, pharmaceutical manufacturers and importers must be appropriately registered with the Pharmacists Council of Nigeria (see next section). The headquarters of most drug manufacturers and importers are located in and around Lagos State and Onitsha, Anambra State. In 2008, there were 140 drug manufacturers registered with the Pharmacy Council of Nigeria (PCN), the government agency responsible for the regulation of pharmaceutical related activities, and 286 drug importers. Among the local manufacturers, over 100 of these are registered to produce an antimalarial medication, while 10 are registered to produce ACTs. Imported ACTs come predominately from India, China, Western Europe, but also from other countries including Morocco, Senegal, Vietnam and Israel[3].

Several multinational pharmaceutical manufacturers have local subsidiaries that import their antimalarial products (e.g. Ipca Laboratories Ltd (India), Sanofi-Aventis (Morocco), Novartis (China, USA)), while other foreign manufacturers may deal with one or more local importers.[4] However, while importers are free to change their suppliers, respondents indicated that it is common practice for importers to act as sole agents for products manufactured outside of Nigeria. This tendency to enter into exclusivity agreements is fostered by the stringency of the registration requirements (i.e. foreign manufacturers must be certified by NAFDAC prior to supplying drugs for import which can be a lengthy process), the amount of time that it takes to develop a relationship with the supplier, and the amount of investment that goes into developing the local market for the imported product. Rather than changing suppliers, respondents indicated that they purchase from multiple suppliers, which allows importers to offer greater product variety to their customers.

The large antimalarial importers interviewed order from their suppliers 3-6 times per year. The quantities procured depend primarily on sales trends, but other factors taken into consideration include levels of remaining stock from previous consignments, knowledge of upcoming large customer orders or tenders (often from government), and changes in policy and/or recommendations.[5,6] They indicated that shipments of orders usually take 4-6 weeks to arrive but can take longer, often due to problems with product availability and clearance at the port of entry. According to one respondent, the cost of freight is built into the product cost; however they bear the cost of transporting the goods from the port to their warehouse. Clearance tax of 2-3% is also paid.

For both manufacturer and importers, promotion is a key aspect of their business. Teams of sales representatives and product detailers are based across the country and frequently visit customers to promote products, generate demand amongst prescribers, and to take and deliver orders. As such,

[3] The product registries provided by NAFDAC are incomplete and these numbers are approximations.

[4] Also derived from incomplete NAFDAC product registries, these examples are drawn from the list of foreign manufacturers that produce a WHO prequalified ACT who export any antimalarial product to Nigeria; for other WHO prequalified manufacturers, Cipla Ltd deals with one local importer, Evans Medical PLC; while Guilin Pharmaceutical Co. Ltd. deals with several local importers, including Asian Tiger Pharma Co., Chez Pharma Nig. Ltd. and Philips Pharmaceuticals Ltd.

[5] Both importers and manufacturers described how changing the malaria 1st line treatment policy to ACTs impacted the sales volumes of their antimalarial products, noting that market share of ACTs continues to grow.

[6] Local manufacturers reported that 70-75% of current antimalarial sales revenues were from non-artemisinin therapies (chloroquine and SP in particular); although the demand for ACTs is increasing and they predicted that ACTs could take up to 70% of antimalarial market share in as little as 6 months.

it is common for these staff to be provided with vehicles. One manufacturer respondent indicated that they are actively involved in a programme for training PPMVs. Bonuses (e.g. buy 10, get 1 free) and gifts (e.g. small appliances, promotional items) may be offered to customers; while discounts of 2-5% may be offered to wholesale customers who qualify as 'authorised distributors' (see next section for description). Discounts may also be offered to customers paying in cash.

Price mark-ups among domestic manufacturers range from 15-40%, while the mark-up of importers was said to be dependent on the costs of products and importing, exchange rate and competition in market. Credit facilities with terms ranging from 7-45 days may be offered to those wholesale customers who qualify as 'authorised distributors'.

3.1.2. The wholesaling of antimalarials in the private sector

In order to manufacture, distribute, or retail pharmaceuticals, businesses must be registered with the PCN. While it is not mandatory for manufacturers, importers, authorised distributors, or wholesalers that the business be owned by a licensed pharmacist, a pharmacist must be named as the superintendent pharmacist as part of the application. Retail pharmacies, however, must list a registered pharmacist as at least one of the owners. As a pharmacist may be associated with one business only, most pharmacists interviewed argued that this limitation dangerously restricts access of the population to good pharmaceutical care. Also by the end of 2008, there were only 13,922 licensed pharmacists in Nigeria (approximately 10,900 people/pharmacist[7]); so this limitation of practice is considered to be the largest barrier for new entrants to the market. Apart from the pharmacist requirement, respondents for all types of business viewed the remaining requirements as reasonable and did not perceive them to be difficult for new businesses to achieve. Proprietary Patent Medicine Vendors (PPMVs), on the other hand, are not required to have a pharmacist attached to the business. Fees for initial PCN registration and renewal are given in Table 3.

Table 3: Fees for initial PCN registration and renewal

Registration Category	Registration Fee (NGN)[8]	Renewal Fee (NGN)
Manufacturer (2+ product lines[9])	200,000	100,000
Manufacturer (1 product line)	100,000	50,000
Manufacturer (single product)	40,000	20,000
Importers	100,000	50,000
Authorised Distributors	80,000	40,000
Wholesalers	50,000	25,000
Retail Pharmacies	5,000	3,000
PPMVs	2,000	1,000

[7] Based on projected Nigerian population for 2008; Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. (2008) World Population Prospects: The 2008 Revision

[8] The avg. exchange rate in June 2009 (the month of data collection) was 1 US dollar to 149.39 Nigerian Naira

[9] A product line is a group of products marketed by a business sharing common active pharmaceutical ingredients that are sold in various strengths or dosage forms (e.g. Coartem 20/120 tablets is one product, but with Coartem-D dispersable tablets, they constitute a product line)

Once the imported or locally manufactured drugs have been cleared for release by NAFDAC, they move down the supply chain to end up in a variety of private sector drug outlets, including retail pharmacies, private hospitals and clinics, and PPMVs through two main channels:

a) *Series of depots specifically engaged in the warehousing and distribution of consumer products.* These depots may be owned by a single enterprise also engaged in either drug manufacturing or importing, thus constituting a vertically integrated supply chain; but more commonly, these depots are owned by separate private enterprises that specialise in logistics and offer warehousing and distribution as a service for a wide range of products, including drugs (e.g. MDS Logistics[10]). Manufacturers and importers will typically have one central warehouse where manufactured goods or received consignments will be stored prior to distributing to regional depots. For those using a third party logistics company, transportation from port to central depot to regional depot may be included in the contracted service. Both the central and regional depots are often used as warehouses from where their sales representatives who detail in the region may pick and fill orders that they themselves generate. In other cases, wholesale customers may come to the depot to collect orders that they have placed by telephone. As the number and distribution of these depots continues to increase, it is becoming more common for importers and manufacturers to sell directly to larger outlets (such as retail pharmacies and private health facilities), bypassing wholesalers.

b) *Private stand-alone wholesalers that purchase products directly from manufacturers and/or importers who then in turn sell to other wholesalers or drug outlets*. Many private wholesalers aspire to enter into 'authorised distributorship' agreements with their supplier. These non-exclusive agreements may only give these wholesalers the right to purchase directly from the manufacturer or importer (with the product often coming from the above depots); but more attractively, these agreements often allow wholesalers access to preferred pricing, discounts, credit facilities, and promotions.[11] In all locations visited during the rapid supply chain analysis, suppliers had multiple authorised distributors. In order to qualify for this preferred status, wholesale businesses may have to demonstrate a certain ability to reach and maintain specified sales targets, an ability to regularly settle accounts, and a capacity for storage and distribution. In order to access the benefits of these distributorship agreements, several interviewees revealed that competing wholesalers may even agree to pool their purchases to ensure that one of them might qualify. Authorised distributors may also act as regional depots for suppliers who often attach sales/marketing representatives that detail prescribers to generate prescriptions/demand. Under some agreements, orders that arise from these marketing activities will then be picked from the wholesaler's inventories, thus contributing to their overall sales.

[10] MDS Logistics is the largest third party logistics company in Nigeria providing logistics and ancillary services to manufacturers, wholesale distributors and importers. They maintain a network of 47 distribution centers in 31 states of Nigeria and over 200 warehouses.

[11] Wholesalers who are not authorised distributors may still be able to purchase from suppliers; however they may not be offered discounts, credit, or other benefits enjoyed by those customers who do qualify.

