

6 Clashes between subsidized and private ACT markets

When administrative, Global Health, and marketing regulations collide

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The World Health Organization's (WHO) international recommendation to use artemisinin-based combination therapies (ACTs) in the mid-2000s spurred pharmaceutical innovations. Initially driven by two multinational firms based in the West—the Swiss Novartis and the French Sanofi-Aventis—and their partnership with universities and/or transnational actors (WHO and Drugs for Neglected Diseases *initiative* [DNDi], respectively),¹ production of these artemisinin-based combinations has increased both in the Asian countries that produce generics and in Africa. Numerous ACTs, combining different molecules with artemisinin derivatives, the use of which may or may not be recommended by WHO, have been put on the market in a variety of ways in countries affected by malaria. National pharmaceutical regulations for these drugs vary, depending on whether or not they are included in malaria treatment lines in various countries; the criteria for granting Marketing Authorizations (MAs) issued by regulatory authorities; and their actual technical, material, and human resources. Global Health actors working in malaria control, primarily the Global Fund and the President's Malaria Initiative (PMI)² for the situations we studied, or Chinese development aid for example in others (Sams, 2016), clearly influence trends in these markets by making ACT available in the countries. By supplying specifically from a few pharmaceutical firms, these Global Health programs support the distribution of certain products that have international certifications. To deal with their dominance over the markets, competing companies are organizing themselves to promote their own ACTs as well.

This chapter discusses these pharmaceutical production and distribution trends and their logics as manifested in Benin and Ghana. Using inventories, we conducted of ACTs sold in formal pharmaceutical distribution facilities (private pharmacies; over-the-counter [OTC] medicine sellers; pharmaceutical depots; public, private, and mission health centers—see Introduction of this book), we will begin by presenting the supply of these medicines in the two countries. Then, we will analyze the composition of these ACT markets to show how directors of the pharmaceutical companies at the source of this supply capture market share by maneuvering between the administrative and Global Health regulations implemented by national and transnational actors and the marketing regulations developed by the firms themselves.³

ACT supply in Benin and Ghana

Subsidized ACTs from European firms and major Asian generics producers

Although in theory the lack of patents on ACT component molecules allows for a competitive market to develop between companies, in actuality Novartis held a virtual monopoly until 2008, when Sanofi-Aventis, in partnership with DNDi, obtained WHO prequalification (Lantenois & Coriat, 2014) for its co-formulation of ASAQ Winthrop®, previously marketed as a co-blister combination (artesunate + amodiaquine).⁴ Novartis' virtual monopoly within subsidized markets is due to the fact that, beginning in 2001, it was the only company marketing Coartem®, a fixed-dose combination of artemether and lumefantrine (AL), prequalified by WHO. To ensure accessibility for all countries in Africa, WHO signed an exclusive 10-year agreement with this company to supply public markets with Coartem®, at a price of USD 2.40 per adult treatment (Orsi & Zimmermann, 2015).⁵ In 2005, the Global Fund signed agreements with the Indian generics manufacturers Ajanta and Cipla to encourage them to produce fixed-dose combinations of AL. Novartis responded beginning in 2006 with an initial price decrease for Coartem® (Singh, 2018). Thus, between December 2008 and December 2009, the global market for subsidized ACTs expanded with these WHO-prequalified AL combinations produced by the Indian companies Ajanta and Cipla, joined later by Ipca. Because combining artesunate and amodiaquine (ASAQ) in the same tablet posed much greater technical challenges, it was not until 2012 that the Indian firm Ipca prequalified its co-formulated ASAQ, followed by the Chinese company Guilin in that same year, then by the Indian companies Ajanta in 2013 and Cipla in 2014 (Orsi, Singh, & Sagaon-Teyssier, 2018).

At the time of our studies between 2014 and 2016, subsidized ACT found in the public sector in Benin and Ghana was, for the most part, purchased by PMI and the Global Fund.⁶ It was manufactured by two European multinationals—Novartis and Sanofi-Aventis—and by two Indian companies manufacturing generics, Ipca and Cipla. With the Global Fund and PMI supply policy conditional on the purchase of ACT certified through WHO prequalification, the sources do not vary between Benin and Ghana. In both cases, Coartem® manufactured by Novartis is by far the predominant medicine, which is mostly found in health centers and public hospitals.

In Benin, subsidized ACTs are only available in the public sector and are purchased primarily by PMI. Only the pediatric formulations of ACT, which are distributed via an intermediary—*relais communautaires*, community health workers assigned mostly in rural areas through specific public health programs—are purchased by the Global Fund and to a lesser extent by UNICEF. At the time of our study, a treatment using subsidized ACT cost between CFA 150 and 600 (between EUR 0.22 and 0.91), depending on the patient's age and weight. The national policy provides for free treatment for children under 5 years. In Ghana, subsidized ACT, primarily purchased with Global Fund donations, has

also been distributed in the private sector since 2010 through the mechanism of the Affordable Medicines Facility-malaria (AMFm), a pilot program developed in eight countries through Roll Back Malaria,⁷ a public-private partnership, and implemented and managed by the Global Fund. Through a co-financing mechanism, AMFm pays 95% of the price of ACT provided by the six companies with whom the Global Fund negotiated an 80% price reduction (Davis et al., 2013). The Global Fund fixes the price at which manufacturers must sell ACT to first-line buyers—namely, private wholesaler-importers—so the ACT cost for them is 5% of the negotiated price, since the Global Fund pays the other 95%. ACT from AMFm is sold in Ghana for 1.5 Ghanaian cedis (GHC), equal to just under USD 1, while the price of ACT produced by a local company, Danadams, for example, ranges between GHC 3.40 and 5.40, or two to three times more. The AMFm aims to promote ACT use while decreasing their cost in order to increase their accessibility and availability in the public sector, but more particularly in the private sector. In addition to being distributed in public health centers, subsidized ACTs are also available in private health centers, pharmacies, and from OTC medicine sellers. This results in locally produced ACTs co-existing with imported ACTs, some with WHO prequalification, on private Ghanaian markets.

