Introduction

Pharmaceutical markets in the Global South: Shaped by history and multiple regulations

Carine Baxerres and Maurice Cassier

Pharmaceutical specialties provide an ideal window into studying contemporary societies and understanding how and why they change. With dimensions that are simultaneously scientific, technical, therapeutic, popular, and commercial, these drugs are central to the health, economic, political, and social issues in play, both on a global and local scales. This economic sector is one of the most active and lucrative on the planet today (Hauray, 2006; Montalban, 2011).

When organic chemistry began to play a role in drug development, these new types of remedies were first produced industrially in Europe in the mid-19th century, and later in the United States. Their development was driven principally by their commercial potential (Faure, 2005). At the time of their emergence, they were poorly suited to the legislation then in place and were subjected to the most unrestrained rules of competition. Firms gradually began to establish "industry" regulations (standardization, increased number of biological trials, systematic control of raw materials and products, formalization of manufacturing protocols, etc.), the primary objective of which was scientific legitimacy for marketing needs (Gaudillière, 2005) before national legislation took over (Borchers, Hagie, Keen, & Gershwin, 2007; Marks, 1997). The goal of our book is to report on and analyze the construction and regulation of pharmaceutical markets in the Global South using case studies from Benin, Ghana, Côte d'Ivoire, and Cambodia.

Recent shifts in the globalization of medicines in the Global South

The globalization of drug markets in the Global South is as old as the history of commercial drug products themselves. Historiography on the expansion of drug markets in Latin America has shown proliferation of imports by private traders, copying of drugs by local pharmacists who set up small firms in the early decades of the 20th century (Garcia, 2020, on Colombia), or commercial strategies by large firms from the Global North to establish themselves in these markets (Cramer, 2010, for Bayer in Latin America between the two world wars). Here we are more directly interested in the regions of Africa and Southeast Asia, which borrowed several market devices to distribute pharmaceuticals. For example, Myriam Mertens (2014) describes, in the context of Belgian

Congo, how procurement contracts from colonial administrations were used by their pharmaceutical industries back home to develop and market new therapies for tropical diseases, as early as the beginning of the 20th century and at a time when these diseases were a leading sector of pharmaceutical innovation. Laurence Monnais studied the circulation and use of medicines in Vietnam in the first half of the 20th century, first through the Indigenous Medical Assistance system and then through a handful of French pharmacies established in cities accessible to wealthy Vietnamese and European customers (Monnais, 2014). French pharmacies were also established in some cities in West and Central Africa; Jean Mazuet, for example, launched in several countries the wholesale companies we mention in the first section of this book. Historians and anthropologists alike have shown how medicines are promulgated in West and Central Africa: distributed free of charge through public health services and by religious missionaries (Vaughan, 1991), occasionally through forced preventive treatment campaigns (Lachenal, 2014), or by establishing commercial entities that create pharmaceutical depots. Some of these French distribution companies remain quite active in West Africa to this day (Baxerres, 2013).

Although our book addresses colonial legacies, it focuses on modern-day cycles of globalization with a concentration on three major shifts since the 1970s. The first is the new geography of the pharmaceutical industry, created when India and Brazil abandoned pharmaceutical patents in 1970–1971 (Cassier & Correa, 2003; Chaudhuri, 2005), at a time when China's model was the public ownership of inventions. Sudip Chaudhuri has clearly laid out the growth of the generics industry in India and the significance of Indian imports into the African countries where he focused his research, Ghana and Tanzania. World Health Organization (WHO) archives on the essential drugs policy advocated since 1977 show that Indian firms sometimes directly approach the WHO to supply that program.[1] This is the story of the expansion of generic drugs, defined as those either manufactured without patents in many countries of the Global South before the World Trade Organization (WTO) TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreements were established in 1994, or after patents have expired.[2] On the African continent, we find national and regional markets based on local production centers being organized beginning in the 1980s and 1990s (Ghana, Kenya, Nigeria, South Africa, Tanzania, etc.) (Chorev, 2020; Mackintosh et al., 2016; Peterson, 2014; Pourraz, 2019). This is discussed in Chapter 1 in the countries of Benin, Côte d'Ivoire, and Ghana. Note, however, that nearly all African industries, with very few exceptions, are heavily dependent on imports of pharmaceutical raw materials from Asia, including in the most industrialized countries such as South Africa (Pelletan, 2019).

The second shift we examine is how the trajectories of market flows have changed. Although the countries studied here—Benin, Ghana, Côte d'Ivoire, and Cambodia—have been heavily influenced since independence by branded pharmaceuticals imported from their colonizers' firms and wholesalers (Baxerres, 2013 for Benin; Pourraz, 2019 for Ghana), the flow of generic imports from Asia now gives them stiff competition. We have witnessed the growth of South-South

trade since the 1970s (Horner & Murphy, 2018), not only in imports of final products and raw materials, but of experts and even direct investments from Indian and Chinese firms as well. Our fields of research have led us to concentrate on movements between Asia and Africa and the agents that underpin them (wholesalers, pharmaceutical representatives, regulatory authorities, foundations, international organizations, etc.), employing a transregional approach in social sciences that is still under construction and lies between cultural areas and global studies (Canzler, Kaufmann, & Kesselring, 2008). To understand these movements, we paid particular attention to the social and professional backgrounds and education of the people we met.

The third major shift began in the 2000s with the appearance of global donor groups that fund large vertical programs to provide pharmaceutical treatments on a mass scale as part of the Global Health framework, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Baxerres & Eboko, 2019; Gaudillière, Beaudevin, Gradmann, Lovell, & Pordié, 2020; Leon, 2015). Here again, Indian generics manufacturers have stepped into a predominant role, providing more than 90% of the antiretroviral drugs to treat AIDS in recipient countries. More recently they have begun supplying artemisinin-based combination therapies (ACTs) to combat malaria, a topic we cover in depth in this book, in the process replacing the Swiss multinational Novartis and the French company Sanofi, who had marketed the first ACTs. This third recent transformation of pharmaceutical markets in the Global South requires us to carefully consider the rationales, motivations, and practices of what we will call "transnational" actors[3] who provide subsidized medicines to countries primarily for infectious diseases and maternal and child health issues. They have a profound impact on these markets, putting the products they promote in often unfair competition with the products available in public and private markets (see the Global Fund's Affordable Medicine Facility–malaria initiative, AMFm, discussed in Chapter 6). The negotiated terms these transnational actors impose on the States of the Global South regarding their pharmaceutical and health policies were also central to our observations. Our findings question the "aid regime" under which many countries live (Lavigne Delville, 2010) even as we are experiencing a "return of the State" (Baxerres & Eboko, 2019). Certain transnational actors sometimes offer aid that achieves cross purposes, all the while supporting pharmaceutical import policies, and then also intervene in initiatives to develop local production.