In 2008, there were 616 businesses licensed to distribute and wholesale pharmaceuticals in Nigeria. Apart from Lagos and Onitsha, other important regional wholesale drug markets are in Kano, Aba, and Ibadan. Wholesalers' choice of supplier is largely dependent on customer demand as suppliers are often associated with particular products. However, there is also a great deal of value placed on offering customers a variety of product choice, so it is common for wholesalers to procure from many different suppliers. To a lesser degree, wholesalers may purchase from a new supplier depending on product price. As for determining purchase volumes, these decisions are based on considering monthly sales and also the time of year to account for the seasonality of malaria transmission. Most orders are placed directly to manufacturers and importers through their sales representatives or via telephone, and these orders may be delivered (directly by sales representatives, waybilled[12] or couriered) or picked up directly from the depot. Orders are placed as required (as often as once a week), and lead times range from a few hours to one week. In terms of financing, suppliers often require that orders be pre-paid or paid cash on delivery. This was cited by many wholesalers interviewed as a barrier to increasing sales volumes as stock purchase size is often constrained by cash flow and limited access to credit. In some instances, particularly for authorised distributors, credit ranging from 7-45 days may be offered by the supplier.

Distribution practices from the wholesale to retail level vary considerably, which ultimately determines the extent of wholesaler geographic coverage. Some wholesalers focus much of their business within the state where they are located with some customers located in adjacent states, while others choose to actively seek out customers from a wide range of states. While all wholesalers prefer to serve their customers directly on their premises, many also deliver using a variety of means (their own vehicles, waybilling and courier services), sometimes employing sales representatives themselves to both take orders and deliver. As there is no price regulation of pharmaceutical products in Nigeria, price mark-ups vary considerably from 1-3%, to 5-10% for those wholesalers that deliver extensively, up to 15% if there is product scarcity. Other factors that influence pricing decisions include competition, volume of customer purchase, product expiration date, and amount of discount received from the supplier. One respondent indicated that intense price competition allows for horizontal trade among wholesalers without significant impact on retail prices. Wholesalers may also offer credit terms of 1-3 weeks to their customers, particularly if the wholesaler has received credit from their suppliers.

[12] In this common method of delivery, orders placed by customers typically in person or by telephone are packed by the supplier and transported via mass transit operators (e.g. bus lines) to regional transport hubs, such as bus or taxi parks in commercial centres, from where the customer will then retrieve their packaged order. The cost of this delivery is typically borne by the customer who pays the fee to the transport operator upon retrieval of the package; however, some suppliers do offer this as delivery method as a service included in the price of the purchased goods.

3.1.3. The distribution of antimalarials to patients & the informal sector

Patients in Nigeria access treatment for malaria in a diverse range of outlets in the public and private sectors. Data from the ACTwatch Outlet Survey[13] conducted by SFH in December 2008 showed that PPMVs (both registered and unregistered) were the most commonly encountered provider of antimalarials in Nigeria and accounted for 68% of all providers (Figure 1), while public and private health facilities and registered pharmacies each accounted for about a tenth of all providers.[14] Note that certain types of informal outlets, particularly mobile vendors and hawkers, are not included in these estimates, although anecdotal evidence suggests that they may be common.

There were 1526 retail pharmacies registered in 2008. Pharmacies and private health facilities are located mainly in urban areas, while PPMVs, although prevalent in urban areas, are typically the most common and accessible medicines outlet in rural areas. In 2006, there were a total of 13,903 PPMVs registered with the PCN and this number is likely to have increased substantially since then. In addition, there are many PPMVs not registered with PCN. As an indication of total numbers, scaling up data from the December 2008 ACTwatch Outlet Survey gives an estimated total of 43,000 PPMVs across Nigeria.[15,16]

Retail pharmacies and private health clinics typically procure drugs from wholesalers or directly from the manufacturer/importer through a sales representative or detailer. Very large private health facilities may procure through a tendering process. Some wholesalers reported to have PPMVs among their customers; however some respondents indicated that PPMVs may be more likely to purchase their supplies from unregistered drug wholesalers commonly found in central markets. These kinds of markets, which are the typical commercial centres selling a wide variety of consumer goods, are found in virtually all cities and towns across Nigeria. Among wholesale respondents who also engage in retail activities, mark-ups were estimated to be in the range of 20-30%; and while interviewees were unsure, PPMV mark-ups were expected to be similar, if not higher.

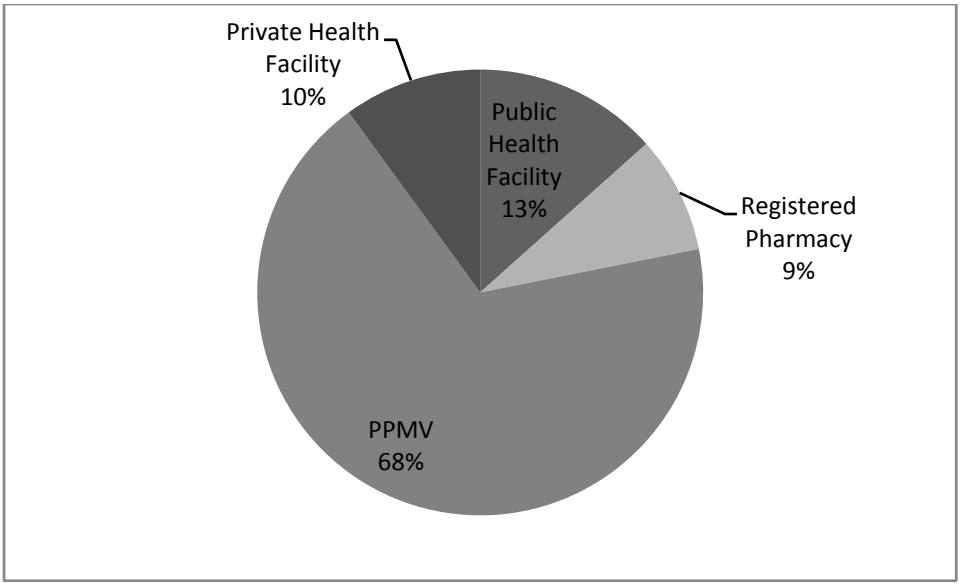
[13] "A total of 607 outlets were sampled (by strata: Lower North, N=155; South/Southeast, N=153; Upper North, N=112; Southwest, N=187). 24 providers refused to be interviewed; 13 outlets were permanently closed; 50 outlets were closed at the time of the visits (up to three visits before exclusion); and in 52 outlets, providers were not available for interview at the time of data collection. These outlets were excluded from the analysis. Overall, 468 providers agreed to participate in the ACTwatch outlet survey. Of these, all 468 outlets stocked antimalarials at any point in the three months prior to the interview, and 444 outlets stocked antimalarials at the time of the interview." *ACTwatch Group*. (2009) Outlet Survey Report (Baseline), Nigeria 2008. www.actwatch.info/results

[14] *ACTwatch Group*. (2009) Outlet Survey Report (Baseline), Nigeria 2008. www.actwatch.info/results

[15] *ibid*.

[16] Rough estimation that used total number of PPMVs found to be selling antimalarials in the 76 sub-districts surveyed during round 1 of ACTwatch Outlet Survey in December 2008, scaled up to all endemic areas using a multiplier based on population estimates from Nigeria census data. See appendix 2.

Figure 1: Retail providers of antimalarials in endemic areas, by type and estimated % of total retail providers (N=462)*



Source: *ACTwatch Group*. (2009) Outlet Survey Report (Baseline), Nigeria 2008. www.actwatch.info/results

*Note that certain types of informal outlets, particularly mobile vendors and hawkers, are not included in these estimates, nor in those shown in other figures, as they were not surveyed during data collection for the first round of the ACTwatch Outlet Survey in December 2008, although anecdotal evidence suggests that they may be common.

The informal market is believed to play a very significant role in the supply chain for antimalarials in Nigeria. It consists of a wide range of facility types, including unregistered PPMVs, and non-traditional medicines outlets such as hawkers/mobile vendors that may operate at transport hubs, supermarkets, community health extension workers, and Role Model Mothers (a type of volunteer community health worker). However the most important type of informal market actor is the market trader that often engages in both drug retailing and wholesaling and can be commonly found in the central markets of cities and towns. It is believed that many of these market traders are registered as PPMVs with the PCN, but operate beyond the scope of their regulated activities. Almost all wholesaler respondents consider these market traders to be important competitors in the wholesale market for antimalarials. Because of the pressure in the formal market to meet sales volume targets, it is believed that much of the inventory sold by informal market traders comes directly from manufacturers, importers and wholesalers themselves. It is also widely accepted that a proportion of the total inventory across the entire private sector (i.e. both formal and informal) consists of smuggled genuine products (or 'parallel imports'), counterfeits, and also drugs leaked from the public sector. Respondents indicated that the informal market traders are attractive to many retailers, particularly PPMVs, because of the competitive prices and convenience (i.e. customers can find all the products they are looking for in one place).