The AMFm opened the subsidized ACT market to more Asian firms, making these drugs available on the private market. ACTs subsidized through this initiative are manufactured by the Swiss and French multinationals, Novartis and Sanofi-Aventis, by Indian generics producers (Artefan[®] from Ajanta Pharma, Lumartem[®] from Cipla, AL from Ipca) and one Chinese producer (Arsumoon[®] from Guilin). AMFm has thus proven very useful in helping these companies, which already do business across the globe, to grow and increase their activities. At the end of the AMFm's 2-year pilot phase, the mechanism became the Private Sector Copayment Mechanism (PSCM) in 2014 and was offered in all countries supported by the Global Fund. The seven PSCM manufacturers remained the same as during the AMFm, with the addition of two Indian generics producers: Strides Arcolab Limited, which manufactures Combiart[®], and MacLeods with Lumiter[®] (see [Figure 6.1](#) below).

Deployment of the AMFm and later the PSCM in Ghana made it possible for Asian ACTs to capture much larger shares of the subsidized market than in Benin, where neither the AMFm nor the PSCM had been implemented. However, during the PSCM, the number of first-line buyers purchasing ACTs decreased to 15 compared to 31 during the AMFm. Funding for Ghana was largely revised downwards to USD 20 million in 2014 and to USD 10 million for both 2015 and 2016, compared to USD 28 million for the single year of 2011 at the time of the AMFm (Anadach Group, 2012). Decreases in funding and in the number of buyers under the PSCM probably did not allow ACTs from Strides Arcolab Limited and MacLeods to capture as much of the market share as their competitors who were already firmly established through the AMFm. The price of subsidized ACTs also increased slightly under the PSCM. At the time of our study, the treatment price was between GHC 1 and 6, or between about USD 0.2 and 1.2, depending on the patient's age and weight.



Figure 6.1 The artemether-lumefantrine produced by Strides Arcolab Limited.

Source: © IRD/Moïse Djalalah, Comè, September 2015

While these mechanisms enable wide distribution of Asian and European ACTs, they also caused local firms in Ghana to suspend ACT production. During the AMFm, these firms found it much more profitable to be a distributor than to manufacture their own ACT since first-line buyers only had to pay 5% of the Global Fund negotiated price and could therefore earn much higher profit margins than local producers.⁸ In this sense, the AMFm is a substantial public subsidy for the private distribution sector. The Ghanaian Ministry of Health used this argument to encourage Ghanaian companies, most of which are also importers and distributors, to participate in the AMFm as first-line buyers (Pourraz, 2019). The PSCM is limited to a 3-year period that is not renewable in Ghana. Once the supply of subsidized ACTs in the private sector was stopped in 2016, coinciding with the end of our field study, local companies could once again consider producing ACTs to recapture the share they previously held in the private domestic market.

Unsubsidized ACTs from Asian, African, and European companies

Through observations conducted in 2007, we have highlighted elsewhere that before subsidized ACTs were available in Benin and Ghana, different combinations from Indian or Ghanaian manufacturing were already offered at a slightly higher price in the chemical shops (today's OTC medicine shops) in Ghana (at around USD 2.5), while ACTs produced by European or Asian companies were only available at higher prices (about EUR 6) in private pharmacies and public health centers in Benin (Baxerres, 2013a). Another study, conducted in 2012 when the mechanisms implemented by the Global Fund (AMFm then PSCM)

had just been launched in Ghana, shows that a comparable range of ACTs was distributed at that time in the retail private sector in the two countries. Whether under a trade name or International Nonproprietary Name (INN), 41 ACTs were counted in Benin, compared to 55 in Ghana; the difference is due to the fact that at the time, there were five Ghanaian companies, the products of which were not available in Benin. With the exception of these companies, the same producers (mainly Asian but also European and African) supplied the private sector in the two countries (Baxerres, Egrot, Houngnihin, & Le Hesran, 2015).

Two or 3 years later, according to our Globalmed studies, the ACT market had changed significantly in both countries. Benin offered a much higher number of products with a broader range of types of combinations than Ghana. During our inventories in both public and private distribution sites, we counted 49 different ACTs⁹ in Benin, compared to 22 in Ghana (see the [table 6.1](#) below). Several of them were only distributed in one of the two countries: 41 ACTs sold in Benin were not available in Ghana, and 12 ACTs distributed in Ghana were not found in Benin. Comparing the list of MAs for ACT, provided at that time by national pharmaceutical regulation officials, the Food and Drugs Authority (FDA) in Ghana and the Directorate of Pharmacies, Medicine, and Diagnostic Investigations (DPMED) in Benin, indicated that there were 71 ACTs in Benin compared to 42 in Ghana.¹⁰ Furthermore, Benin offered eight different types of artemisinin-based combinations, compared to three in Ghana; we will return to this aspect later in the chapter. The prices of these drugs varied depending on the brands in the two countries. An unsubsidized adult treatment sold in the private retail market in Benin, ranged between CFA 1425 and 4660, or between about EUR 2 and 7. In Ghana, the price of an adult ACT treatment varied in the private sector, for both subsidized and unsubsidized ACTs, from GHC 3.5 to 36.24, or approximately USD 0.7 to just over USD 7, depending on the brands and distribution sites.¹¹

The source of unsubsidized ACTs differed for the two countries. While the majority of companies were also Indian, there were more Indian companies in Benin (25 versus 10, according to our inventories); the same was true for European

Table 6.1 Evolution of the ACT markets in Benin and Ghana

	<i>Benin</i>	<i>Ghana</i>
Number of ACTs distributed in 2012	41	55
Number of MAs for ACTs in 2014	71	42
Number of ACTs distributed in 2015	49	22
Number of combinations in circulation in 2015	8	3
Sources of ACTs in 2015	25 Indian, 13 European, 7 Chinese, 4 African	10 Indian, 4 European, 2 Chinese, 5 African

Source: Authors.

companies (13 in Benin versus 4 in Ghana) and Chinese companies (7 in Benin versus 2 in Ghana). African companies were nearly equal (5 in Ghana, 4 in Benin). By contrast, African companies in Ghana were almost all local (four out of five),¹² while in Benin, these medicines came from companies in other franco-phone countries (Côte d'Ivoire, Democratic Republic of the Congo, and Togo).¹³ Despite the challenges posed by the AMFm described earlier, Ghanaian local production nevertheless slightly changed the structure of the ACT market in this country. Surprisingly, only 14 ACTs had a common MA in both countries. These were primarily products from European companies and large Asian generic manufacturers positioned on the subsidized markets. As for Indian companies, other than the 6 main ones mentioned earlier, 14 were doing business in Benin and not in Ghana, and 9 were in Ghana but not in Benin.

