3 Distribution and access to medicines

Role of the pharmacist monopoly

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Introduction

The States of the world, whether in the "North" or the "South," use a variety of mechanisms to regulate pharmaceutical distribution, chosen at different points in history for various reasons. These mechanisms are built around the issue of the pharmacist's monopoly, granted by the State, and the scope of this monopoly, which varies by country.

France is the emblematic example of a country where this monopoly is most broadly applied (Fouassier, 2017).[1] The monopoly of French pharmacists is an ancient institution that gradually formed between the 11th and 18th centuries (Leca, Maurain, Moine-Dupuis, & Rousset, 2017) and was established by the "Germinal law" under Napoleon Bonaparte on 21 Germinal year XI (1803), even before the advent of industrial drug production. This monopoly was granted to pharmacists in exchange for their incorporation as a true profession, one requiring competence guaranteed by a diploma (Guerriaud, 2017). The French pharmacy sector was built up over the 20th century through the consolidation of the pharmacist profession (Van den Brink, 2017). Development was very different in the United Kingdom, where this sector was formed by the market using the free trade model. Stuart Anderson (2005) notes that, through the Pharmacy Act of 1868, "the emphasis on 'trade' as opposed to dispensing activities was maintained" (p. 79). The English retail distribution model is now described as "based on opening private pharmacies' capital and an economic approach to the profession. (…). Opening the capital of private pharmacies should increase competitiveness and promote lower prices, since economic interests are at the forefront" (Debarge, 2011, p. 202).

This monopoly can be applied to various aspects of pharmacy practice. It may be a professional monopoly, i.e., access to the profession in which only pharmacists can manufacture and/or distribute medicines. It may be a retail sales monopoly, i.e., a dispensing monopoly in which retail drugs may only be sold in pharmacies. Finally, it may be a monopoly of ownership in which only pharmacists can own an establishment in which pharmacy-related activity is practiced, be this the manufacture and/or wholesale and/or retail distribution of a drug (Leca et al., 2017). In France, only pharmacists may prepare medicines for human

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use, regardless of context—industrial, compounding, hospital, or dispensary—and engage in wholesale or retail sales of medicines. In return for this monopoly, pharmacists have an obligation to perform their public health missions. "One of the most important considerations is personal and exclusive practice: 'pharmacists who have a private pharmacy must personally practice their profession. (…). The same is true for managing pharmacists (along with their delegates and deputies) involved in bulk drug manufacturing or distribution'" (Guerriaud, 2017, pp. 24–25). Such personal practice is especially required for a private pharmacy, where the pharmacy owner cannot be engaged in any other activity. In addition, private pharmacists must provide the necessary information and advice for the proper use of the medicinal product. This point is another strong argument for justifying the monopoly in France, one repeated in the pharmacist's code of ethics. In France, one often hears that "medicines are unlike any other product, and as such require compliance with precautions for use or contraindications. (…). Whenever they feel it is necessary, pharmacists should encourage their patients to consult a qualified practitioner. (…). Thus, private pharmacists must yet again put the interests of public health before their own economic interests" (Guerriaud, 2017, p. 25).

But historians remind us that the French government granting this monopoly is part of a broader movement through which the State has, since the French Revolution, maintained a privileged and protective relationship with the legal, medical, and pharmaceutical professions, known as the liberal professions.[2] According to Jean-Paul Gaudillière, "in this system of professions, the status of medicines was initially intended to defend the monopoly in drug preparation and sales granted to degreed pharmacists on the basis of their scientific skills" (Gaudillière, 2005, p. 133). Thus, restricting actions to pharmacists alone also guarantees them an economic monopoly, "by defending access to the profession and exclusive sales" (Guerriaud, 2017, p. 12). Pharmacists are not only health professionals; they also have "commercial status or practice their profession within a commercial enterprise." They nearly always perform "commercial acts remunerated by a mark-up that is also commercial in nature" (Fouassier, 2017, p. 52).