As indicated on the diagram in Appendix 1, the private sector supplies antimalarials to the public sector, typically through a tendering process but also via ad hoc small/emergency purchases. There are two state-level Central Medical Stores (CMS) in Benue and Ekiti states that are now wholesaling to the private sector. Interviewees from PCN indicated that this was a pilot programme that may be extended to include additional state CMSs.

3.2. Antimalarial products in the private sector

There are currently more than 265 artemisinin-based antimalarial products registered with NAFDAC for distribution in Nigeria. Of these, only 33 are manufactured in the country while the remainder are imported from mainly China, India and Western Europe. More than half of these registered products are ACTs (177), of which 15 are manufactured in Nigeria. A list of domestically manufactured artemisinin-based antimalarial products is included in Appendix 4.

To estimate market shares of different antimalarial products, data on the recalled volumes the week preceding the survey from the first round of the ACTwatch Outlet Survey conducted by PSI and SFH in December 2008 were used to calculate adult equivalent treatment doses (AETD) for each antimalarial drug sold in tablet form only (see Appendix 3)[17]. The categories of antimalarial type (WHO approved ACT, Non-WHO approved ACT, Non-artemisinin therapy, Artemisinin monotherapy) used for analysis were selected to best illustrate the potential impact of the AMFm, as only WHO approved ACTs will be eligible for the AMFm subsidy.[18] Depending on the brand, the government-recommended first line treatment, artemether lumefantrine, falls into either the WHO approved ACT or Non-WHO approved ACT category.

In terms of where antimalarials were dispensed, only 5% of all AETDs distributed or sold were provided through public health facilities (which include university and general hospitals, federal medical centres, primary health centres and community health extension workers), while the remaining 95% was sold through the private sector (Figure 2). 62% of all types of AETDs were provided through PPMVs, while Registered Pharmacies were the second largest source of antimalarials (28% of AETDs). [19]

The December 2008 ACTwatch Outlet Survey data also revealed that non-artemisinin therapies continue to dominate the volumes dispensed. Of all AETDs sold or dispensed, 84.4% were non-artemisinin therapies, while 9.2% were artemisinin monotherapies (Figure 3, rightmost bar labelled 'Total'). This pattern was consistently observed across all outlet types (Figure 3), even among public health facilities where one would expect recommended treatment guidelines to be more strictly observed. Also of note was that ACTs constituted less than 2% of the volume sold through PPMVs.[20]

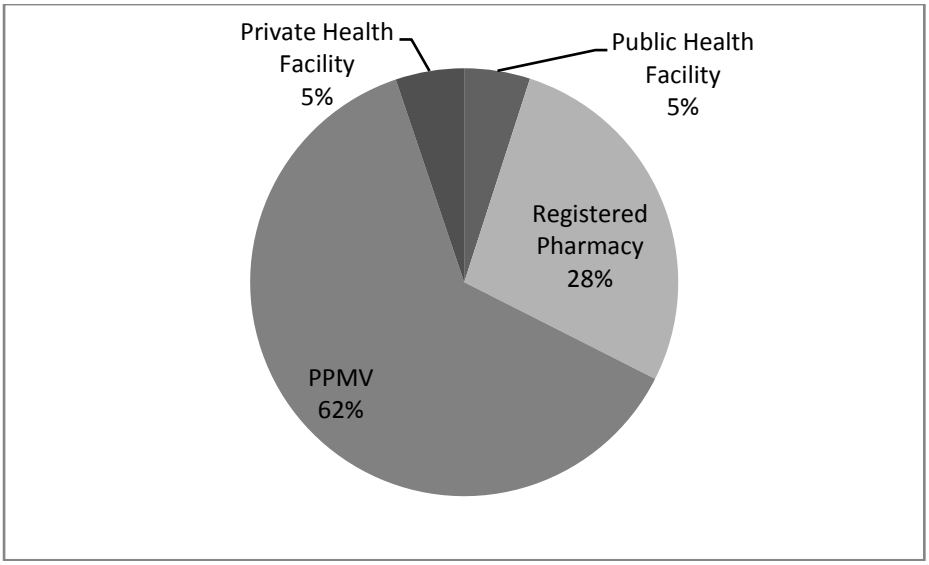
[17] The ACTwatch December 2008 Outlet Survey baseline report for Nigeria does not include pediatric formulations in the volumes and prices reported.

[18] The ACTwatch December 2008 Outlet Survey report for Nigeria presents four ACT categories throughout: First line treatment, WHO approved ACT, Nationally registered ACT, Non-WHO/nationally registered ACT. Because first three categories are not mutually exclusive, for the purpose of the rapid assessment we have retained the category of WHO approved ACT, as well as a second category, non-WHO approved ACT. The category of non-WHO approved ACT estimates the volume of ACTs distributed in the past week that are not approved by the WHO, regardless if they are nationally registered or not. We calculated volume of non-WHO approved ACTs by adding the volume of Nationally registered ACTs to the volume of Non-WHO/nationally registered ACTs and subtracting the volume of WHO approved ACTs distributed, as they were reported in the ACTwatch baseline Outlet Survey Report.

[19] *ACTwatch Group*. (2009) Outlet Survey Report (Baseline), Nigeria 2008. www.actwatch.info/results

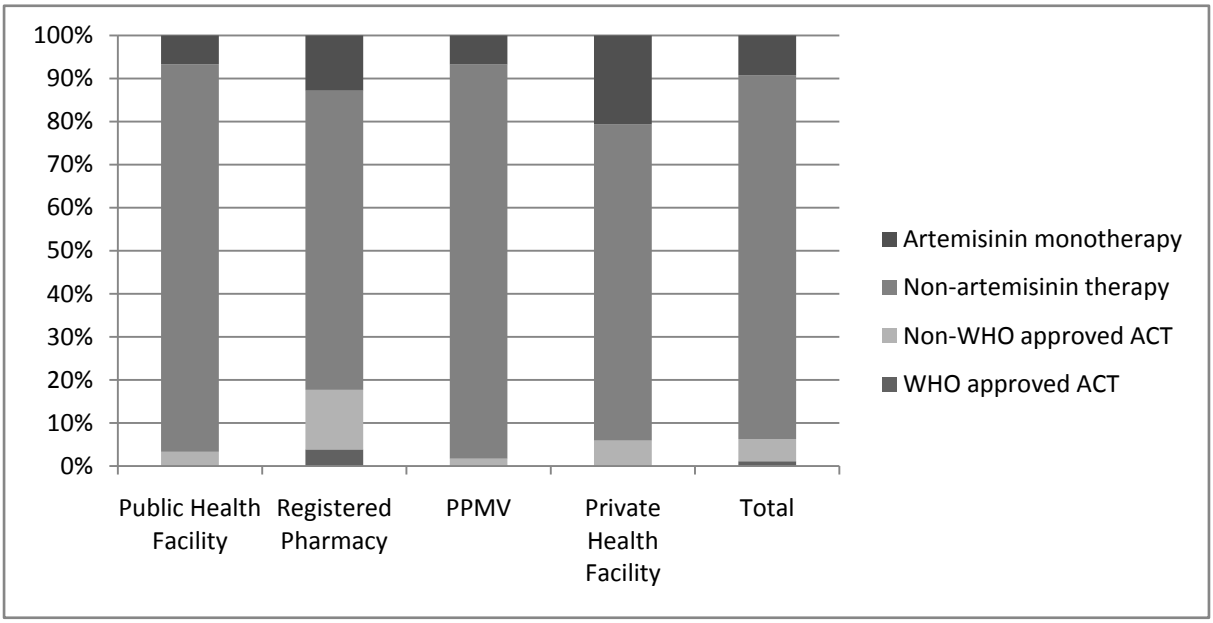
[20] *ibid.*

Figure 2: Total volume of all antimalarials sold or distributed in the past week by outlet type (n=18,548 AETDs)



Source: *ACTwatch Group*. (2009) Outlet Survey Report (Baseline), Nigeria 2008. www.actwatch.info/results

Figure 3: Breakdown of total volume of antimalarials sold or distributed in the past week by antimalarial category and outlet type