In this book, we analyze the product hierarchy that results from these three historical changes: between innovative drugs and generics, between brand-name and generic drugs marketed under INNs (International Nonproprietary Names), and between different standards for copies. This hierarchy is objectified by norms governing intellectual property and standards, such as those defined by the WHO or the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH).[4] Research on "similars" or generic drugs in South America and Africa has noted the dissemination of increasingly high standards of equivalence (Chorev, 2020; Correa, Cassier, & Loyola, 2019; Hayden, 2013), especially through the implementation in the early

2000s of the WHO prequalification program (Lantenois & Coriat, 2014). This hierarchy is also subjectified in the imaginaries of consumption that mix colonial and postcolonial legacies, the new dominance of Asian medicines, and the ascendency of Global Health.

Multiple markets and regulations

A true understanding of pharmaceutical markets requires an interest in the history of pharmaceutical regulation as well as in the history of the tensions between market rules and the emergence of pharmacy policy and marketing authorizations (MAs) to protect population health. Historians have provided key contributions here, though until recently their work was largely focused on the markets of the industrialized and innovative countries of the Global North since the early 1800s. Olivier Faure's work on pharmacists and the dynamism of the drug market in 19th-century France contains a wealth of information on pharmacists' involvement in commercial and industrial logics (Faure, 1996) and on how the "dominant logic of commerce" incessantly spilled over into pharmacy-related frameworks and laws, including by pharmacists (Faure, 1993). Harry Marks' work on the history of pharmaceutical regulation in the United States highlights the role of distrust, particularly toward pharmaceutical companies, involved in the adoption of new standards for clinical research (Marks, 2000). The "adverse health events" associated with the use of therapeutic agents are used to justify strengthening the rules governing drug MAs (Bonah & Gaudillière, 2007; Chauveau, 2008).

The book edited by Jean-Paul Gaudillière and Volker Hess (2013) on the ways of medicine regulation proposes a synthetic model to explain the variety of regulatory tools deployed during the 20th century: professional, administrative, industrial, public, and legal. Regulation of pharmaceutical markets extends beyond the actions of the State, mobilizing professional pharmacist and physician organizations, and to a significant extent, academies of medicine, government committees and agencies, companies and industrial associations, consumer and patient associations, and the legal professions. An equally impressive array of knowledge and instruments is applied to cover procedures developed by professionals, drug patents, MAs, quality standards, post-marketing surveillance, clinical trials, and case law. This model is heuristic for analyzing pharmaceutical regulations in the Global South, as it was primarily developed from the history of pharmaceutical markets in the industrial and innovative countries of the Global North, with the exception of public and citizen regulation of patents during the AIDS crises in Brazil and India (Cassier, 2013). However, the research published here, which focuses on the sociology and anthropology of regulations from independence to recent cycles of globalization, reveals a history and modes of regulation that are somewhat different.[5]

The "professional" mode, primarily represented by pharmacists, is influential in Ghana, Benin, and Côte d'Ivoire (see Chapters 1–3), even though the creation of Orders and Faculties of Pharmacy is quite recent,[6] whereas this profession was for a time decimated in Cambodia (Chapter 4). One of the most urgent challenges

faced by all four countries is the limited number of pharmacists who can be trained to populate the regulatory authorities, industrial firms, and distribution system that are part of the large market sector.

The "administrative" mode is characterized by the legacies of colonial pharmaceutical legislation, in this context from the United Kingdom and France (Chapters 1 and 3). Drug agencies are a relatively recent creation: in the late 1990s in Ghana, where the pharmacy board was established in 1961; in 2017 in Côte d'Ivoire; and not until 2020 in Benin, where the drug agencies replaced a Ministry of Health Directorate that was created at independence in 1960 and where they are still fairly incomplete. These agencies can foment strong tensions. More generally, the pharmaceutical policies of the countries studied are in turmoil, torn between public health needs and economic and industrial interests, and between the legacy they inherited and their desire for reform. The situation in Benin particularly illustrates these tensions. A period of major reforms in the pharmaceutical sector began in 2017 just as our research was ending there, following the election of President Patrice Talon. Reforms continue to this day and are discussed in this volume (see in particular Chapters 2 and 3).

The "industrial" mode of regulation operates through the foreign firms, mainly Western and Asian, that distribute their products in the countries we study, but also through local manufacturers. Industrial firms are unevenly distributed in these countries, except in Ghana, where the State has encouraged direct investments by multinational firms since independence along with the formation of an industry supported by national capital. We show that establishing local production tends to stimulate administrative regulation (Chapter 1). Industrial standards are hierarchical: local products that cannot access international certifications from WHO or industrialized countries' agencies are certified by the drug agencies of Ghana or Nigeria. Ghana's Food and Drugs Authority (FDA) assists local firms in adopting Good Manufacturing Practices (GMP).

Although pharmaceutical manufacturing is relatively modest in the countries we discuss herein, except in Ghana and to a lesser extent in Côte d'Ivoire and Cambodia, occupations associated with drug distribution form a large and influential economic sector. These include traders, formal and informal salespeople and resellers involved in wholesale and retail distribution, and pharmaceutical representatives whose activities extend beyond the pharmaceutical marketing of the Global North (Greffion, 2014; Ravelli, 2015). One of the original features of our book is the depth and breadth of information on the market regulations at play in the distribution sector, which is primordial in the contexts of the Global South, as shown by Kristin Peterson (2014) in Nigeria and Mathieu Quet (2018) in the links he studies between India and Kenya. The framework of practices and codes of conduct for professions and market activities presupposes pharmaceutical regulatory mechanisms, which are currently undergoing reforms in the countries studied and which give rise to bitter conflicts, as mentioned above in Benin.

Jessica Pourraz's work in Benin and Ghana, conducted as part of our project, has highlighted the need for another mode of regulation: the "global mode," which "overlaps and weakens the most traditional form of medicine regulation

by States" (Pourraz, 2019, p. 58). This is discussed in the second part of the book devoted to ACTs, which lead us into our analysis of pharmaceutical markets in the Global South (see Chapters 5–7). Jessica Pourraz, who focused on national and transnational regulations as well as local production of ACTs in Benin and Ghana, describes three distinct regulation methods that are juxtaposed to and may either strengthen or oppose each other: administrative State methods, industrial rules (in Ghana only), and regulation led by transnational Global Health actors. This latter form of pharmaceutical market regulation is the focus of Nitsan Chorev's recent book (2020) on what she calls "developmental foreign aid" in East Africa, in which she shows the actual impact of foreign aid on the growth of the local pharmaceutical industry in Kenya, Tanzania, and Uganda.