The current debates on the pharmaceutical monopoly in Europe are especially polarizing. Proponents and opponents of the monopoly regularly inveigh against each other, one side propounding the demands of public health and the other the primacy of economic freedom and competition between economic actors. It is frequently noted, particularly in France, that this monopoly maximizes the ability to fulfill public health requirements. It is "a remarkable tool in the service of safeguarding health security" (Guerriaud, 2017, p. 11). This is something that British and American pharmacy experts generally disagree on. In this chapter, we examine this monopoly and the consequences of the different ways it is applied to retail and wholesale distribution in Benin and Ghana as a result of the institutional and legal legacies of their former colonial powers.[3]

Legislative differences in pharmaceutical distribution

Pharmacies, pharmaceutical warehouses, and over-the-counter medicine sellers

In Benin, as in France, the pharmacist's monopoly prevails. It was established by Order no. 73-38 of April 21, 1973, establishing and organizing the Ordre national des pharmaciens or National Order of Pharmacists.[4] Private pharmacy is defined as "a health facility opened and managed by an owner-pharmacist," dedicated to dispensing prescriptions and preparing medicines and pharmaceutical products. Retail medicines in Benin can only be legally distributed in these private pharmacies.[5] As in French law, a licensed pharmacist must be registered with the Order of Pharmacists and may only own one pharmacy. In 2015, there were 243 private pharmacies in operation in the country,[6] which are authorized to sell all drugs registered in Benin.[7]

In Ghana, two types of licenses are granted for the retail sale of pharmaceuticals. One is the general license for pharmacies managed by a qualified pharmacist who is registered with the Pharmacy Council, but who may be an employee and not necessarily the owner.[8] The other is the limited license granted to "over-the-counter (OTC) medicine shops," commonly known as "chemical shops," which are managed by non-pharmacists with a minimum academic level (Middle School Leaving Certificate[9]) who must attend mandatory post-registration training sessions on a regular basis.[10] Shops are inspected by Pharmacy Council agents and must comply with certain conditions, such as space and ventilation, before obtaining authorization.[11] Unlike pharmacies, the OTC medicine sales license is granted for an individual who operates a single store.

Figure 3.1 OTC medicine shop in Accra.

Source: © IRD/Carine Baxerres, mai 2015

There were 2175 pharmacies and 10,424 OTC medicine shops in Ghana in 2015.[12] Ghanaian pharmacies are allowed to sell all Food and Drugs Authority (FDA) categories of pharmaceuticals, i.e., prescription-only medicines (also known as Class A drugs), those pharmacists can recommend based on their scientific expertise (pharmacy-only medicines, called Class B drugs), and OTC medicines (Class C drugs).[13] The only drugs permitted to be sold in OTC medicine shops are those designated as Class C by the authorities, including some public health program products such as antimalarials or contraceptives. Antibiotics are not officially to be sold in these stores, with the exception of cotrimoxazole.

In Benin, although the status of OTC medicines is not recognized, since 1975 there have been private pharmaceutical warehouses in rural areas, the owners of which do not have a degree in pharmacy; they must have an education at least equivalent to the Certificate of Primary Studies and receive "appropriate training" when they first open (Article 1, Decree no. 2000-410 of August 17, 2000). These shops are authorized to sell essential medicines from a limited list[14] and were established to expand pharmacy services in the country. However, they are subject to strict legislation that, in our opinion, impedes their development.[15] In keeping with the pharmacist's monopoly, these facilities are under a pharmacist's supervision and shut down if a pharmacy opens within a 10-km radius. Warehouse owners must obtain their supplies from a private pharmacist. Products must be sold at the retail price even though they are purchased at a pre-established margin from the pharmacists, who sell them to the warehouse at a price marked up from the wholesale prices they paid. This category is therefore both underdeveloped and shrinking in Benin: there were 279 such facilities in 2006, 250 in 2007, 179 in 2013, and only 165 in 2018.[16]

Pharmacies are not equitably distributed throughout either Ghana or Benin, but instead are concentrated in urban areas. In Benin, 97 of the 243 pharmacies operating in 2015 were in the economic capital (Cotonou), 29 were in the adjacent cities to the west (Godomey and Abomey-Calavi), and 33 were in the administrative capital (Porto-Novo) located 42 km northeast of Cotonou, meaning all were located in cities and the southern part of the country. In Ghana, 1323 of the country's 2175 pharmacies operating in 2015 were located in the Greater Accra area. In Accra itself, our field surveys showed that pharmacies were mainly found in the city's most exclusive districts (Agblevor, 2016). The semirural area where we worked in this country, Breman Asikuma in the Central Region, had no pharmacies at all. The semirural area where we conducted our surveys in Benin, in the Mono department, had one pharmacy at that time, in the city of Comé.