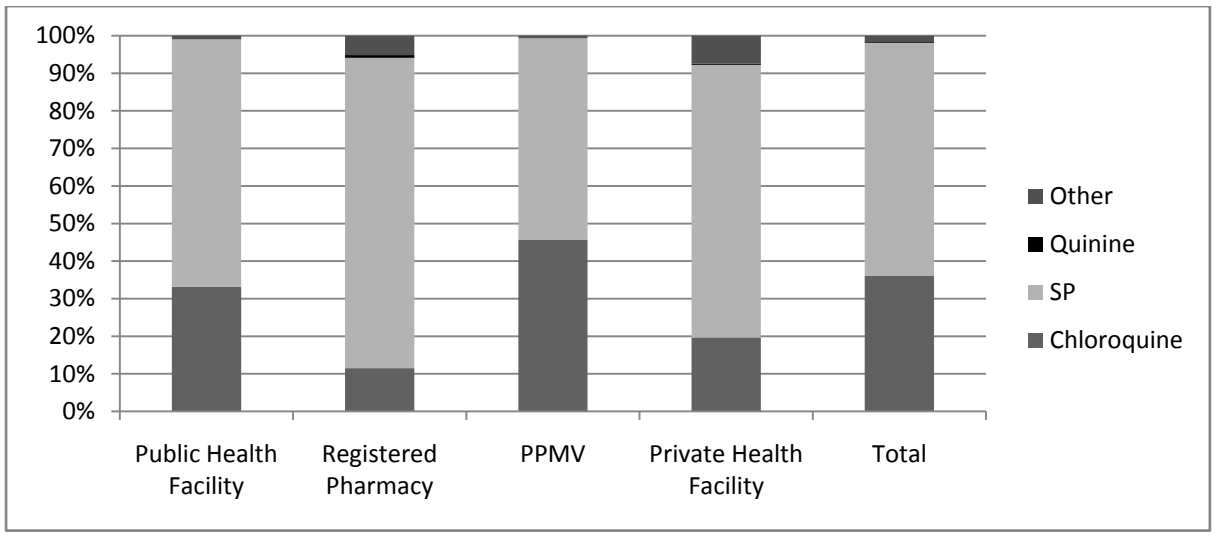


Source: *ACTwatch Group*. (2009) Outlet Survey Report (Baseline), Nigeria 2008. www.actwatch.info/results

Looking more closely at the volumes of non-artemisinin therapies dispensed across outlet types (Figure 4), chloroquine and SP are the dominant antimalarials. Sulphadoxine pyrimethamine accounts for as little as 54% of non-artemisinin AETDs dispensed within PPMVs to as high as 83% among registered pharmacies. It is also worth noting that among PPMVs where 62% of all adult treatment courses of any kind are dispensed (Figure 2), 92% of what is dispensed consists of non-artemisinin therapies; chloroquine and SP combined account for 99% of these volumes.[21]

[21] *ACTwatch Group*. (2009) Outlet Survey Report (Baseline), Nigeria 2008. www.actwatch.info/results

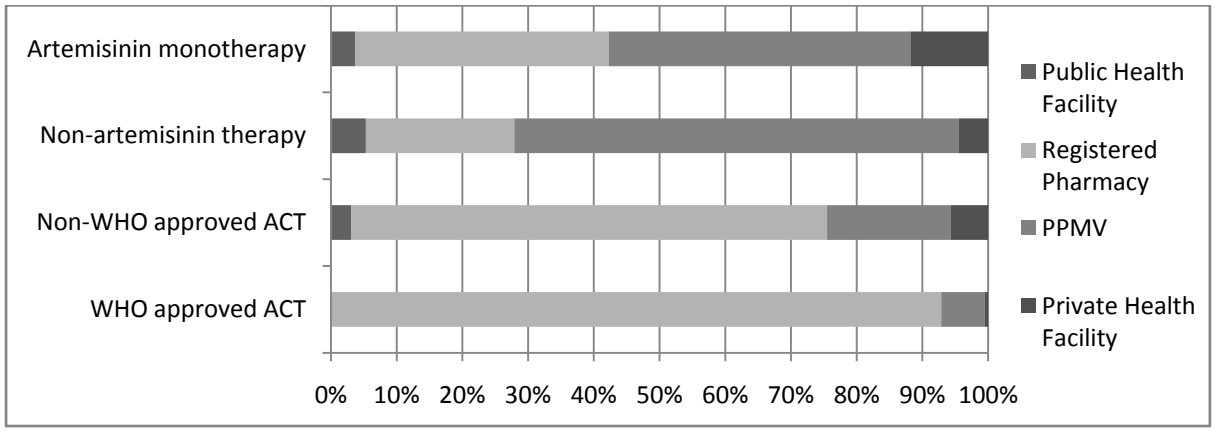
Figure 4: Breakdown of non-artemisinin therapy volumes sold or distributed in the past week by product and outlet type



The market share of the various outlet types also varies by antimalarial type. Figure 5 shows the distribution of recalled sales volumes collected from round 1 of the ACTwatch Outlet Survey by antimalarial and outlet type. Registered pharmacies account for the majority of ACTs distributed for both ACT categories. With particular regard to the market share of WHO approved ACTs, over 90% of the AETDs dispensed were distributed through registered pharmacies with none of this medication being recorded as dispensed from public health facilities.[22]

In contrast, the market for non-artemisinin therapies (particularly chloroquine and SP) is dominated by PPMVs, accounting for 67% of the recalled sales volumes of this type of antimalarial. This is followed by registered pharmacies where 22% of the recalled sales volumes for non-artemisinin therapies were dispensed. Artemisinin monotherapies were found to be sold predominantly in PPMVs and registered pharmacies with each accounting for approximately 40% of the volumes dispensed.[23]

Figure 5: Market share of antimalarial sales volume by outlet type and treatment type



Source: *ACTwatch Group*. (2009) Outlet Survey Report (Baseline), Nigeria 2008. www.actwatch.info/results

[22] *ACTwatch Group*. (2009) Outlet Survey Report (Baseline), Nigeria 2008. www.actwatch.info/results
[23] *ibid.*

4. Barriers to widespread distribution of ACTs in the private sector

Respondents generally reacted positively to the proposed AMFm mechanism and agreed that this initiative could help to improve access to effective treatment for malaria. Both importers and wholesalers indicated a willingness to participate because it was an opportunity to help address an important health problem in Nigeria as well as to potentially improve overall sales, particularly since sales of all types of antimalarials reportedly constitute between 20-40% of total sales revenue.

Experiences of subsidising ACTs in other countries provide indications of the potential impact on market share such a subsidy could have in Nigeria. Preliminary results from the ACT Leaf programme in Uganda show that the subsidised product has achieved approximately 30% share of the market for malaria treatment[24] after 6 months of operation, while in Tanzania, the Clinton Foundation subsidy pilot achieved nearly 50% market share in some of the studied areas after one year.[25] Those wholesalers that stock the current recommended first line antimalarial, artemether lumefantrine, and Coartem in particular, indicated that they would be willing to increase their stocks once subsidised; and those that did not stock it were willing to do so under the AMFm. In general, the wholesalers interviewed believed that significant substitution of older antimalarials (i.e. chloroquine and SP) could occur if the subsidised price was comparable to that of the older products and if supported by appropriate interventions; this substitution, however, will not be complete as familiarity with these older products will still generate some demand. Respondents from different levels of the supply chain also predicted that this substitution would take time as consumers switch from their current preferred antimalarial to the subsidised antimalarial, giving businesses time to adjust their product lines and business model (e.g. marketing, distribution, etc.) Respondents also predict that the level of substitution would be less among more expensive medicines due to consumer preference for premium priced products.

Despite some reservations regarding availability of stock and supplier pricing, almost all respondents interviewed at the intermediate wholesale level (i.e. wholesalers who purchase from manufacturer or importer) believed that the increase in sales volume of the subsidised product both from substitution away from cheaper antimalarials and ACT market expansion would compensate for the decrease in absolute profit per pack sold so long as consumer demand is developed and maintained through appropriate product promotion. To further guarantee the volumes necessary to maintain profit, several of those interviewed suggested limiting the number of participating wholesalers.

In addition, interviewees identified several potential challenges that could inhibit the availability of ACTs in the private sector (which are discussed in further detail below):

1) Leakage to the informal sector
2) Top-level availability of subsidised product
3) Poor acceptance of subsidised product among consumers
4) Opposition from local manufacturers of antimalarials
5) PPMVs and improving accessibility to subsidised product
6) Geographical accessibility of subsidised product

[24] From discussions with staff from Medicines for Malaria Ventures in April 2009
[25] Sabot OJ, et al. (2009). Piloting the global subsidy: the impact of subsidised artemisinin-based combination therapies distributed through private drug shops in rural Tanzania. PLoS One. Sep 2;4(9):e6857.