Of course, these figures do not illustrate the varying influence of these different companies in terms of distribution volumes or sales. The work of Fabienne Orsi and her collaborators highlights that 2012 was a major turning point for subsidized ACT markets (Orsi et al., 2018; Orsi & Zimmermann, 2015). As noted earlier, Novartis was the only company producing a WHO-prequalified ACT until 2008, but the tides began to turn with the arrival of Sanofi that year. Between December 2008 and December 2009, the market saw the addition of three ACTs produced by the Indian companies Ajanta, Cipla, and Ipca, which had obtained WHO prequalification for their AL. The arrival of Indian competitors gradually put an end to the Novartis monopoly. In 2012, ACTs from three Indian companies represented 67% of the volume purchased for the public sector with subsidies from the Global Fund in Africa (Orsi et al., 2018).¹⁴ As part of the Globalmed program, our research at the crossroads of qualitative and quantitative approaches also gives some indications of the respective weight of various firms in the private markets in 2015 and 2016. Data collected during an ethnography conducted with two wholesalers in Okaishie in Accra highlight that Indian companies (six of them) and to a lesser extent Chinese companies (two) have an especially strong presence. They account for over 80% of ACT sales for these wholesalers. Novartis, for its part, with its subsidized and unsubsidized Coartem[®], accounted for 14% of ACT sales.¹⁵ The Indian firms with products being not subsidized accounted for 27% of ACT sales. Products from the two Indian companies in question were each distributed exclusively by a single Ghanaian wholesaler. One of these two wholesalers was also a drug manufacturer. By contrast, as noted earlier, local companies were virtually absent from ACT sales (3.5). In Benin, based on sales data collected over 2 months during our ethnographies in two pharmacies in Cotonou and one pharmacy and one pharmaceutical depot in the Mono department, even though only unsubsidized ACTs are distributed there, Novartis accounted for just over 7% of sales and Indian and Chinese companies just over 65% (55% and 10.1%, respectively), with European products making up the remainder.

In the next section, we analyze the role of national and transnational actors involved in regulating subsidized markets. Then we will look at private markets

and attempt to analyze the weight of economic actors who invest in them and the marketing strategies they deploy.

Market competition and sharing

Intertwining administrative and Global Health regulations

The construction of subsidized ACT markets by Global Health actors

Understanding the presence of ACTs produced by Novartis, Sanofi-Aventis, Ajanta, Cipla, and Ipca in public health facilities and, beginning in 2010, in a portion of the Ghanaian private sector is explained by how the global ACT market is constructed. Similar to markets for other drugs made available to countries through Global Health programs (antiretrovirals, tuberculosis drugs, contraceptives, etc.), this market is governed by a triptych of biomedical, technical, and financial norms defined by WHO and transnational actors (Global Fund, PMI). The pharmaceutical industry producing these medicines is closely aligned with the directions taken by international public health policies and the Global Health actors that fund them (Fournier, Lomba, & Muller, 2014). WHO plays a decisive role as prescriber (Orsi & Zimmermann, 2015) by defining the reference treatment and developing technical standards by publishing usage recommendations and guidelines, as well as through the Essential Medicines List that it published for the first time in 1977 and updates regularly.

WHO is also involved in the quality certification process for ACTs through its prequalification department (Lantenois & Coriat, 2014). WHO prequalification requires that production sites comply with good manufacturing practice (GMP), requiring companies to invest significantly in applying their standards and ensuring that the generic drugs they produced are similar to the reference drug. It also requires them to conduct very expensive bioequivalence studies, though these differ depending on where they are conducted. This means international financing conditioned on the purchase of WHO-prequalified ACTs favors those pharmaceutical companies with the means to obtain prequalification, namely, multinationals and the large Asian generics producers, at the expense of local companies. Thus, in 2017, out of the total 46 antimalarial drugs approved worldwide through WHO prequalification, nearly half ($n = 21$) were produced by Indian companies, 13 by other Asian companies, and 12 by Western multinationals (Singh, 2018).¹⁶ For African producers, WHO prequalification acts as a barrier to entry to subsidized markets and contributes to a hierarchy of markets and generics producers. The normative system, conveyed here by Global Health actors who hold the power to include or exclude, becomes a regulatory tool for markets that knew how to mobilize manufacturing actors from the North and the main generics producers in the South to their advantage. This system leads to a certain type of ACT being available in the public sector as well as in the private Ghanaian

market, via the AMFm and then the PSCM. The effects of this regulation in private markets differ from those observed in the public sector where most ACTs are sold at a very low cost and even provided free of charge to some categories of the population such as young children in Benin. However, by imposing a sale price on private intermediaries, the AMFm and the PSCM are imposing a form of regulation in the Ghanaian private sector; in this case, it is economic and runs counter to Ghanaian market rules that encourage the law of supply and demand and free competition between economic actors. Ghana, unlike Benin, does not regulate drug prices. Yet, the fact that ACTs from the AMFm and PSCM are sold at a much lower price than their competitors and that distribution intermediaries can earn a comfortable margin on these products contributes to the AMFm's, and later the PSCM's, ability to crowd out other ACTs from the market that could circulate. This was also the case in the Beninese informal market where retailers only distributed AMFm-subsidized ACTs (Baxerres et al., 2015).