Jean-Paul Gaudillière and Volker Hess characterize a model of citizen or public regulation that appears in specific circumstances, such as during health crises linked to drug-related adverse events (e.g., thalidomide) to supplement and reinforce MA standards; during a treatment-access crisis (e.g., AIDS); or to adapt patent law (Krikorian, 2014; Cassier, 2013). This citizen regulation does not feature in our work since this research was mainly focused on malaria, an acute pathology that has not seen patient-driven collective organization despite its severity and prevalence. We do, however, observe a form of regulation shaped by consumers, which we characterize as "popular" (see Chapters 4, 7, 8, 10, and 11). More fluid than other forms, this type of regulation is transmitted from one person to another and is exercised through the subjectivities forged by people's perceptions of their bodies, health, illness, and their health-care and treatment experiences. It is also limited by the availability of medical consultations and products and, more broadly, by local contexts. This popular regulation refers to a part of the disciplinary corpus of medical anthropology forged in both the Global South and North, which emphasizes both universalisms and particularisms that are observed locally (Benoist, 1996; Saillant & Genest, 2005), individual agency and vulnerability to social structures (Fassin, 1996; Scheper-Hughes, 1992), and the intimate and socialized processes involved in health (Fabrega, 1974; Kleinman, 1988). It falls under the umbrella of "pharmaceuticalization," a concept used by medical anthropologists since the late 1990s to describe the realities they observe as pharmaceuticals spread through many facets of social life.[7]

Mathieu Quet and his colleagues use the example of Southeast Asia to expand the concept of regulation, without describing each one in detail, to think symmetrically about the standards and laws that govern official markets and those that organize unofficial markets, since these latter are particularly extensive in the countries they study: "As we will show in the case of pharmaceutical regulation in Southeast Asia, the gravitating forces are as much located within as outside the control of central powers" (Quet et al., 2018, p. 2). In this, they converge with the anthropology of informal markets studied in Cameroon by Sjaak Van der Geest (1987), in Benin by us (Baxerres, 2013), and in Madagascar by Chiarella Mattern (2017). More generally, pharmaceutical anthropology, which investigates pharmaceutical systems, broadens the concept of these systems beyond the health institutions-based definition by associating them with all of the medicine supplies

and services available in a given territory. This means focusing on both formal (public and private) and informal (Desclaux & Lévy, 2003), not just State pharmaceutical supply and distribution processes. It is a comprehensive approach to regulation, from the laws and guidelines of the medical professions to the practices and codes of conduct of sellers in formal and informal markets, and from commercial treaties to illicit cross-border transactions. Mathieu Quet and his colleagues are careful to capture these rules in the course of "social practices." This approach is able to highlight several pharmaceutical orders or regimes, as well as any friction, interaction, or harmonization between them. One of the harmonization processes studied by these authors is the State-run training for informal sellers observed by Laurent Pordié in Cambodia. Also in Cambodia, in Chapter 4, Eve Bureau-Point describes her research on forms of State supervision of the informal market, which since 1999 has granted licenses to "blue pharmacies" after training informal vendors. These processes are also described in Chapter 3 regarding the activity of Ghanaian wholesalers, which allows us to grasp the permeability of informal and formal practices and how they shift from one to the other, particularly businesses that are launched and formed within a capitalist system (Baxerres, 2018). The harmonization of rules presupposes specific investments by the State, in this case training programs for informal vendors and a system of special licenses.

Anthropologists have analyzed how drug markets continually challenge the limits of health controls in terms of "commodification" (Nichter, 1996). Sjaak Van der Geest uses this term to describe the disconnect between therapeutic value—assessed and controlled by registration and surveillance rules—and market value, as well as the gradually increasing importance of the latter over the former. However, that author considers the commodification created by informal markets to be a "lesser evil" since it gives patients access to therapies (Van der Geest, 2017). We have shown that drug distribution-related commodification processes were not specific to the informal markets of the Global South and that they are active in countries in the Global North as well, outside (or through the loopholes) of standards and laws (Baxerres, 2014).

Thus, the pharmaceutical markets we study are at the mercy of the numerous types of regulations described above: administrative, professional, industrial, commercial, global, and popular. The histories of each of the four countries we examine here and their regional industrial and political contexts determine the differences in how these various regulations are deployed.

From the social lives of medicines to the making of pharmaceutical markets

To understand the links that bind the societies of the Global South to pharmaceuticals, we must go back to colonial times and unravel the thread of history to the present day, pausing to examine various time periods and the actors—economic, political, local, national, and international—who have affected it along the way. The countries we discuss—Benin, Ghana, Côte d'Ivoire, and

Cambodia—have different pharmaceutical supply and distribution processes in place. The form these processes take is influenced by historical elements: the colonial power and its pharmaceutical legislation, the conflicts and political regimes that the countries subsequently experienced (such as the Khmer Rouge period in Cambodia), and the economic zone of influence to which they belong (language, currency, and economic community, such as the Commonwealth). These various elements determine the extent of support for production activities, the diversity of import sources, and whether wholesale and retail distribution are broadly supervised by the State or left to the dynamism of economic actors. Our research questioned the impact of these structural elements (presented primarily in the first section of the book) on pharmaceutical consumption practices and how people use commercial drug products (elucidated in the third section of the book). Our main comparison is between Benin and Ghana, two West African countries, one formerly colonized by France and francophone, the other formerly colonized by the United Kingdom and anglophone. This comparison comprises 7 of the 11 chapters of the book. Côte d'Ivoire (one chapter) and Cambodia (two chapters), both former French colonies, provide perspective on the analyses of Benin and Ghana and enrich the understanding of the issues surrounding medicines in Global South societies. The prominent French-speaking perspective of our research constitutes one of the originalities of our work, as these contexts are less comprehensively described in the international social science literature on medicines, particularly with regard to the African continent. Another originality is the comparison between two "models" for medicines, one French-speaking, the other English-speaking, that we propose.[8]

A strength of our research is that it can compare and contrast a variety of regulatory mechanisms and hierarchies in pharmaceutical markets. It proposes an integrated consideration of all the social levels—and the categories of actors that come into play—involved in pharmaceutical markets within the studied Southern context: production, distribution (wholesalers and retailers), prescription, consumption, and uses.[9] This contribution is made possible by our multidisciplinary approach that combines the anthropology of drug distribution and use with the sociology of innovation and pharmaceutical regulation, which include an historical sociology approach and social epidemiology. We employ a cross-section of specific research methods from these disciplines, detailed below, which synergistically complemented each other. This approach allows us to go beyond conceptualization in terms of "social life of medicine" and "biographical stages of the drug" (Whyte et al., 2002), which is now classic and very didactic in the social sciences. As Desclaux and Egrot (2015) have rightly pointed out, this approach was undeniably valuable when first proposed: it sought to highlight the tensions or synergies associated with transitions from one stage to another, encourage monographs in the early stages of their research, introduce the political dimension, examine North and South with the same theoretical approach, conjugate theories of globalization and medical anthropology, and offer a reading list to order the work. Nevertheless, as with any model, its weaknesses lie in its strengths so it can lead to flattening social realities by presenting them in too linear a manner.

Our goal in this book is to focus on the confrontation and superposition of the challenges, actors, and processes generated by commercial drug specialties in the contexts we studied. We have found an intimate link between pharmaceutical distribution and consumption; drug production and use; local production and distribution since the same actors may be involved, particularly in Ghana; and local production and the strengthening of State mechanisms. The different chapters and sections of the book articulate these levels of social realities to reflect their complexity, both with regard to antimalarial treatments—their development, circulation, competition, and the attachments they generate (discussed in Part 2)—and more generally with regard to production and distribution practices and their impact on State sovereignty, formal and informal economies, the individual health of consumers, and public health (Part 1); and finally with regard to the activity of pharmaceutical representatives, the diversity of medicine supply and biomedical services, and their influence on how people manage their health and on their imaginaries of pharmaceutical consumption (Part 3).