4.1. Leakage to the informal sector

This continues to be an immense challenge in Nigeria as the continuity of quality assurance mechanisms built into the regulation of the pharmaceutical supply chain (e.g. monitoring of storage conditions, product expiration, etc.) cannot be enforced, thus negatively impacting treatment outcomes. It is widely believed that the informal sector is a very significant source of drugs for businesses at the outlet level, with much of their inventory originating from the formal sector. While respondents conceded that eliminating the informal sector was an unrealistic goal, they also indicated the unfeasibility of imposing regulation on the sector. Instead, most respondents suggested that improved product tracking by a regulatory body from the point of manufacture to dispensing could help to prevent such leakage and ultimately improve end-user product quality. With the recent introduction of the PCN Drug Distribution Inspection Committee (DDIC), there appears to be greater commitment to 'sanitising' the drug distribution system in Nigeria in such a way, largely based on regular inspection of documentation throughout the supply chain, and some proposed reforms have already been pilot tested in three states, including Lagos. However, it is widely recognised that PCN lacks the necessary funds and human resources to meet its current service standards, so it is unlikely that the DDIC will be able to implement the recommended reforms in time for introduction of the AMFm.

Several wholesale respondents also attributed poor levels of regulatory compliance within the formal drug sector to the same funding and capacity constraints, but also to a perceived lack of power on the part of PCN to enforce regulations and impose penalties. This situation could possibly be improved through more coordination between PCN and NAFDAC on monitoring and enforcement, and by establishing greater clarity and distinction on the mandated roles of the two government agencies.[26]

Because the proposed 1st line buyers under the AMFm in Nigeria include SFH, several respondents suggested that 2nd line buyers could be selected among reputable wholesalers who have had previous dealings with SFH and whose superintendent pharmacist plays an active role in the running of the business. This will guarantee revenue at the wholesale level by ensuring that retailing outlets do not bypass wholesalers while pharmacists, who have their license at stake, will ensure that subsidised ACTs are sold to duly registered outlets. Many respondents indicated that if too many wholesalers were permitted to sell the subsidised product, it would become increasingly difficult to trace any leakages.

Also to minimise the prevalence of counterfeits, supporting interventions to differentiate the subsidised product from fake products should be put in place, such as tamper-proof safety seals, distinct packaging, and promotion to increase awareness of where to purchase the subsidised product in the community.

[26] Respondents from PCN also described how their shift toward a more participatory monitoring model (with more frequent informal visits) and away from a model more dependent on formal inspections has improved compliance overall and has been warmly received by private sector businesses.

4.2. Top-level availability of subsidised product

Several respondents strongly felt that sustained regular availability of the subsidised product from manufacturers and importers will be crucial to avoid price speculation associated with scarcity. They believed that poor availability would prevent the subsidised products from being sold at the target price. This would have a negative impact on consumer confidence and would create a more lucrative environment for counterfeiting and leakage.

4.3. Poor acceptance of subsidised product among consumers

While respondents predict that many people will switch to the subsidised product once available, they were also adamant that there will still be a significant market for other antimalarials, such as the niche market for premium products. Other reasons given for the poor acceptance of the subsidised product include the excessive pill burden of artemether lumefantrine and also the continuing popular support for the older antimalarials, such as chloroquine and SP even among pharmacists and medical doctors. The December 2008 ACTwatch Outlet Survey results show that such non-artemisinin therapies, and particularly sulphadoxine pyrimethamine, are still the most commonly dispensed antimalarials across all outlet types, even in public health facilities.[27]

In addition to the comparatively low price, the familiarity of these older products and past successful treatment experiences also drive the continued demand for chloroquine in particular. Increased sensitisation about the treatment failure rates and the additional costs that could be faced due to treatment failure both among health professionals and the community could help to increase substitution toward subsidised ACTs away from chloroquine and SP. As price setting in the private sector appears to be influenced in large part by product availability, perhaps banning of chloroquine and SP retailing (except for certain conditions such as malaria among sickle cell patients and IPT) could create product scarcity that would drive up prices and facilitate substitution toward subsidised ACTs. Unpublished data from the ACTwatch Supply Chain Study indicates that this is being experienced in Uganda where such a ban has been imposed. A ban could, however, push the wholesaling of chloroquine and SP further into the informal sector and make counterfeiting and smuggling of banned products more lucrative. Additionally, while a ban on artemisinin monotherapies (AMTs) has not been imposed, one respondent indicated that NAFDAC has stopped registering new AMTs, and that upon expiry those AMTs already registered will not be renewed. Certificates of registration issued by NAFDAC are valid for a period of 5 years.

4.4. Opposition from local manufacturers of antimalarials

Because local manufacturers will not be able to access AMFm funds to subsidise their products, they will likely lose significant market share upon introduction of the AMFm. This will be compounded by substitution away from locally manufactured AMTs and older medications, toward the subsidised ACT. The manufacturers interviewed question the sustainability of the AMFm and criticised the lack of consideration given to developing pharmaceutical self-sufficiency in Nigeria. These respondents urged that local manufacturers should be assigned a role under the AMFm, perhaps in distribution or

[27] *ACTwatch Group*. (2009) Outlet Survey Report (Baseline), Nigeria 2008. www.actwatch.info/results

repackaging in the short-term or contracted local manufacturing of the subsidised product in the medium-term; otherwise they could pose a significant threat to the success of the subsidy.[28]

4.5. PPMVs and improving accessibility to subsidised product

Because PPMVs handle the majority of antimalarial volumes at the outlet level in Nigeria (most of which are not ACTs), all respondents recognised the importance of their participation in the AMFm. PPMVs have a reputation for providing poor pharmaceutical care to consumers, as they often dispense medicines that they are not permitted to sell (e.g. injectables and antibiotics), diagnose without proper training and operate without proper registration. As a result, many wholesaler respondents (almost all of whom were pharmacists by training) indicated that they were reluctant to engage them as customers.[29] Furthermore, they believe that PPMVs are more likely to purchase their supplies from the informal sector. To ensure that PPMVs can more readily procure supplies through the formal sector, relations between pharmacists and PPMV operators must improve, perhaps through redoubled efforts to register PPMVs and their premises with PCN, and to train PPMV operators on dispensing, storage, diagnosis and stock management.

Also as the greatest potential for substitution from older therapies to ACTs rests among PPMVs who are often not targeted by sales representatives for detailing, several respondents suggested that more PPMVs could be included in the usual marketing and sales activities (including order taking and delivery) already being done by private sector distributors; however this would increase marketing expenses.

4.6. Geographical accessibility of subsidised product

Because sales volume targets are common and important features of authorised distributorship agreements between suppliers and wholesalers, discussions on incentives tended to focus more on how these could be used to improve distribution. Most wholesalers indicated a willingness to do more deliveries and push 'further into the grassroots'. To do this, they requested help with costs associated with logistics (purchase and maintenance of vehicle, fuel, accommodation while in the field, per diems, etc.) and staffing. Apart from direct cash incentives, they suggested easier access to credit facilities, and to low-interest and low-collateral loans. Suggested non-financial incentives included guaranteed territory for distribution, better access to good warehousing facilities, and marketing assistance from suppliers (e.g. suppliers could distribute lists of authorised distributors through their network of sales representatives in the field). Because the relationship between the supplier and authorised distributor is an important one to which many wholesalers aspire, perhaps this can be leveraged to include some socially responsible targets related to improving geographical coverage.

[28] Respondents did not elaborate on specific threats, but emphasized that local manufacturers are powerful actors that could exhibit considerable influence as lobbyists and on drug distribution practices

[29] One pharmacist respondent indicated that they require all wholesale customers to produce evidence of current PCN registration prior to being served

5. Discussion on the national drug monitoring system

5.1. Pharmacovigilance system in Nigeria

The majority of pharmacovigilance data in Nigeria is generated via passive surveillance in health facilities. First, primary evaluation of the potential event is done at the health facility. In some facilities, there are committees tasked to review potential adverse events. If deemed to be an adverse event, a NAFDAC adverse event reporting form ('yellow form') should be completed and forwarded to the NAFDAC Pharmacovigilance Centre with any necessary attachments. These forms are provided to all health facilities free of charge. The forms also have pre-paid postage, so that once completed, they can be dropped in the post for forwarding to NAFDAC.

The NAFDAC Pharmacovigilance Centre has an expert committee that reviews these adverse events and determines if these reports should be forwarded to the WHO International Drug Monitoring Programme in Uppsala, Sweden. The NAFDAC Pharmacovigilance Centre will also send a report to the owner/manufacturer of the product and decide which steps are to be taken (e.g. whether to recall the product, whether to have the manufacturer review the formulation or withdraw the product totally from circulation).