When the PSCM ended in 2017, the Global Fund set out to evaluate pharmaceutical production capacities in Africa in order to be able to procure drugs locally.¹⁷ USAID, one of the United States development aid agencies in the health sector, is also part of this new trend but contributes directly to implementing GMP standards for pharmaceutical manufacturing units, for example, in Nigeria to source some drugs locally.¹⁸

WHO prequalification does not, however, replace registering drugs by national regulatory authorities. Firms must also comply with a country's national regulations for registering and distributing their product in both the public sector and private markets.

State regulation: Between public health concerns and business interests

While WHO prequalification can guarantee a drug's quality, it cannot exempt the manufacturer, or any other distributor, from requesting an MA in the countries where it hopes to distribute the product. Regulators issue MAs based mainly on the information provided by manufacturers and contained in a dossier, which constitutes a written representation of the drug (Hauray, 2006). By requiring companies to produce numerous documents and to verify the efficacy and safety of their treatments, the MA is a remarkable form of State control (Urfalino, 2007). Benin and Ghana are equipped with regulatory systems, although very different (see [Chapter 1](#)), allowing them to conduct drug registration, control, and certification activities to assess their quality and safety before these drugs are distributed to the public. As State monopolies through their national regulatory authorities, these activities are the most traditional way to regulate drugs, what Jean-Paul Gaudillière and Volker Hess (2013) describe as administrative regulation.¹⁹

In Benin and Ghana, the steps for granting an MA are quite similar: from the submission to the analysis of the pharmaceutical dossier, the process focuses on technical aspects like security, safety, and efficacy, as well as the health products' therapeutic value. In both cases, these technical aspects of the dossier are reviewed by a group of experts, and analyses are conducted in laboratories on

drug samples provided by the requesting company. In Ghana, a report of an FDA-Ghana inspection is added to the dossier, unlike in Benin where the DPMED does not conduct inspections of foreign drug manufacturing sites (see [Chapter 1](#)). Expert evaluations, quality control test results, and inspection results (in Ghana) are also added to the dossier, which is reviewed by a committee which must decide whether to register the medicine in the country for marketing.

Nevertheless, differences emerge between the two national regulatory authorities' practices.²⁰ In Benin, in the case of one molecule that was already widely available on the market and had no treatment advantages, experts responsible for evaluating the MA applications were asked to compare the pharmaceutical's suggested pre-tax price to the prices of drugs that are already available.²¹ Even though in theory the suggested price must be lower for the MA to be issued, our observations show that this criterion is usually not included. This promotes the addition of products on a market that is already widely saturated by the number of available drugs.

By contrast, in Ghana, there are no criteria limiting the number of me-too drugs.²² More liberal approaches adopted by Ghanaian health officials for pharmaceutical registration, and distribution should logically have led to a much greater number of MAs issued for ACTs than in Benin, the health officials of which claim to promote a more controlled pharmaceutical distribution system with greater administrative oversight. However, the actual number of MAs issued in Benin and Ghana shows a very different reality. As discussed earlier, comparing lists of MAs for ACTs revealed 71 different ACTs in Benin versus 42 in Ghana. Benin also offered a much greater variety of combination types than Ghana. In addition to the AL combination recommended as first-line treatment by national policy and ASAQ recommended in some specific cases (PNLP, 2005), six other combinations were available in Benin that were not subject to any usage recommendations from WHO or the National Malaria Control Program.²³ However, this is not the case of Ghana, which, beyond AL, which is also the most common ACT, distributed ASAQ and dihydroartemisinin-piperaquine (DHPP), all three of which are recommended by the national policy for malaria control (Ministry of Health, 2010). The fact that the FDA in Ghana restricts ACT registration to the three combinations that are officially recommended by national treatment guidelines limits the number of MAs, and allows companies that only produce these combinations to penetrate private markets. This control is further strengthened by the AMFm and the PSCM, which only allow the distribution of these three types of ACTs on the private market. It also limits the number of new combinations and inhibits competition on a market that, in Ghana, is not regulated by the State per se but governed by the law of supply and demand.²⁴ In the public sector, the Global Fund and PMI are forced to buy only those ACTs recommended by national policies, again limiting the types of combinations available in public health facilities. Various regulatory methods deployed around ACT availability, whether supported by Global Health programs or by States, contribute to an intertwining of national and global institutional regulations.

The alignment of FDA registrations of ACTs with the National Malaria Control Program recommendations highlights the FDA's reliability in Ghana (see [Chapter 1](#)). It underscores how public health interests were prioritized over commercial logics and the desire to promote appropriate ACT use expressed by Ghanaian regulatory officials. Although more liberal overall, the Ghanaian private ACT market is ultimately much more regulated than in Benin, where the ACTs registered by the DPMED are not aligned with the combinations recommended by the national policy. Therefore, no fewer than 50 different ACTs are available for sale in a single Beninese pharmacy. This is not the case in Ghana, where pharmacies are not required to distribute the majority of drugs authorized in the country: only six to seven different ACTs are usually available there. Add to this the AMFm regulatory system, the operations of which, as illustrated in the previous section, "have 'cleaned' the market up of any other ACTs that could have circulated" (Baxerres et al., 2015, p. 151).

The situation is reversed, however, when looking at a therapeutic class that is unregulated by transnational actors, such as anthelmintics, which have lower public health stakes than the management of malaria. There were 23 MAs for drugs consisting of albendazole or mebendazole in Benin compared to 57 in Ghana.²⁵ This observation corroborates the hypothesis that unlike in Benin, the private ACT market in Ghana is regulated both by aligning registrations with national policy recommendations and by Global Health initiatives, namely, the AMFm and PSCM, which limit the availability of some ACTs to a specific drug category.