This book covers the institution and regulation of pharmaceutical markets in several countries of the Global South. These markets are not free-standing entities, supported through the spontaneous intersection of supply and demand, but are supported by a set of institutions, rules, policies, calculations, and values: hence the interest in studying "the laws of the marketplace" or "trade arrangements" that bolster them, as Michel Callon invites us to do in his work (Callon, 1998, 2017). We pay close attention to the actors who establish, maintain, and develop these markets, from private wholesalers to pharmacists, from central purchasing offices to health centers (public or private, for-profit, or mission), from industrialists to pharmaceutical representatives, from experts in drug agencies or departments to ministers of health or industry, to the self-medication practices of consumers and patients, who have unequal access to care when it comes to paying for essential drugs, even if these are subsidized per the cost recovery principle adopted in Bamako in 1987 (Ridde, 2005). In addition to the plurality of regulations and market laws, we are careful to consider the asymmetries of actors' resources and power, such as when the World Bank influenced the creation of Benin's Essential Drugs Purchasing Office in the late 1980s. The imbalances and points of friction in these markets were also considered, such as when local producers in Ghana were excluded from the ACT market, unable to compete with the prices of subsidized drugs distributed in the country by the Global Fund in the early 2010s. Similarly, we analyze the economic sovereignty strategies used in Côte d'Ivoire with the constitution of a holding company owned by a group of pharmacists.

Several factors lead us to understand these markets as dynamic, open, and conflicting systems. These factors include the situated and historicized analysis, the numerous regulations, the interactions and circulation of humans and capital between distribution and production, various financial flows that support the purchase of medicines from international financiers to end users, and the frictions and imbalances that run through these markets. It is important to understand how they function in order to propose possible avenues for reflection to reform

and "change" them, as Michel Callon invites us to do. We attempt this in the conclusion of the book.

A multidisciplinary methodology using an ethnographic, socio-historical, and population-based approach

The data collection methodology we used mixes extended and in-depth observation with open and semi-structured interviews, archive consultation, and questionnaires given to representative samples of the population. It illustrates the richness produced by drawing from a variety of approaches and disciplines. Essentially qualitative, our method uses tools from ethnography that overlap with techniques used in history where the qualitative intersects with the quantitative, as well as some purely quantitative aspects.

To support the aspects discussed in this book, we believe it is imperative to precisely describe the data we collected and the methods used to do so. These form the basis of our contributions and support the credibility of our work. We decided to present them in three study packages: the first one is mainly ethnographic, the second socio-historical, and the third is epidemiological.[10]

The study of medicine distribution, circulation, and uses in Benin, Ghana, and Cambodia

These studies were mainly conducted between 2014 and 2017, both in the economic or administrative capitals of the countries (Cotonou, Accra, and Phnom Penh) and in semirural areas: the Mono department in Benin, located between 50 and 80 km northwest of Cotonou; Breman Asikuma and the surrounding areas of Jamra, Ayipey, and Kuntanase in Ghana, about 150 km northwest of Accra; and the Battambang province in the northwestern part of Cambodia, about 250 km from Phnom Penh (see Figures 0.1, 0.2, and 0.4).

An ethnography of various wholesalers and retailers lasting 4–6 months was conducted in Benin and Ghana. Some of the retailers were exclusively distributors, while others also provided health-care services. In Benin, Anani Agossou, Moïse Djralah, Aubierge Kpatinvoh, and Stéphanie Mahamé, all master's degree students or research assistants at the time, conducted ethnographies with two wholesalers, three community pharmacies, two pharmaceutical warehouses, five informal vendors, four public health centers at different levels of the national health pyramid, two mission health centers, and three private health centers. In Ghana, Eunice Ayimbila, the late Sandra Serwah Bredu,[11] and Grace Kumi Kyeremeh, who had the same status as their counterparts in Benin, carried out ethnographies in three private pharmacies, six over-the-counter (OTC) medicine shops, one mission hospital, three public health centers at different levels, and one private health center.[12] During these ethnographies, many open-ended interviews were conducted with as many actors as possible, distributors as well as buyers and suppliers. At the intersection of qualitative and quantitative approaches, information was also systematically collected about the products sold, their name, price,

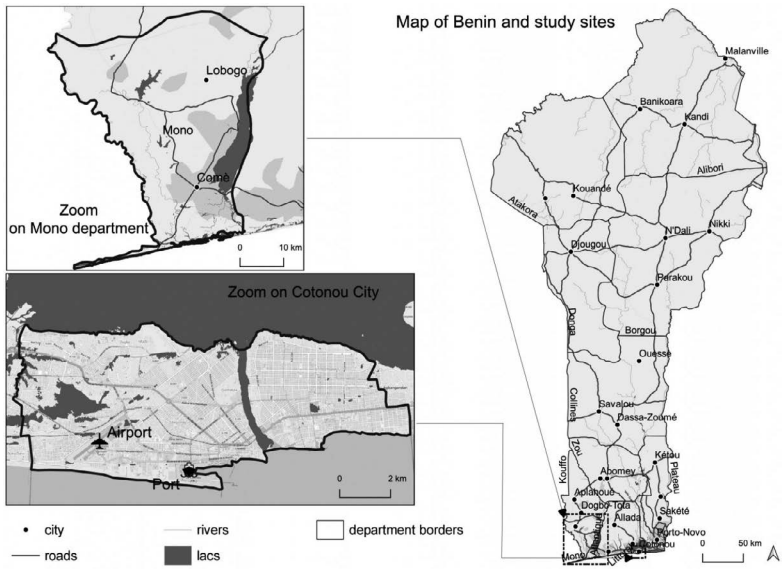

Figure 0.1 Map of Benin and study sites.

Source: Data available for free on the Web and work of Artadji Attoumane (IRD, LPED)

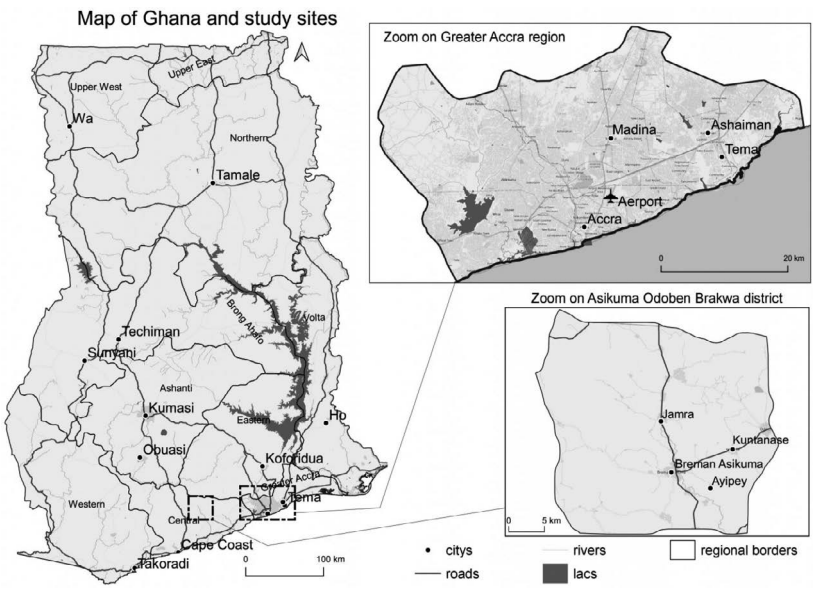

Figure 0.2 Map of Ghana and study sites.