This is the most formalised adverse events monitoring in the country and occurs at the facility level in the out-patient and in-patient settings. Within the community, reporting of adverse events is dependent on the initiative of both the individual to report the event and on the provider of pharmaceutical care to probe their patient or customer for any potential adverse reactions during subsequent visits. The same adverse event reporting forms are in theory available to health professionals from NAFDAC for this type of passive surveillance; though it is unclear how many reported adverse events are identified in this way. One respondent indicated that NAFDAC is presently training health care workers at different levels of the health system, including Community Health Workers, on how to better identify and report adverse events. This could also be reinforced through enhanced pre-service pharmacovigilance training for pharmacists or as continuing education, and discussion in professional newsletters, communiqués and circulars.

In the private sector, drug manufacturers conduct 'in-house' adverse events monitoring. Manufacturers appear to have a variety of methods to identify potential adverse events: customer call centres, feedback from point of sales and prescribers, and through ad hoc surveys of customers (e.g. patients and/or outlets). One manufacturer has standard reporting forms that are carried by field staff/sales representatives. Potential adverse events are first investigated internally, primarily to determine if the product implicated is genuinely theirs. Manufacturers typically employ a regulatory affairs manager or medical adviser who may then liaise with NAFDAC on the subject and determine appropriate action.

The sharing of results from internal investigations among manufacturers with NAFDAC seems to be voluntary. Therefore, less severe events which may not be deemed serious enough to communicate to NAFDAC will likely not contribute to national adverse events databases. These events are also less likely to be picked up in the facility-based system as they typically will not present at health facilities.

It is unclear how similar in-house adverse event reporting forms of drug manufacturers are to the NAFDAC standardised form, or even if a basic set of common essential indicators are being collected. If this could be established, then data on adverse events from the parallel public and private pharmacovigilance systems could be more readily combined to provide a more complete national picture of the incidence of adverse events.

The time required to complete and submit reporting forms in health facilities is also considered to be an important factor limiting the completeness of reporting. One respondent suggested that perhaps the data requirements and the process of event reporting could be reviewed to see if this time burden can be reduced. The effectiveness of training and its impact on the completeness of reporting could also be studied in order to optimise these inputs.

It is, however, well known that self-treatment and advice from non-professionals is common for malaria treatment in Nigeria, which renders the predominantly facility and professional driven form of pharmacovigilance largely ineffective at the community level. Outside of the health facility setting, these pre-paid reporting forms are still meant to be used but the collection of adverse event data is largely initiated through voluntary patient reporting. And because most antimalarials will be consumed outside of health facilities, it is likely that only severe adverse events will be captured by the facility-based reporting system since these are most likely to present at a health facility. Less severe adverse events will likely be under-reported. Efforts to increase awareness within the community could be made to help individuals recognise potential adverse events (e.g. "if you recently took a medication and felt unwell, worse off, or failed to recover, you should…"), know who to speak to about the episode (e.g. speak to the person from whom you purchased the medicine, health professional at government health facility, etc.), and a very basic understanding of what information they should bring with them (e.g. original packaging, prescription, description of types and timing of signs and symptoms, etc.) Better training of PPMV owners and dispensers to increase use of adverse events reporting forms could also improve reporting.

5.2. Drug quality monitoring in Nigeria

According to NAFDAC, drug quality is monitored at various levels of the supply chain. Primarily, drugs are tested by NAFDAC at the point of entry (either at import for internationally manufactured products, or at the factory gate for locally made products) where they are sampled, tested and certified prior to being released for distribution within Nigeria.

Once the products have entered into local distribution, NAFDAC also conducts routine sampling and testing of products at all levels of the supply chain (distribution, wholesale, retail and household) to support public health programmes. In theory, this level of monitoring allows NAFDAC to identify where breakdowns in pharmaceutical management practices (e.g. poor storage conditions, lost records, etc.) may have occurred in the supply chain that lead to drug quality issues and to trace back to where in the supply chain these failures occurred, identify implicated products, isolate them and issue recalls as necessary. Due to the limited scope of this rapid analysis, the implementation and effectiveness of such practices at ensuring drug quality could not be evaluated.

5.3. Antimalarial drug resistance monitoring in Nigeria

According to the National Malaria Control Programme, data for drug resistance surveillance comes from routinely collected data as part of the National Health Management Information System (NHMIS), from 14 sentinel sites located throughout the six geopolitical zones of the country, and also ad hoc population level surveys. For routinely collected data, reporting is monthly; however completeness and timeliness of reporting is often affected by the deficiency in capacity, inadequate resources, poor communication and transmission of data from health facilities at State and local government levels.

As much of the treatment at the community level is delivered through private channels, many instances of treatment failure may not be picked up through the regular methods of data collection, underestimating the prevalence and rates of drug resistance. Improvement in drug resistance monitoring at the community level could be achieved perhaps through interventions aimed at increasing private sector involvement in national drug monitoring activities.

6. Discussion on the proposed tax exemption for subsidised ACTs

For Nigeria, it has been proposed that NGOs experienced in international drug procurement and supply chain management, rather than private commercial sector drug importers, serve as the 1st line buyers of subsidised ACTs under the AMFm in order to take advantage of tax exemptions afforded these types of organisations under current legislation.

Most respondents who were asked for their opinions on this arrangement responded positively, primarily because they expressed concern over the feasibility of meeting target price points at each stage of the supply chain: the 1st line buyer tax exemption provides more leeway to meet those targets while ensuring enough of a margin can be gained.

Passing on of tax savings could also lead to additional profits for the 2nd line buyer which could be invested into improving distribution and geographic coverage. Alternatively, the additional profits generated by the tax exemption could be used by the 1st line buyer to provide a greater range of incentives, both financial and non-financial, or to address some of the other potential challenges identified.

7. Discussion on private sector capacity to repackage and relabel

Certain respondents were also asked to comment on their capacity and willingness to either repackage or re-label imported subsidised ACTs. Responses varied considerably.

In general, the process of approval for repackaging a pharmaceutical product with NAFDAC is perceived to be straightforward as it is essentially the same as registering a finished product. The business must pay the registration fee, submit a sample of the finished product and describe how the product will be sold and distributed. NAFDAC may ask them to resubmit another sample once the packaging has been finalised. NAFDAC may also then inspect the facilities, but this has not been the experience for all respondents.

Among respondents who do not locally manufacture antimalarials, most indicated that they did not currently repackage or re-label. While they said that to do so would be feasible, they believe that it would be better for their suppliers to do the repackaging, preferably the manufacturer. One respondent indicated that his operations were optimised to do only warehousing and distribution and that including repackaging and/or relabeling would require additional space, staff and equipment.

Another respondent highlighted past experience with the introduction of SP for community-level distribution in the public sector. At that time, the manufacturer of this particular SP was able to provide the product in special packaging in order to differentiate it from the identical product available in the private sector. This respondent suggested this as an option for the AMFm in Nigeria.

One large importer of antimalarials that does not currently repackage or re-label imported goods indicated that they would be interested in repackaging once their manufacturing plant is completed in about 18 months where they will then have the facilities to do so.

Among local manufacturers who also engaged in importing of antimalarials, responses were varied. One local manufacturer who produced a full range of oral antimalarials also imported injectable antimalarials as there were no manufacturing facilities for injections in Nigeria. These imported products arrived as finished products. When asked if they would consider repackaging, the respondent indicated that they prefer to import finished products as it would not be cost-effective for them to repackage or re-label because the labour and materials required are cheaper in the country where most of their imports originate. In Nigeria, another barrier to expanding operations to include repackaging is the issue of unreliable electricity supply and the substantial cost of running generators.

Another manufacturer interviewed that also imported antimalarials did engage in the repackaging of these 'semi-packaged' or 'palletised' imports. They also noted that 85% of inputs used for packaging are imported, including the cardboard (although printing is done locally). For the finishing of imported blistered ACTs, the rough cost of packaging constitutes 6-20% of the final price of the product, depending on the cost of imported inputs. As this respondent is a large manufacturer, they already have fully operational packaging facilities and run their packaging lines 24 hours a day. Because of this and despite having to import most of the packaging material, the respondent felt that it is more cost-effective to repackage locally rather than import finished product.

The Society for Family Health (SFH) was also interviewed for this topic because of their extensive experience with importing health products. Presently, SFH repackages condoms and intrauterine devices (a non-pharmaceutical contraceptive), applies a safety seal to some other contraceptive products (pills and injections), and inserts literature into a variety of packaged products. All packaging materials are sourced locally, except for the safety seals which are imported, and the repackaging operations take place in their Lagos central facilities. As an NGO, SFH saves 5% on the products they import for repackaging as they are not required to pay VAT which allows them to offer competitive pricing and gives them an advantage in negotiations. Consequently, the cost of repackaging and applying the safety seal only has a small impact on the final selling price of the product.