Lastly, it is important to highlight another form of national regulation active in Ghana but not (or minimally) in Benin. Ghana is one of the rare sub-Saharan countries to have implemented, in 2003, a universal health insurance program, the National Health Insurance Scheme (NHIS), which has actually been effective (Blanchet, Fink, & Osei-Akoto, 2012). The list of drugs reimbursed by the NHIS is a way to encourage health practitioners to prescribe these medicines rather than nonreimbursed drugs. By setting the prices and type of drugs that it reimburses, the NHIS also plays a key role in the drug regulatory system in private markets, even though in Ghana, as we have seen, prices and various intermediaries' profit margins are not set by national authorities. Health insurance systems and their decisions about which drugs to reimburse and at what price also shape pharmaceutical markets (Gaudillière & Hess, 2013) and play an important role in regulation, on a national scale in Ghana, which intertwines with the systems described earlier.²⁶

Both in Ghana and Benin, ACT markets are governed by a jumble of regulations stemming from both national institutions and Global Health actors. To penetrate markets, pharmaceutical companies are forced to adapt their strategies to the features of the institutional and regulatory environment where they operate (Singh, 2018).

Market regulation and economic actors' business strategies

As noted, the institutional regulations developed by national and transnational actors play the most vital role in subsidized ACT markets. In the unsubsidized private sector, however, market forces are the biggest driver, above and beyond institutional regulations for market authorization. These forces are developed by the economic actors: manufacturing companies and distributors.

When European and "big" Asian generic companies want to have it both ways

First, companies that produce the WHO-prequalified ACTs discussed earlier also develop strategies for unsubsidized private markets. Whether based in the West or in Asia, they all offer unsubsidized ACTs sold in private pharmacies in both countries and by OTC medicine sellers and health centers in Ghana. They play on both sides of the field, so to speak, and thus profit from the market hierarchy created by the systems of norms and standards described earlier with regards to WHO prequalification. Some of these companies sell their unsubsidized products under the same trade name as their subsidized ACT. Novartis, for example, sells Coartem® in both types of markets but with different packaging: in a blister pack with illustrations for the subsidized market and a sturdy individual box with no illustration for the unsubsidized private market. Despite being identical to the blister pack, this second product is not sold at the same price and is perceived much differently.²⁷ In local terms, it is called "original coartem," sold at GHC 25 in Ghana and CFA 4085 in Benin (or just over EUR 6), absolutely not perceived in the same way as the "coartem ACTs," costing thanks to AMFm GHC 4 and CFA 600 (or less than EUR 1). Novartis' market shares have soared in the two countries. The same is true for Cipla, the Indian company, which sells its AL drug under the same name (Lumartem®) but at different prices for the public and private markets. For some authors, "this behavior indicates the firm strategy to gain legitimacy" (Singh & Orsi, 2018, p. 48). Other companies sell their product under an INN in the subsidized markets and under a trade name in unsubsidized markets. These trade names may vary from one country to another. Ipca, for example, sells subsidized AL, but markets it as Laritem® in Benin and Lumarex® in Ghana for the private market at higher prices (around EUR 4). Sanofi sells ASAQ Winthrop® in subsidized markets and Coarsucam® at nearly CFA 4000 in private pharmacies in Benin. Some companies sell one ACT combination for subsidized markets and another for unsubsidized markets. Still, other companies develop a strategy for private markets in one country even though they are only there through subsidized markets in another. The Indian firm Strides Arcolab, for example, sells its subsidized Combiart® in Ghana for less than GHC 1.5 (under USD 1) and the same drug only in unsubsidized markets in Benin for nearly CFA 3000 (EUR 4.5). These differing configurations around products' commercial names and INNs and their presence on specific markets all reveal the marketing strategies firms cleverly developed based on national contexts and targeted

market segments. Sudip Chaudhuri discusses how multinational pharmaceutical companies develop a “dual-brand strategy,” which “enables them to be present not only in the price-insensitive segment of the market but also in the price-sensitive segment” (Chaudhuri, 2016, p. 108). Firms must also consider any transnational regulations in place, which in this case include the presence or lack of AMFm and subsequently PSCM initiatives in private markets.

For this last reason, as noted earlier, some European companies, the ACTs of which are not prequalified by WHO, are present on the unsubsidized private markets in Benin but not in Ghana; examples include the French Bailly Creat and Medicale Pharmaceutique, the Belgian Dafra Pharma, the Swiss Mepha and Nyd Pharma, and the German Denk Pharma. The greater number of European companies represented in Benin is due to its private sector’s continued reliance on France and Europe for pharmaceutical supplies (Baxerres, 2013a). These companies often specialize in generic drugs. Many of them do not manufacture but distribute internationally; they are central procurement offices that purchase products they then repackage with their brand and resell in several countries, especially in Africa.

*When small and medium Indian and Ghanaian companies
take back market share*

Indian companies that make ACTs with no WHO prequalification also develop business strategies to conquer private markets in Benin and Ghana. The Indian industry is described worldwide as the “pharmacy of the developing world,” making Africa the destination receiving the second highest amount of its pharmaceutical exports, after North America.²⁸ The Indian generics industry accounts for 20% of the global generics supply and generates over 50% of its total sales revenue by exporting to nearly every country in the world (Singh, 2018). It is the world’s third largest producer of pharmaceuticals (Horner & Murphy, 2018). Apart from the “big” Indian generics producers with the financial and technical capacities to integrate into the highly regulated markets of the North or subsidized ones elsewhere, there are many small and medium Indian firms that earn a significant part of their income in the “semi-regulated markets” in Asia and Africa (Singh, 2018, p. 29; Chaudhuri, 2016).²⁹ Some specialize exclusively in these markets, or even in a single country, as discussed earlier. Indian companies develop various strategies. Sauman Singh has proposed a categorization of the three different “entry modes” that they use to integrate into markets of other countries, each one having advantages and disadvantages: (1) exports, (2) contractual agreements (licensing, franchising, management contract), and (3) production in countries targeted by joint ventures or through acquisition of a firm in the country of establishment. For marketing operations required for exportation, the Indian firm can go through an Indian intermediary (indirect exports), go through its own channels, or by using one or more local intermediaries (direct exports). “To reduce uncertainty, firms start their international activity through indirect export to countries where

the perceived psychic distance is small. That is, they select countries which are comparatively well known and similar regarding business practices, education, industrial development, and other factors” (Singh, 2018, p. 18–19). This echoes our previously published observations: generics from India were introduced to West Africa by anglophone countries, particularly beginning in the 1970s in the fellow Commonwealth countries of Ghana and Nigeria, before becoming part of markets in francophone countries later, but in dramatic fashion, beginning in the late 2000s (Baxerres, 2013b).