Source: Available for free on the Web and worked by colleagues and work of Artadji Attoumane (IRD, LPED)

quantity, and how they were purchased (upon presentation of a prescription, by asking for advice, or spontaneously specifying the desired product). These data, recorded in Excel files, enabled the quantifications contained herein. At the end of each of these ethnographies, semi-structured interviews were conducted with between 10 and 20 people carefully chosen for their category (facility staff, clients, suppliers, pharmaceutical representatives, etc.) and the interest they brought to the study.

In Ghana, Carine Baxerres led the study of wholesale distribution and pharmaceutical representatives. This study was generally conducted around the Okaishie market in Accra, which plays an important role as the center of pharmaceutical wholesale distribution in Ghana.[13] The ethnography of two private wholesalers was conducted over eight 15-day research trips between 2014 and 2016. Some 40 semi-structured interviews were held with retailers (whom she then accompanied when they made their pharmaceutical purchases), directors or representatives working for both small and large private wholesalers and for pharmaceutical firms, informal actors operating in the Okaishie market, and institutional and transnational actors.

In Benin, Stéphanie Mahamé followed up the 2014–2016 data collection on wholesale distribution with a study of pharmaceutical representatives from 2017 to 2020 as part of her sociology-anthropology PhD.[14] Data were collected over

Figure 0.3 Overlooking the drug lane sector of Accra's Okaishie market.

Source: © IRD/Carine Baxerres, Accra, August 2014

20 months of ethnography and included observations in a mission health center and a private clinic and shadowing of three pharmaceutical representatives during their daily activities. The ethnography was also interspersed with semi-structured interviews with drug reps, health workers, and State actors. Overall, 52 interviews were conducted in Benin. Several questions were examined more extensively during a subsequent 15-day research trip to Côte d'Ivoire through nine interviews with pharmaceutical representatives and pharmacists from the Pharmacy Directorate.

To investigate how medicines are used, two teams—Anani Agossou, Emilienne Anago, and Audrey Hémadou in Benin; and Emelia Agblevor and William Sackey in Ghana—conducted semi-structured interviews with the parent (usually the mother) and/or a grandmother of 30 families in Benin and 30 families in Ghana. Participating families were selected based on their socioeconomic status (income, housing, vehicle ownership, employment activities, and education level) to ensure representation across a broad range of the existing situations in the urban and semirural contexts studied.[15] The graduate students and research assistants in both countries used their survey observations to classify families as "wealthy," "middle-class," or "poor." Each family had to include at least one child under the age of five. Following the interviews and again combining qualitative with quantitative data collection, family members' medicine consumption was tracked bimonthly for 4–8 months based on their availability.

Eve Bureau-Point led the study in Cambodia, conducted between January 2015 and June 2016 with Malinda To, research assistant. Semi-structured and open-ended interviews were also held with 30 retailers (in pharmacies and pharmaceutical warehouses), 8 private medical practice proprietors (doctor, nurse, midwife), 10 semi-wholesalers, 7 public health center staff members, 3 informal vendors, 3 medical sales representatives, 5 representatives from "pharmaceutical companies," and 15 members of Ministry of Health staff.[16] Direct observations were made on site with these various distribution actors of the modes of interaction between sellers and buyers. The same qualitative-quantitative data collection tool used previously in Benin and Ghana was employed here to collect systematic information from 270 purchases in Phnom Penh and 121 in Battambang on the products sold and the modes of purchase. Semi-structured interviews were conducted with 24 mothers from diverse socioeconomic backgrounds to assess medicine use.[17] Once again we tracked these families' medicine consumption bimonthly for an average duration of three and a half months.

Finally, Maxima Missodey, doctoral student working with Globalmed, led the study of the contextual issues surrounding the standardization of herbal medicines in Ghana. Her ethnographic study employed participant observations and interviews. The observations were carried out in two OTC medicine shops in Breman Asikuma in the Central Region and an herbal medicine shop and pharmacy in the Greater Accra Region. The observations were carried out over a period of 8 months between 2016 and 2017. The interviews were conducted with 14 manufacturers and 10 distributors of manufactured herbal medicines. Additionally, exit interviews were conducted with willing customers who came to

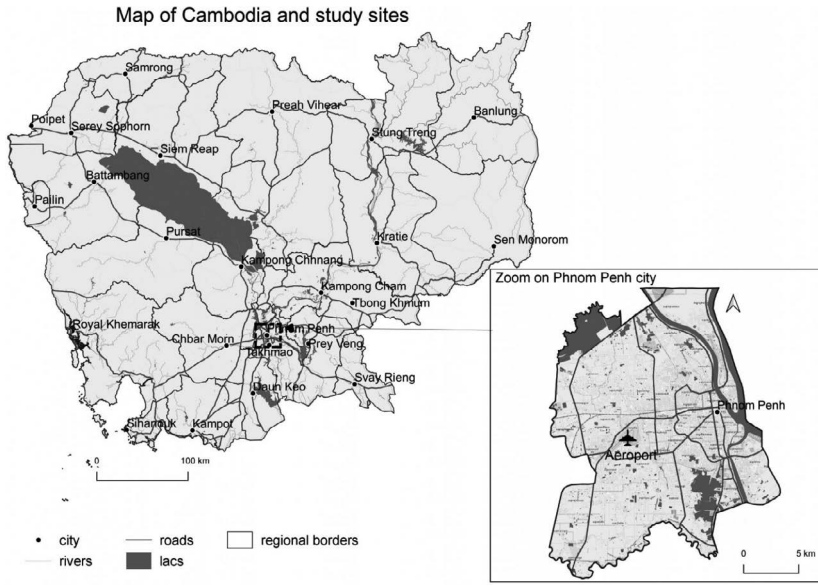

Figure 0.4 Map of Cambodia and study sites.

Source: Available for free on the Web and worked by colleagues and work of Artadji Attoumane (IRD, LPED)

buy from the medicine outlets (30 customers from the herbal medicine shop and 7 from the pharmacy in Greater Accra Region). The exit interviews focused on the medicines purchased and general information on the consumption of herbal medicines.

These studies were supervised by Carine Baxerres, who partnered with Adolphe Codjo Kpatchavi in Benin, Daniel Kojo Arhinful in Ghana, and Eve Bureau-Point in Cambodia. The same data collection tools (observation checklists, interview guides, family medicine consumption tracking sheets, and drug purchase data collection sheets) were used in all three countries. Eunice Ayimbila, Carine Baxerres, Aubierge Kpatinvoh, Stéphanie Mahamé, Maxima Missodey, and Kelley Sams were responsible for analyzing the data collected in Benin and Ghana. Eve Bureau-Point was responsible for data collected in Cambodia.