Retail distribution in these two countries thus differs significantly. What about wholesale distribution?

Wholesaler-distributors versus private wholesalers

The legislation governing private wholesaler operations in Benin and Ghana is radically different. In Benin, wholesalers are considered full public service actors

and legislation significantly limits their activity, whereas in Ghana, they have much greater leeway in how they conduct business.

In France, pharmaceutical wholesaler practices were codified and the profession of "wholesaler-distributor" was recognized by legislation in 1962 with the introduction of social security. The expansion of social security to include the costs of treatment required stronger regulation by the State, which sought to more effectively control product costs (Chauveau, 2005).[17] Drug prices and distributor profit margins also began to be established at that time (Lanore, 2008; Le Guisquet & Lorenzi, 2001). Prior to that, when the first pharmaceutical distribution companies appeared at the end of the 19th century, they freely advertised their services and engaged in unbridled competition (Chauveau, 2005; Faure, 2005; Sueur, 2018). In Benin, although the country had only recently gained independence when the French legislation on wholesaler-distributors was introduced and the country had no universal system for covering health expenses,[18] very similar regulation was adopted specific to pharmaceutical distribution. The first wholesalers set up their businesses in Benin in the 1980s before there was any specific legislation for that industry (see Chapter 2); provisions were later ratified by Decree no. 2000-450 of September 11, 2000, implementing Act no. 97-020 of June 11, 1997. These provisions stipulate that "wholesale distribution companies" are a "pharmaceutical and wholesale establishment for medicines and wound-care products opened and managed by a pharmacist (…) of Beninese nationality engaged exclusively in this activity." The company must be "owned by a pharmacist or a company whose general management is provided by a pharmacist. The chairperson and the majority of the members of the board of directors must be pharmacists." As in French legislation (Lomba, 2014), these companies have binding public service obligations. They must "carry an assortment of pharmaceuticals representing at least nine-tenths (9/10) of those authorized in Benin," which they import. Each must also "carry stock, at all times and at a minimum, covering three months of typical customer use." In addition, "the sales prices charged for medicines registered in the Republic of Benin by a wholesaler-distributor company to retail pharmacists or public health facilities are fixed by decree adopted by the Council of Ministers." Therefore, as public health actors, these companies are not in competition with each other through their products or their prices.[19] They cannot legally invest in promoting medicines, nor can they engage in retail sales. Because of these binding obligations, at the time of our research study, five players shared the private pharmaceutical market.

Completely different legislation governs private wholesalers operating in Ghana. These laws provide the actors who invest capital in this domain with significant room for maneuvering. Again, as noted previously regarding pharmacies, these individuals may or may not be pharmacists. Those who are not are required to employ a registered pharmacist (see Act no. 489 and Act no. 857). They do not sell all the medicines authorized in the country; some only distribute a single product or drugs manufactured by a single pharmaceutical company. These factors explain why there are so many: 576 were operating in the country at the end of 2013, only a small portion of whom (38 companies) had multiple branches in

Figure 3.2 Inside one of the seven private buildings of the Okaishie market where the wholesale distribution of medicines takes place.

Source: © IRD/Carine Baxerres, août 2014

different parts of the country.[20] Most of these companies (377) were both wholesalers and retailers, and 199 were wholesalers only. A significant proportion of them imported drugs after registering with Ghana's FDA.[21] Many were located in the so-called drug lane section of the Okaishie market in Accra (see Figure 3.2 above).

Unlike their Beninese counterparts, private wholesalers in Ghana promote the medicines they distribute, especially when they import the products as well. Depending on their company's capital and number of employees, owners either hire "sales reps" or "medical reps" or handle promotion themselves (see the section in Chapter 9 on this subject). Another major difference in pharmaceutical distribution between the two countries is that drug prices and wholesaler and retailer distributor profit margins are freely set by the market in Ghana, whereas they are set by public authorities in Benin, as we noted earlier.[22] In Ghana, therefore, private wholesalers compete on the basis of both price and products.

The legislative elements described earlier show that, for both wholesale and retail distribution, the pharmacist's monopoly is very strong in Benin but quite limited in Ghana, similar to what Aurélie Mahalatchimy (2017) notes for the United Kingdom. What consequences can we demonstrate when the pharmacist's monopoly is applied so differently?