Sauman Singh uses the pharmaceutical market in Mali to underscore how Indian firms were introduced into francophone countries in Africa exclusively through exports. This also occurred in Benin, the pioneering country in West Africa until 2012 when it was overtaken by other countries. Indian firms must use wholesale-distribution services operating in Benin that all distribute the same products at the same price (see [Chapters 2 and 3](#)). “Concerning Sub-Saharan Africa, market entry through export is further facilitated by the prevailing free trade regime as most countries do not impose tariffs on imports of finished formulations. Exporting allows Indian firms to take advantage of their low-cost domestic production. Also, it is a low-risk entry mode and does not necessitate a firm to undertake direct investment in host countries which is costlier, and firms risk losing the capital if the foreign market engagement fails” (Singh, 2018, p. 153). [Chapter 1](#) examined joint ventures and acquisitions in the country of establishment and showed that the regulatory and fiscal conditions in francophone West African countries are not conducive to setting up local manufacturing plants.

Penetration of pharmaceutical markets is more diversified in anglophone countries, as our studies have shown in Ghana. In addition to conventional exports, [Chapter 1](#) highlights several Indian joint ventures or acquisitions of local firms. Examples of this include the locally established firms Unichem Industries Limited, Eskay Therapeutics Limited, and Pharmanova Limited. Contract agreements are also used to penetrate markets; we saw some contracts between Indian firms and private Ghanaian wholesalers, sometimes with exclusivity clauses for the firm’s product or products. It is said locally that wholesalers have “the monopoly” on such and such a product. “Contract manufacturing” is another type of agreement; in this case, the Ghanaian wholesaler has an Indian firm manufactured product under its own brand. We observed several cases of ACTs produced through contract manufacturing in Ghana, especially when the PSCM was beginning to lose its efficiency. One private Ghanaian wholesaler explained: “I came with the concept of AL, artemether lumefantrine; the SS means single strength, that will be 20/120mg. And then I have DS, which is double strength, 40/240mg; and then I have the Forte, which is the 80/480mg. I started the registration of these in 2013. And it was done in 2014. And I started this because we realized that the AMFm was not going to be sustainable. So, if the AMFm initiative is not going to be sustainable, then it means after AMFm, after the private sector co-payment mechanism, there will be a gap. (...). So strategically, I decided to bring mine in case the Global Fund was not interested in continuing. Or in case they are not

adequately funded, and then we will still have efficacious antimalarials to still give to our people. (...). Not too expensive. I am selling mine for 8.00 cedis, while the Global Fund one is selling for 4.50. (...). For the start, from 2010, it didn't make business sense to import antimalarials, but now it makes a lot of business sense..." (interview, Accra, March 15, 2016). Some Ghanaian wholesalers who had invested during this time in contract manufacturing with Indian firms to distribute ACTs also use packaging that quite closely resembles that of subsidized ACTs (see [Figure 6.2](#) below).

Ghanaian wholesalers are then responsible for promoting the products. These contracts are beneficial for both the Indian and Ghanaian parties. "The primary advantage of Indian firms is their low-cost production abilities, but they lack market information, distribution channel and human resources for product promotion in host countries. Local operators, on the other hand, are well aware of the specificities of their home country market. They possess assets in the form of local marketing and distribution networks, market intelligence and can easily access local labor market. Further, they are familiar with regulatory frameworks, have connections in government offices and know the right approach to get things done" (Singh, 2018, p. 157). Thus, some unsubsidized ACTs produced in India for which the Ghanaian wholesaler has exclusive rights and has developed a very effective promotion campaign capture substantial market share. This is the case for Lonart[®], manufactured by a medium-sized Indian firm, Bliss GVS, and distributed in Ghana exclusively by one of its largest wholesalers working in the country, Tobinco (see [Figure 6.3](#) below).³⁰

With the end of AMFm and the PSCM's reduced efficiency, most of the Ghanaian manufacturing firms went back to focusing on ACTs, but lagged

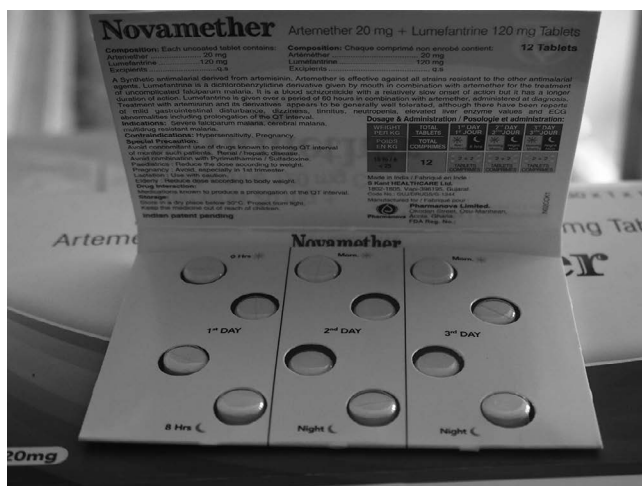


Figure 6.2 ACT produced in India for exclusive distribution in Ghana by Pharmanova.