8. Concluding Remarks

Analysis of the current antimalarial product market indicates the enormous potential for impact in increasing access to effective antimalarials through the private commercial sector in Nigeria by subsidising ACTs under the AMFm. While generally welcoming the idea of such an intervention, respondents underscored the importance of understanding the structure and operation of the private commercial drug distribution system in order to ensure the successful implementation of the AMFm.

Through discussions with individuals from both the public and private sectors, a number of key barriers were identified, ranging from poor product availability at the top of the distribution chain to poor consumer acceptance of the subsidised product at the opposite end of the chain, and also recommendations to address them, as summarised below:

- Implement a major public promotion campaign for the subsidised product to sensitise the population to the availability of low-cost effective antimalarial treatment in both the public and private sectors, to reduce domestic demand for antimalarials purchased in the informal sector, and to attract patients to formal structures to purchase subsidised ACTs.

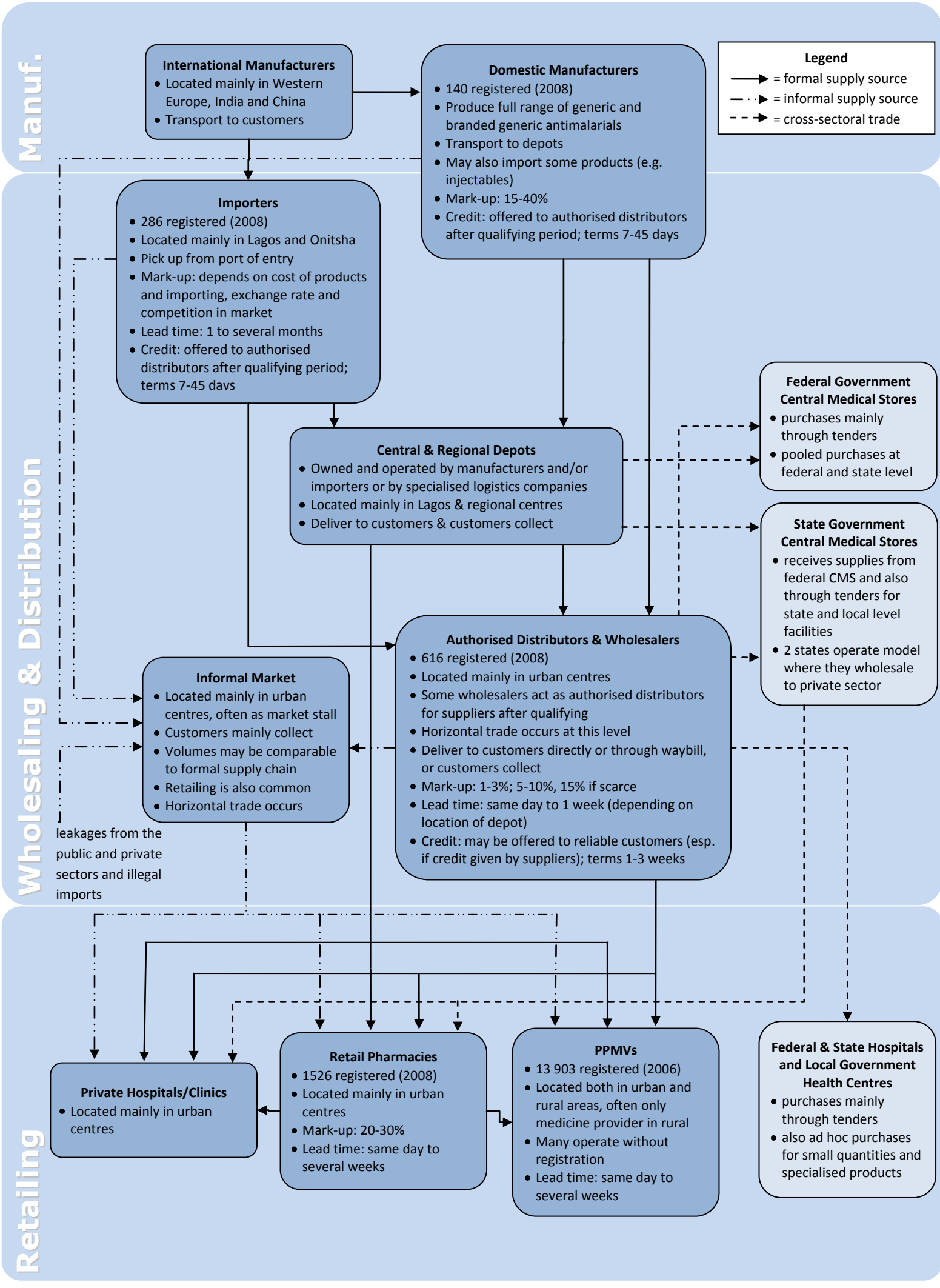
- Ensure sustained top-level availability of the subsidised product to avoid price speculation associated with scarcity.

- Strengthen regulatory capacity through improved funding and greater powers to enforce regulations to better prevent leakage of subsidised product to the informal sector, minimise prevalence of counterfeit products, and improve end-user product quality.

- Engage appropriately with the influential domestic pharmaceutical manufacturing sector to minimise their opposition to the AMFm.

- Leverage PPMVs and use appropriate incentives to improve widespread access to quality ACTs.

Appendix 1: The private for-profit sector supply chain for antimalarials



Appendix 2: Population data used to scale-up ACTwatch Outlet Survey Data to generate national estimates of retail provider numbers

Stratum name	Lower North	South East South South	Upper North	South West
Population of 19 sub-districts visited for the ACTwatch Outlet Survey	239,305	250,447	248,101	253,563
Total stratum population from 2006 census	24,854,886	33,808,676	59,670,684	21,669,296
Adjustment factor to scale up Outlet Survey data	103.9	135.0	240.5	85.5

Appendix 3: Antimalarial doses used to calculate adult equivalent treatment doses

Drug	Treatment regimen		
Amodiaquine	9 X 200 mg	or	11 X 153.1 mg
Artemether	14 X 50 mg	or	7 X 100 mg
Artemether – Lumefantrine	24 X 20 mg / 120 mg	or	12 X 40 mg / 480 mg
Artemisinin –Napthoquine	8 X 125 mg / 50 mg		
Artesunate	14 X 50 mg	or	7 X 100 mg
Artesunate - Amodiaquine	12 X 50 mg + 12 X 153.1 mg	or	6 X 100 mg + 12 X 270 mg
Artesunate – Mefloquine	12 X 50 mg + 6 X 250 mg	or	6 X 100 mg + 6 X 250 mg
Artesunate – SP	3 X 200 mg + 3 X 500 mg/25 mg 6 X 100 mg + 6 X 500 mg/25 mg	or or	3 X 200 mg/500 mg/25 mg 6 X 200 mg/500 mg/25 mg
Chloroquine	15 X 100 mg	or	10 X 150 mg
DHA – Piperaquine	8 X 40 mg/320 mg	or	12 X 30 mg/225mg
DHA – SP	3 X		
Halofantrine	6 X 233 mg		
Quinine	18 X 100 mg	or	6 X 300 mg
SP	3 X 500 mg/25 mg		