ACT: An exploration of the Asia-Africa trajectory, local production, and national and transnational regulations in Benin, Ghana, and Côte d'Ivoire

Mainly performed in Benin, Ghana, and Côte d'Ivoire, this series of studies involved travel to various innovation and manufacturing sites as well as to the headquarters of international organizations throughout Europe and Africa.

Maurice Cassier examined the trajectory of ACTs between 2008 and 2019, drawing on multiple sources to do so. He studied the accounts of Chinese inventors

who discovered artemisinin and invented combination therapies, including of their collaborations with the WHO and multinational companies.[18] He also consulted the archives of the Tropical Disease Research (TDR) group, the WHO, and Roll Back Malaria in Geneva, including industry agreements on R&D,[19] industrialization, and distribution. He hunted through the archives of patents filed for single-tablet fixed-dose combinations, especially for artemether-lumefantrine. Finally, he used materials from a detailed investigation on the invention and industrialization of the artesunate-amodiaquine combination (ASAQ), during two periods of research, the first in 2008–2009 (under a contract with the French National Research Agency Pharmasud) and second in 2016–2019. He conducted semi-structured interviews with personnel from the universities and start-ups that developed the fixed-dose combination of ASAQ and from the Sanofi company that mass produced it, and with the organizations MSF (Médecins sans Frontières or Doctors Without Borders) and DND*i* (Drugs for Neglected Diseases Initiative) that governed this system. This investigation took Maurice Cassier from the

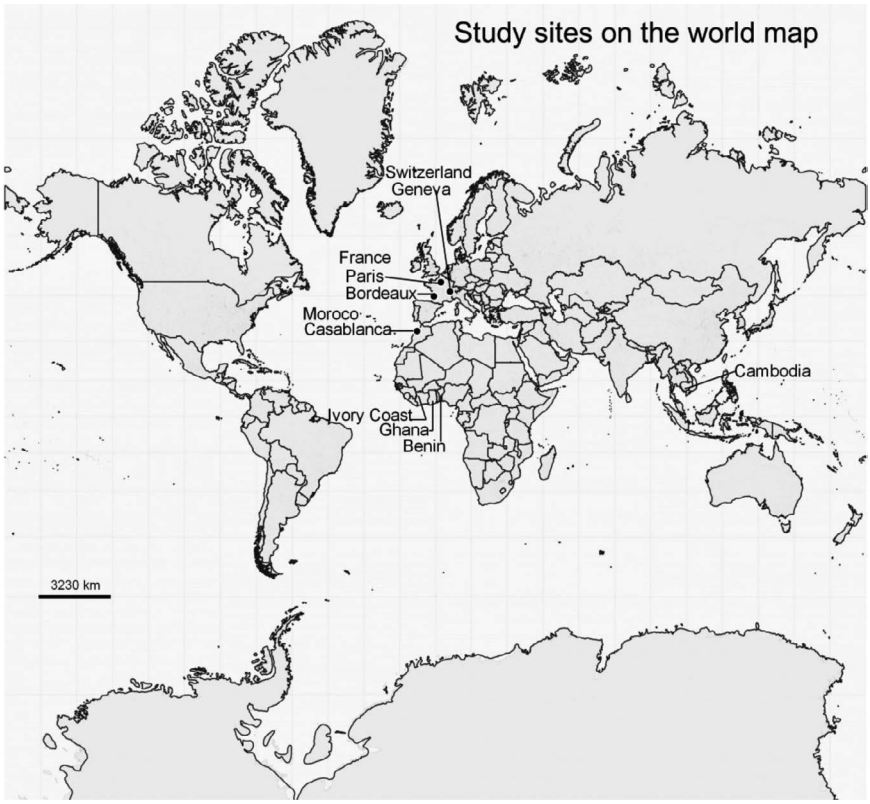

Figure 0.5 Study sites on the world map.

Source: Available for free on the Web and work of Artadji Attoumane (IRD, LPED).

French city of Bordeaux to Sanofi's factories in Casablanca, Morocco, with stops along the way in Geneva, Switzerland, and Sanofi's headquarters in Paris. He also directed and coordinated the research on local production conducted in Ghana, Benin, and Côte d'Ivoire.

Jessica Pourraz conducted her research as part of a sociology PhD (Pourraz, 2019) at EHESS. The empirical data were collected over 14 months between August 2014 and May 2017 in Cotonou, Accra, Geneva, and Paris. She conducted semi-structured interviews and observations with various actors involved, such as national pharmaceutical regulatory authorities (the Directorate of Pharmacies, Medicine, and Diagnostic Investigations or DPMED in Benin and the FDA in Ghana), transnational actors that fund ACTs (United States Agency for International Development [USAID], President's Malaria Initiative, Global Fund, UNICEF, and the World Bank), the WHO, national malaria control programs, ministries of health in Benin and Ghana, and pharmaceutical industries and the associated union in Ghana. In total, Jessica Pourraz held nearly 100 interviews (32 in Cotonou, 58 in Accra, 5 in Geneva, and 2 in Paris). She also conducted observations at a pharmaceutical company producing ACTs in Accra, at the DPMED, and at Ghana's FDA during meetings of the technical committees that issue pharmaceutical MAs. She also observed working meetings between national malaria control programs and their international partners, between Ghanaian industry and the United Nations Industrial Development Organization (UNIDO), and at a training session on pharmaceutical policies organized for African regulatory pharmacists by the WHO in Geneva. Finally, Jessica conducted extensive research at the National Archives of Ghana to collect historical sources to trace the history of Ghana's pharmaceutical industry since independence, and at the WHO archives in Geneva on the history of malaria control in Africa. Daniel

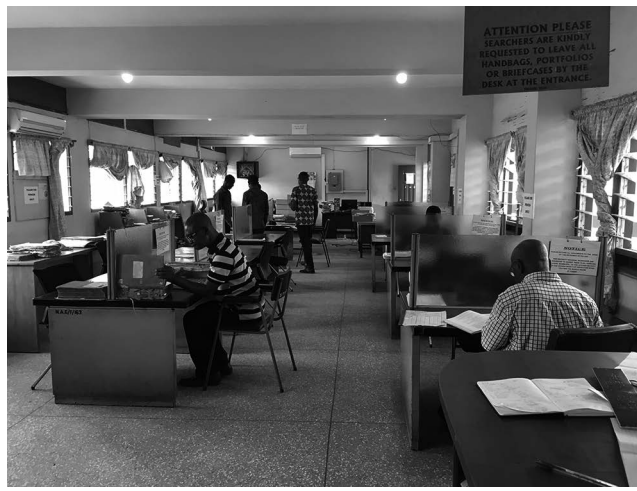

Figure 0.6 Consultation room of the National Archives in Accra.

Source: © IRD/Carine Baxerres, Accra, October 2019

Kojo Arhinful in Ghana and Adolphe Codjo Kpatchavi in Benin provided instrumental support to her investigations by introducing her to various actors in the ministries of health and sharing their extensive knowledge of the health system in their countries.