Source: © IRD/Carine Baxerres, Accra, November 2015

behind the contract manufacturing wholesalers because of the time needed to restart their ACT production chains and the difficulty in repositioning themselves on the markets (finding distributors, capturing market shares). In 2016, the company Entrance, for example, registered Lufart[®], an AL combination, and began to develop another DHPP-based ACT. Some of these firms, like the wholesalers mentioned earlier, also used packaging similar to that of subsidized ACTs. Producers and wholesale distributors are not the only forces involved here. Retailers and consumers also participate in the market regulation of drugs when they choose to buy one ACT instead of another, in relation to the social stratification of pharmaceutical markets. Chapters 10 and 11 discuss this issue, looking at the market as a whole.

Conclusion

Beyond the most traditional form of pharmaceutical regulation administered by the States, we have highlighted how other ways ACTs are regulated become intermingled in Benin and Ghana: the “global mode” of regulation, developed by Global Health actors (Pourraz, 2019) and the market mode, which contribute in their own way and jointly to shaping pharmaceutical markets. Each regulatory way has corresponding specific combinations of practices, values, and logics, thus underscoring various rationales underpinning the process of drug management (Gaudillière & Hess, 2013). Investigating pharmaceutical regulation in the countries of the Global South through the prism of ACTs requires considering both



Figure 6.3 Advertising roadside billboard photographed in Accra.

Source: © IRD/Carine Baxerres, Accra, November 2015

the role of the States as well as the weight and effects of Global Health programs, industrials, and actors in private distribution. In the following chapters, we will see how prescribers and individual consumers of drugs also participate in structuring these markets.

Global Health programs appear to play a considerable role in structuring pharmaceutical markets in the Global South for the subsidized products used to treat priority health issues (AIDS, tuberculosis, malaria, contraceptives, etc.), including in countries where pharmaceutical distribution is generally largely liberalized, as in Ghana. In response, Asian generics manufacturers, local African firms, and European firms—large and small—deploy marketing strategies to conquer private unsubsidized markets. These firms are linked in such efforts by retailers who offer consumers the ACT “that they need” based on their socioeconomic status. In Ghana, local wholesalers, who are in stiff competition with each other, play a significant role in the structuring of the ACT markets. In particular, they strongly promote the ACTs produced by small and medium Indian firms for which they have the exclusive sales rights or for which they contract out manufacturing for themselves. Firms, the drugs of which are not prequalified by the WHO and the products of which are not subsidized by Global Health actors, play these economic market-sharing games to capture substantial shares.

As Mathieu Quet and his collaborators have pointed out regarding the “Regulation Multiple” in South-East Asia—“confronted as it is with multiple realities and real-world practices” (Quet et al., 2018, p. 2)—this chapter highlights how various layers of regulation governing ACT markets stack up on each other and create drug hierarchies. The regulations implemented by Global Health actors are intertwined with national regulations for malaria (recommended combinations) and, more broadly, pharmaceutical markets (issuance of MAs).³¹ Moreover, market regulations are also at work: companies’ commercial strategies include attractive packaging and invented trade names, which may change by market segment and targeted country or remain steady and unchanging to further establish their reputation. Sometimes these various regulations conflict with each other, as regularly demonstrated in the court cases between pharmaceutical companies and States.³² This was not the case at the time of our studies for the situations we have described, where these regulations appear to have adapted quite well to each other in the end.

Notes

1. For more about these partners, see the previous chapter. The role of the DNDi is to develop new treatments for neglected maladies. Novartis is presented as the largest pharmaceutical multinational and Sanofi is the fourth largest (Chaudhuri, 2016). By transnational actors, we mean the various types of extra-national actors currently working on public health issues in so-called “Southern” countries: bilateral institutions (the various cooperation services) and multilaterals (World Bank, Global Fund); non-governmental organizations (NGOs); foundations; and public-private partnerships (see Baxerres & Eboko, 2019).

2. The Global Fund is a multilateral initiative to fight AIDS, tuberculosis, and malaria created in 2001 by the Secretary-General of the United Nations, Kofi Annan. The President's Malaria Initiative (PMI) is a United States bilateral development program created by President George Bush in 2005.
3. For information on these different modes of regulation, refer to the Introduction of the book.
4. Prequalification guarantees the generic's quality and similarity with the reference medicine. This quality standard for medicines is certified by WHO each time for each company/product pair.
5. For more details about this agreement, refer to the previous chapter.
6. The World Bank and UNICEF also work in Benin, but to a much lesser degree.
7. Ghana, as well as Kenya, Madagascar, Niger, Nigeria, Tanzania, Uganda, and Cambodia, participated in the AMFm pilot phase between 2010 and 2012. The Roll Back Malaria (RBM) partnership, which brings together UNICEF, the United Nations Development Programme, and the World Bank, was created in 1998 by the WHO Director-General at the time, Dr. Harlem Gro Brundtland, with the goal of implementing a coordinated global response to the fight against malaria.
8. The estimated profits on ACTs for first-line buyers range from USD 0.63 to USD 0.92 per treatment sold (Pourraz, 2019).
9. Here we have considered both the marketing name (INN or trade name) and the producer. The different dosages proposed by the companies based on the patient's weight are not incorporated into these figures.
10. Thus, there is a difference between the issued MAs and the actual products distributed in the country.
11. Based on fluctuating currency exchange rates, the euro is generally slightly higher than the dollar (EUR 1 \approx USD 1.15). Quoting the prices in euros for Benin and in dollars for Ghana, as is the practice in these two countries, highlights how each of these financial, and by extension, cultural contexts have an impact in Benin and Ghana, respectively.
12. The fifth African company was located in Senegal. The ACTs produced in Ghana were Camosunate® and Danmether® by Danadams; Globartem® and Gloderp® by African Global Pharma; Artifran® and Asumod® by Phyto Riker GIHOC; and Malar-2® by Ernest Chemists. During our field studies in Ghana and in addition to the inventories conducted at the start of the research, we also found Lumether® by Kinapharma and Lumenate® by Pharmanova, two firms that were also local.
13. The only pharmaceutical company located in Benin, Pharmaquick, did not produce ACT; [Chapter 1](#) has more on this company.
14. The countries covered in this study are Central African Republic, Côte d'Ivoire, Ethiopia, Gambia, Kenya, Mozambique, Namibia, Nigeria, Rwanda, Sao Tome and Principe, Sudan, Tanzania, Uganda, Zambia, and Zimbabwe.
15. These figures should be interpreted with caution. They are based on sales volumes rather than price analysis and are not representative of the Ghanaian market since they only come from two wholesalers. Moreover, Ghanaian wholesalers differ significantly from one another in terms of products distributed and sales (Baxerres, 2018). One of the two wholesalers in our ethnographies, for example, was the exclusive distributor of one of the ACTs produced by an Indian company, which meant its sales were overrepresented.
16. These figures include different dosages for each medicine.
17. In collaboration with the Federation of African Pharmaceutical Manufacturers Associations (FAPMA), the Global Fund held a consultative meeting in June 2017 with manufacturers and technical partners based in Africa to discuss the status of local pharmaceutical production capacities and opportunities. A survey was launched to help the Global Fund Supply Department assess African producers' ability to