Appendix 4: Lists of registered artemisinin-based antimalarials in Nigeria

PRODUCT NAME	ACTIVE INGREDIENT	NAME & ADDRESS OF APPLICANT	NAME & ADDRESS OF MANUFACTURER	PRESENTATION
ACTIMAX ORAL SUSPENSION (RASPBERY,BANANA,OR	ARTEMETHER 15MG,LUMENFANTRINE 90MG	DIVINE ESSENTIAL FORMULATIONS KM 10, LASU OJO ROAD,	SAME AS APPLICANT	SUSPENSION X 60ML
ACTIMAX TABLETS (OTC)	ARTEMETHER 40MG,LUMENFANTRINE 240MG	DIVINE ESSENTIALS FORMULATIONS KM 10,LASU OJO ROAD,EGAN	SAME AS APPLICANT	TABLETS X 2 X 6'S
ACTIVIN TABLETS (POM)	ARTESUNATE 100MG,AMODIAQUINE 300MG	DIVINE ESSENTIALS FORMULATIONS KM 10,LASU OJO ROAD,EGAN	SAME AS APPLICANT	TABLETS X 2 X 6'S
ACTPRO AL TABLETS (OTC)	ARTEMETHER 20MG,LUMENFANTRINE 120MG	ECOMED PHARMA LTD. PLOT 32, LYNSON CHEMICAL AVENUE, KM 38, LAGOS	SAME AS APPLICANT	TABLETS X 24'S
ACTPRO TABLETS (OTC)	ARTESUNATE 50MG,AMODIAQUINE 153MG	ECOMED PHARMA LTD KM 38,LAGOS-ABEOKUTA EXPRESSWAY,	SAME AS APPLICANT	TABLETS X (12 + 12)
ARENAX ARTESUNATE X 6'S	ARTESUNATE 100MG	SWISS PHARMA NIG. LTD 5, DOPEMU RD., AGEGE, LAGOS	SAME AS APPLICANT	TABLETS
ARENAX PLUS TABLETS (OTC)	ARTEMETHER 20MG,LUMEFANTRINE 120MG	SWISS PHARMA LTD; 5, DOPEMU ROAD, AGEGE, LAGOS.	ECOMED PHARMA LTD; PLOT 32, LYNSON CHEMICAL AVENUE, KM.	TABLETS X 2 X 14'S
ARNET TABLETS (POM)	SODIUM ARTESUNATE, 50MG	VITAPHOS LAB (H) LTD 3, ADEDOTUN DINA CRESCENT, MARYLAND,	SAME AS APPLICANT	TABLETS X 12'S
ARTELUM TABLETS	ARTEMETER 40MG, LUMEFANTRINE 240MG	MAY & BAKER NIG LTD 3/5, SAPARA STREET, IKEJA INDUSTRIAL ESTATE, IKEJA,	SAME AS APPLICANT	12
ARTEMAX	ARTESUNATE 100MG	SWISS PHARMA NIG. LTD. 5, DOPEMU ROAD, AGEGE - LAGOS.	SWISS PHARMA NIG. LTD. 5, DOPEMU ROAD, AGEGE - LAGOS.	TABLETS
COFETRAN TABLETS (OTC)	ARTEMETHER 20MG,LUMEFANTRINE 120MG	CHAN MEDI PHARM LTD. LITTLE RAYFIELD, JOS, PLATEAU STATE	ECOMED PHARMA LTD. KM 38, LAGOS-ABEOKUTA	TABLETS X 2 X 12'S
COTEMAL TABLETS (OTC)	ARTEMETHER 50MG,AMODIAQUINE 153MG	CHAN MEDI PHARM LTD. LITTLE RAYFIELD, JOS, PLATEAU STATE	ECOMED PHARMA LTD. KM 38, LAGOS-ABEOKUTA	TABLETS X 1 X 24'S
DART ARTESUNATE & AMODIAQUINE	ARTESUNATE 200MG, AMODIAQUINE HCL 780MG	SWISS PHARMA NIG LTD, 5, DOPEMU RD, AGEGE, LAGOS.	SAME AS APPLICANT	TABLET
DART TABLETS FOR CHILDREN (OTC)	ARTESUNATE 50MG,AMODIAQUINE HCL 260MG	SWISS PHARMA NIG. LTD 5,DOPEMU RD, AGEGE, LAGOS	SAME AS APPLICANT	6'S
DART TABLETS FOR CHILDREN (OTC)	ARTESUNATE 50MG,AMODIAQUINE 153MG	SWISS PHARMA NIG. LTD. 5, DOPEMU ROAD, AGEGE, LAGOS	SAME AS APPLICANT	TABLETS X 6'S
DIASUNATE CAPLETS (POM)	ARTESUNATE 100MG + AMODIAQUINE 400MG	EMZOR PHARM. IND. LTD. PLOT 3C, BLK A, ASWANI MARKET RD, ISOLO LAGOS	SAME AS APPLICANT	CAPLETS X 6'S
EFONREX DS CAPSULES (OTC)	ARTESUNATE 100MG, AMODIAQUINE 400MG	BOND CHEMICAL INDUSTRY LTD; ADESAKIN LAYOUT,OFF IWO	SAME AS APPLICANT	CAPSULES X 6'S
EFONREX TABLETS (OTC)	ARTESUNATE 50MG AMODAQUINE 153.8MG	BOND CHEMICAL IND. LTD ADESAKIN LAYOUT, AWE, OYO STATE, NIGERIA.	SAME AS APPLICANT	TABLETS X 24
FARENAX TABLET(FORMERLY FANSUNATE) (OTC)	ARTESUNATE 200MG SULPHADOXINE 500MG PYRIMETHAMINE	SWISS PHARMA NIG. LTD 5,DOPEMU RD,AGEGE,LAGOS	SAME AS APPLICANT	6'S
FARENAX TABLETS FOR CHILDREN (OTC)	ARTESUNATE 50MG,SULPHADOXINE 500MG,PYRIMETHAMINE 25MG	SWISS PHARMA NIG. LTD 5,DOPEMU RD, AGEGE, LAGOS	SAME AS APPLICANT	4'S
GENOMSUNATE CAPSULES (OTC)	ARTESUNATE 50MG,AMODIAQUINE 200MG	GENOM PHARMACEUTICALS LTD. LAGOS-ABEOKUTA EXPRESSWAY, TOLLGATE	SAME AS APPLICANT	CAPSULES X 12'S

LA-TESEN DROPS (OTC)	ARTEMETHER 20MG/ML,LUMEFANTRINE 120MG/ML	AFRAB-CHEM LTD. 22, ABIMBOLA STREET, ISOLO IND. ESTATE, ISOLO,	SAME AS APPLICANT	DROPS X 8ML
LA-TESEN SUSPENSION (OTC)	ARTEMETHER 20MG/5ML,LUMEFANTRINE 120MG/5ML	AFRAB-CHEM LTD. 22, ABIMBOLA STREET, ISOLO IND. ESTATE, ISOLO,	SAME AS APPLICANT	SUSPENSION X 60ML
LUMETHER PAEDIATRIC DISPERSIBLE TABLETS (OTC)	ARTEMETHER 10MG, LUMEFANTRINE 60MG	VITAPHOS LAB. NIG. LTD; 3, ADEDOTUN DINA CRESCENT, MARYLAND,	SAME AS APPLICANT	TABLETS X 24'S
LUMETHER TABLETS (OTC)	ARTEMETHER 20MG,LUMENFANTRINE 120MG	VITAPHOS LAB. LTD. 3, ADEDOTUN DINA CRESCENT, MARYLAND,	SAME AS APPLICANT	TABLETS X 2 X 12'S
LYNSUNATE TABLETS (OTC)	ARTEMETHER 20MG,LUMEFANTRINE 120MG	LYN-EDGE PHARM. LTD. NO. 113 OLD ABA RD, PORT HARCOURT, RIVER STATE.	SAME AS APPLICANT	TABLETS X 2 X 12
MALACT TABLETS (OTC)	ARTESUNATE 100MG,AMODIAQUINE HYDROCHLORIDE 400MG	MAY & BAKER NIG PLC. 3/5 SAPARA STREET, IKEJA INDUSTRIAL ESTATE IKEJA	SAME AS APPLICANT	TABLETS X 6 X 6'S
QINGHAO CAPSULES (POM)	ARTEMISININ 50MG,PIPERAQUINE PHOSPHATE 150MG	FIDSON HEALTHCARE PLC; KM. 38, LAGOS – ABEOKUTA EXPRESSWAY, OTA, OGUN	SAME AS APPLICANT	CAPSULES X 10'S
QUINARNET TABLETS (OTC)	ARTESUNATE 50MG,AMODIAQUINE 200MG	THERAPEUTICS LAB.LTD. 372, IKORODU ROAD, MARYLAND, IKEJA, LAGOS	VITAPHOS LAB. LTD. 3, ADEDOTUN DINA CRESCENT, MARYLAND,	TABLETS X 12'S
TEMECXIN TABS	DIHYDROARTEMISININ 60MG	BOND CHEMICALS IND LTD ADESAKIN LAYOUT, AWE	SAME AS APPLICANT	8'S
THERAMETHER SUSPENSION (POM)	ARTEMETHER 15MG/ML	THERAPEUTIC LABS NIG. LTD. 372,IKORODU RD., MARYLAND	SAME AS APPLICANT	100ML
VAMI'S ARTESUNATE TABLETS(POM)	ARTESUNATE 50MG	TUYIL PHARM. IND LTD 22,STADIU RD., ILORIN	SAME AS APPLICANT	12'S
WAIPA TABLETS (OTC)	DIHYDROARTEMISININ 30MG, PIPERAQUINE PHOSPHATE 25M	KUNIMED PHARMACHEM LTD. 1, ADELANWA ST., VALLEY EST., DOPEMU	SAME AS APPLICANT	12'S