Claudie Haxaire studied in Côte d'Ivoire some of the aspects that Jessica Pourraz worked on in Benin and Ghana. Both a pharmacist and anthropologist, she taught at the Faculty of Pharmacy in Abidjan from 1979 to 1984 and regularly visited the country thereafter for ethno-pharmacological research missions. Between 2014 and 2017, this gave her the opportunity to participate in observations and informal meetings with the country's pharmaceutical stakeholders. These guided the semi-structured interviews she conducted and facilitated more targeted participant observations (visits to three manufacturing units, the public health pharmacy, and the analysis laboratory; and participation in a meeting of the technical committee regarding issuing an MA). This methodology also included participation in several symposia, including SympoINDUS19 in Abidjan in February 2019 for pharmaceutical industrialization and manufacturing in West Africa and the workshop to develop Côte d'Ivoire's new public health code for medicines. Her analysis of gray literature and information collected from the Internet and specialized journals led to the identification of companies listed as ACT manufacturers (four out of eight such firms in that country), wholesale distributors (initially three companies, then four), the central purchasing office, the national public health laboratory, the Directorate of Pharmacy, Medicine, and Laboratories (DPML; Direction de la Pharmacie et du Médicament et des Laboratoires), and the National Program for the Development of Pharmaceutical Activity (PNDAP; Programme National de Développement de l'Activité Pharmaceutique). On the basis of this information, she held 45 semi-structured interviews with the identified actors (experts who authored the reports, directors and deputy directors of state structures, pharmacists in charge of private manufacturing units or wholesale distributors, manufacturing unit directors to discuss financial aspects, commercial representatives, and international experts). The term of this project overlapped with the reform of the regulatory authority (DPML) into an agency. Claudie Haxaire followed this long process, staying in contact with the experts who were in charge of submitting legal texts and application decrees involved in founding the drug agency in Côte d'Ivoire. She collected the various actors' opinions on this ongoing issue.

Throughout our research and in addition to interviews, we stayed in close contact with the national actors responsible for pharmacy and medicine regulations, both during and predating our investigations. One example is Joseph Nyoagbe, head of the Pharmacy Council in Ghana from 2005 to 2016, who wrote the preface to this book.[20] We shared our results with health authorities and pharmaceutical system actors in Benin, Ghana, and Cambodia in 2016, 2017, and 2018. In March 2018, we organized an international colloquium on current issues regarding medicines in Africa in Ouidah, Benin, the final round table of which was illustrative of the bridges that we sought to create throughout this joint research between the academic, State, and transnational sectors, between researchers and

Figure 0.7 Participants at the Globalmed symposium in Ouidah, Benin.

Source: © IRD/Charlie Marquis, Ouidah, March 2018

students in social sciences and pharmacy, and with national and regional political actors (Baxerres & Marquis, 2018). Roch Appolinaire Houngnihin, professor of socio-anthropology in Benin, was key to the success of this scientific event, which was a testimony to the action-–research character of our work.

The study of pharmaceutical consumption in Benin and Ghana

This consisted of a series of quantitative surveys of the general population in the urban areas of Cotonou and Accra and in the same rural areas as the qualitative studies described above. We wanted to survey more remote rural areas than those studied in the qualitative research, which we qualified above as semirural. The surveys were conducted in the commune of Lobogo in Benin's Mono department and in the Kuntanase village of Breman Asikuma in Ghana's Central Region in Ghana (see Figures 0.1 and 0.2).

To ensure the sample population surveyed would be representative, households were randomly selected based on their GPS coordinates (Apetoh, 2020). The same methodology was applied in Cotonou, Madina (a neighborhood in Accra), and Lobogo. We first defined the study area in each of the survey areas based on administrative divisions. In Benin, we considered the entire city of Cotonou (13 districts, nearly 800,000 inhabitants) to be one study area and the rural Lobogo (17,000 inhabitants) in the Mono department to be another. In Ghana, our urban study area was Accra's eastern suburb Madina (nearly 140,000 inhabitants), which has a diversity of socioeconomic status comparable to the composition of the city of Cotonou.[21] To obtain sufficient power in the statistical tests, we calculated the number of families needed using Schwartz's formula (Schwartz, 1996), which gave us a minimum of 600 families to survey.[22] Kuntanase, a municipality located in the Breman Asikuma district, was an exception: given the size of this village, we decided to conduct an exhaustive survey, visiting all of the families (n = 853). To constitute our sample in the other three areas, we randomly selected a sufficient number of GPS points in the defined spaces using the Google Earth Pro™ application and the Geomidpoint.com website to generate the points (Apetoh, 2020;

Damien, Baxerres, Apetoh, & Le Hesran, 2020). We identified the building closest to each GPS coordinate point, and socio-anthropological investigators visited each one. If the building housed only one family, the family was included in the study after obtaining informed consent from a head of the household.[23] If there were several families in the building, one was selected at random and included in the study. The responsible adult in each family was questioned about the family's socioeconomic characteristics and their usual health-care practices, especially if malaria was suspected.

To study the health problems encountered, health-care practices, and medication use, we randomly selected one adult (≥18 years) and one child (<12 years). The adult and the child's caregiver were queried by questionnaire using two approaches. First, they were asked about any "health events"[24] experienced in the week prior to the interviewer's visit. They were asked to describe the symptoms presented, treatment decisions, and modalities (self-medication, consultation, advice from family or friends), therapy(ies) used, and where these were purchased. Secondly, if there had been no health event in the previous week, they were asked when was the last time they took a medicine, what it was, for what reason (symptoms, illnesses), for what purpose (preventive, curative, health maintenance), whether or not the drug was prescribed, and where it was purchased.

These quantitative data were collected by Edwige Apetoh in Benin as part of her epidemiology PhD (Apetoh, 2020), and in Ghana by William Sackey, a research assistant also involved in qualitative studies. They were under the supervision of Jean-Yves Le Hesran in both countries, who worked with Daniel Kojo Arhinful in Ghana. They were assisted in both Benin and Ghana by socio-anthropological investigators, some of whom were also involved in the qualitative studies: Anani Agossou, Ines Boko, Ruth Boko, Moïse Djralah, Audrey Hemadou, Bernadette Kokoye, and Aubierge Kpatinvoh in Benin; and Salomey Pomaah Adjani, Alberta Addo, Emmanuel Andam, Esther Appiah, Derrick Frimpong, Raymond Lamptey, Eric Nartey, and Ohene Sakyi in Ghana. They did a remarkable job, employing patience and pedagogy to create exceptional contact with the people surveyed and collect high-quality data. The data were analyzed by Georgia Damien, Michael Addo Preko Ntiri, Edwige Apetoh as part of her PhD; and Marina Tilly, Arnaud Gbenou, and Hajar Ahachad as part of their master's degree in public health (Ahachad, 2020; Gbenou, 2017; Tilly, 2017).