- supply essential medicines. For more information, see the Consultative Meeting Presentations: https://www.theglobalfund.org/media/6582/psm_2017-06-globalfund-fapmeeting_presentation_en.pdf, accessed March 2, 2020.
18. USAID supports numerous African producers through the Promoting the Quality of Medicines project. The United States bilateral agency would no longer require WHO prequalification as a condition. Its purchasing department, with its own quality assurance system, implemented its own quality assessment criteria for drugs (source: interviews with USAID supply managers, October 2017, Geneva).
 19. These authors adopt John Pickstone's concept of "Ways of Knowing" and identify five "ways of regulating drugs": administrative (government interventions), which is the most traditional way; professional (scientific societies); industrial (firms); public (civil society); and juridical (law professionals, legal associations).
 20. We conducted an ethnographic study of the drug committees that oversee the technical evaluation of the applications and issuance of MAs covering several days at the DPMED in Benin and the FDA in Ghana. We analyzed the decision-making process and highlighted the evaluation criteria and differences in regulatory practices between national authorities.
 21. The price of drugs in Benin is set by the State (see [Chapters 2 and 3](#)).
 22. The term "me-too" "means a substance developed to penetrate a niche market already occupied by a similar specialty, without providing any new profits" (Hauray, 2006, p. 147).
 23. The Beninese national policy recommends the use of ASAQ in the event of unavailability or intolerance to AL and for children under 6 months. In addition to AL and ASAQ, we found the following combinations in Benin: dihydropterin + piperazine; dihydroartemisinin + sulfadoxine-pyrimethamine; artesunate + sulfadoxine-pyrimethamine; artesunate + mefloquine; sulfamethoxypyrazine + artesunate + pyrimethamine; and artemisinin + naphthoquine. Until 2006, WHO recommended the use of four combinations that could be used as first-line treatments for malaria: AL, ASAQ, artesunate-mefloquine (ASMQ), and artesunate-sulfadoxine-pyrimethamine (ASSP) (WHO, 2001, 2006). The DHPP combination was added later (WHO, 2015).
 24. The AMFm program was strongly criticized by PMI and USAID representatives who opposed any form of subsidies for the private sector. From their perspective, AMFm had introduced a way to regulate the private market, which should be regulated solely by the rules of free competition. On this topic, see also [Baxerres et al. \(2015\)](#).
 25. Source: inventory, conducted in June 2019, of drugs containing albendazole and mebendazole, distributed in pharmacies in Cotonou for Benin and the MA list of products containing albendazole and mebendazole provided by the FDA in Ghana in 2015.
 26. However, Ghana's NHIS is facing a host of problems, as we will see in [Chapters 9 and 10](#).
 27. The different perceptions that consumers have about drugs based on their trade name and their brand are explored in [Chapter 11](#).
 28. Indian companies in particular hold a central place in the global fight against AIDS, tuberculosis, and malaria (Singh, 2018).
 29. There are 3000 pharmaceutical firms in India and over 10,000 legal manufacturing units belonging to them (Cepuch & Ashalhani, 2018).
 30. One of Tobinco's tactics was running very effective advertisements for Lonart® on Ghanaian television and roadside billboards: A mosquito is tried in a court of law, and the judge hammered his gavel as a box of Lonart® appeared.
 31. Negotiations and power games between national and transnational actors are interesting to study. Revolving instead around the transnational actors' advantage, they nevertheless highlight the States' leeway and the procedures implemented to (re)conquer their sovereignty (Baxerres & Eboko, 2019; Pourraz, 2019; Pourraz, Baxerres, & Cassier, 2019).

32. See the 2001 lawsuit filed by 39 pharmaceuticals against the Government of South Africa regarding antiretroviral drugs (Whyte, Van der Geest, & Hardon, 2002); those against the Swiss company Novartis and the Indian government in 2007, 2009, and 2012 on the Indian law on patents and its application for Glivec®, a cancer drug produced by the firm (Chaudhuri, 2013) and, more broadly, the confrontations between the State and the pharmaceutical companies in India and Brazil (Cassier, 2013).

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Understanding Drugs Markets

An Analysis of Medicines, Regulations
and Pharmaceutical Systems in the Global
South

Edited by **Carine Baxerres**
and **Maurice Cassier**

First published 2022
by Routledge
2 Park Square, Milton Park, Abingdon, Oxon OX14 4RN

and by Routledge
605 Third Avenue, New York, NY 10158

Routledge is an imprint of the Taylor & Francis Group, an informa business

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British Library Cataloguing-in-Publication Data

A catalogue record for this book is available from the British Library

Library of Congress Cataloging-in-Publication Data

A catalog record has been requested for this book

ISBN: 978-0-367-35067-3 (hbk)

ISBN: 978-1-032-04313-5 (pbk)

ISBN: 978-0-429-32951-7 (ebk)

DOI: [10.4324/9780429329517](https://doi.org/10.4324/9780429329517)

Typeset in Goudy
by KnowledgeWorks Global Ltd.

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