Notes

1. WHO archives: E19372_2 –J5 – collaboration with industry.
2. Generics were included in U.S. legislation as early as the 1960s to reduce treatment costs (Greene, 2014) and in some Latin American countries (Colombia),and were later supported by the WHO's Essential Medicines Policy (Borchers, Hagie, Keen, & Gershwin, 2007; Whyte, Van der Geest, & Hardon, 2002). Numerous historical (Greene, 2014 for the United States; Garcia, 2000 for Colombia), anthropological (Hayden, 2013 for Mexico), sociological (Cassier & Correa, 2019 for Brazil; Nouguez, 2017 for France), and other studies have examined how generics' equivalence with originator drugs is regulated.

3. The expression "transnational actors" combines different types of extra-national actors currently involved in a country's public health issues: bilateral institutions (the various international aid agencies) and multilaterals (World Bank, Global Fund), nongovernmental organizations, foundations, and public-private partnerships that are sometimes aligned with the pharmaceutical industry.
4. The WHO Prequalification of Medicines Programme (PQP) was first applied in 2001 to antiretrovirals for AIDS, then to antimalarials and tuberculosis drugs, and gradually from 2006 on to contraceptives, antivirals for flu, and treatments for acute diarrhea and neglected tropical diseases. The ICH was founded in 1990 and is made up of pharmaceutical regulatory authorities and industry associations from the European Union, the United States, and Japan (Pourraz, 2019).
5. Moreover, Jean-Paul Gaudillière and Volker Hess state that the "ways of regulating" they identify at the end of their historical investigations do not constitute a fixed model, but that they are themselves socio-historical entities.
6. Although relatively recent, these organizations differ between the countries discussed. Pharmacy education began as early as 1921 in Ghana, where the first university department opened in the 1950s. In Côte d'Ivoire, the Faculty of Pharmacy began teaching in 1977, whereas in Benin, it began in 1999 and the first class of pharmacists graduated in 2006.
7. "Pharmaceuticalization" is the process by which social, behavioral, or physical conditions are treated with drugs or considered to require drug treatment by patients, physicians, or both. Developed in sociology, this concept is widely used in anthropology (Collin & David, 2016; Desclaux & Egrot, 2015; Nichter, 1996). It extends beyond the influence of biomedicine alone, also reflecting the autonomy of individuals who may use medicines outside of health-care relationships and facilities.
8. At the beginning of this research program, we conceived of two pharmaceutical models in West Africa, one "administered" in francophone areas and the other "liberal and market based" in anglophone areas (Baxerres, 2013). The various studies we report in this book have allowed us to expand and add complexity to this initial modeling, which is overly binary and reductive. While the more or less liberal character of pharmaceutical distribution models between English-speaking and French-speaking countries is globally relevant (see Chapter 3), the work on the "administrative" and "industrial" modes of regulation highlights the importance not only of institutional and historical legacies, but also of the degree of State political and financial autonomy, medication supply (imported and/or locally produced), and market structures and connections to Asian manufacturers. Rather than two models, these aspects show there are many possible scenarios in and between French-speaking and English-speaking countries, and that within the same country approaches may coexist that are quite liberal in some ways (distribution) yet highly administered or supervised in others (production, prescription), as is the case in Ghana.
9. However, we did not study the economics of clinical trials, which is an important and growing issue in the Global South (Sunder Rajan, 2012).
10. Research authorizations were obtained from national ethics committees in Ghana (May 10, 2014, GHS-ERC), Benin (No. 30 dated December 3, 2013, CER-ISBA), Cambodia (466, NECHR), and France (December 10–11, /2013, CCDE).
11. Sandra Serwah passed away during the Globalmed program following an illness. We pay tribute to her here.
12. Because different laws govern the pharmaceutical systems in Benin and Ghana, each category of actors plays a different role in pharmaceutical distribution. OTC medicine sellers in Ghana are private actors authorized to sell OTC drugs that require no medical prescription. They do not have a pharmacy degree. In Benin, drug warehouses, located only in rural areas, are businesses run by non-pharmacists

who are restricted to a limited list of drugs for distribution and must be supervised by the pharmacist in the closest pharmacy. Informal vendors in Benin distribute drugs outside of the formal circuits prescribed by the State: in markets, in shops, door to door, at home, in public transport hubs, etc. We encounter these categories of actors throughout the book.

13. The Druglane sector of the Okaishie market in Accra specializes in the sale of medicines and acts as the center of pharmaceutical wholesale distribution in Ghana. It consists of seven private buildings that are home to more than a hundred companies that invest in the medicines trade (Baxerres, 2018). Carine Baxerres has an upcoming book about Ghanaian medicine traders, much of which will be dedicated to this sector of the Okaishie market.
14. This thesis is being jointly supervised by the University of Abomey-Calavi in Benin and the Ecole des Hautes Etudes en Sciences Sociales (EHESS) in Paris, France. It is entitled "Pharmaceutical representatives and their activities in Benin. Contribution to the study of the social construction of drug markets in Africa" and will be defended in 2021.
15. By family, we mean people who live in a residential unit and share meals that have been prepared or purchased for all of them.
16. The categories of actors involved in drug distribution in Cambodia, according to the current laws, differ from those working in Benin and Ghana. Drug warehouses operating in Cambodia are run by health professionals (assistant pharmacists or retired doctors, nurses, or midwives) and are found in both rural and urban areas. Informal vendors work in unregistered pharmacies, in small grocery shops, or directly in the street. In local use, the term "pharmaceutical company" refers both to local medicine manufacturing firms and medicine import-export and distribution companies. Semi-wholesalers purchase their supply from "pharmaceutical companies," sell wholesale or retail, and have a pharmacy license. They are not authorized to import. Sometimes they run an import company alongside their pharmacy.
17. 3 living on <USD 100 per month, 10 on USD 100–400 per month, 8 on USD 400–2000 per month, and 3 on >USD 2000 per month.
18. Tu Youyou, discoverer of artemisinin; Zhou Yiqing, inventor of the artemether and lumefantrine combination; Li Guoqiao, inventor of the dihydroartemisinin and piperazine combination; as well as Jianfang's (2013) book.
19. R&D: this abbreviation refers here to the research and development activities for commercial drug specialties performed within pharmaceutical companies or in smaller organizations (university laboratories, start-ups, etc.).
20. This book will also be published in French, and the preface of that volume will be written by a major pharmacy actor in Benin.
21. The city of Accra is composed of numerous dissimilar neighborhoods (some quite posh, others very working class). Because it is much larger than Cotonou, working across the entire city would have required stratifying the neighborhoods. We chose to focus on the Madina neighborhood because its working- and middle-class population is closest to that of Cotonou, which we studied in Benin.
22. Here we use the same definition of family as in the qualitative studies, i.e., a unit of residence and shared meals.
23. An adult responsible for the family who was present at the time of the interviewers' visit and who was able to answer questions about family characteristics and health care practices. In most cases this was the mother.
24. We created this "health notion" in social epidemiology for the purposes of this study. The idea was to ask families about broader issues than just the "health problems" defined by biomedicine. By using the term "health event," we can include all the reasons why people use medication.

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