Consequences for pharmacy practice

Rather than presenting an exhaustive review of all current pharmacy practices in Benin and Ghana, in this section, we will examine only those aspects that best illustrate the consequences of how the pharmacist monopoly is applied in the two countries. We could have described some of the informal practices in pharmacies and pharmaceutical depots in Benin, such as the sale of drugs without a prescription, but these have been discussed elsewhere for Benin (Anago, Djralah, Kpatchavi, & Baxerres, 2016) and other countries (Kamat & Nichter, 1998; Van Der Geest, 1987).

A large informal drug market in Benin[23]

The below figure (see Figure 3.3) summarizes the information presented earlier, clearly highlighting one of the major consequences of these legislative differences (in bold). Ghana's population and size are more than double that of Benin, but that does not explain the disproportionate number of legal retail pharmaceutical distribution structures in the two countries. While Ghana had 2175 private pharmacies in 2015, Benin had a mere 243. More than 10,000 (10,324) OTC medicine shops were operating that year in Ghana, compared to 179 pharmaceutical depots in 2013 in Benin. Admittedly, private pharmacies in Ghana, like wholesalers operating in that country, do not distribute most authorized medicines, so the profile of these structures differs between the two countries. Nevertheless, it is clear that the gap left by official distribution structures in Benin is filled by a large informal market for medicines.[24]

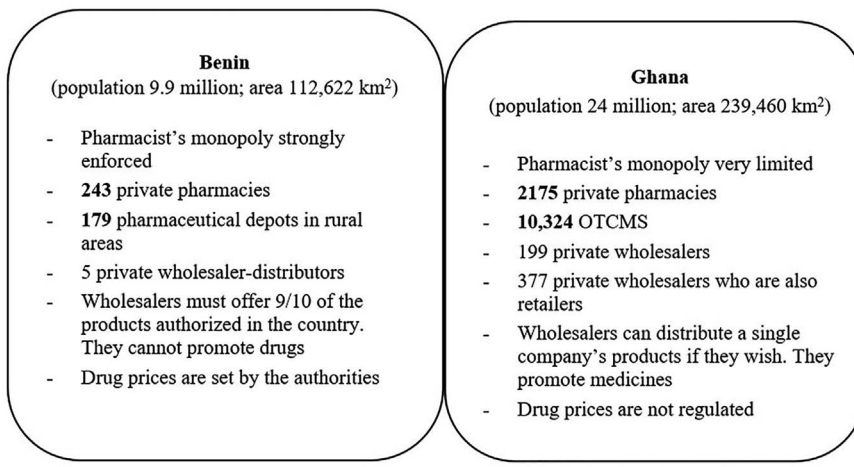

Figure 3.3 Summary of formal pharmaceutical distribution data in Benin and Ghana.

Source: Pharmacy Council Ghana 2015, DPMED Benin 2013 (2015 population figures)

We did observe informal itinerant sellers in the Accra city center, who generally sold medicines they had just purchased from private wholesalers in the surrounding area.[25] In rural areas around Breman Asikuma, we met some street vendors, several of whom were in fact associated with a local OTC medicine seller and, as such, peddled medicines to the most remote villages and hamlets.[26] During an observation of an OTC medicine shop in a rural area, one of these vendors, who had come to obtain supplies, explained: "I have been in the drug business for about 10 years now. I started with one man whom I peddled with, but now that man owns a chemical shop. But me, I haven't been able to establish my own" (field diary, June 10, 2015). Several OTC medicine shop owners we interviewed in rural areas had been street vendors in the 1980s, 1990s, and even 2000s. We also observed informal itinerant vendors on public transport, particularly inter-municipal or interregional buses.[27] The foregoing is not to deny the presence of an informal drug market in Ghana but to emphasize that that market has nothing in common with the one we have been studying since the mid-2000s in Benin. From the most remote villages of Ghana to the densely populated working-class neighborhoods and even shantytowns, OTC medicine shops with a Pharmacy Council authorization can be found absolutely everywhere in the country.

The informal market in Benin was highly developed at the time we conducted our research. A previous study we conducted in Cotonou with retailers as well as with the wholesalers in the sprawling Dantokpá market (Baxerres, 2013) focused on describing the gradual emergence of this informal market in the early 1950s, how it functioned, and the role it played for the city's residents, primarily as a distribution outlet. Some 4–6 years later, not much had changed. The quantitative survey we conducted among nearly 600 households on access to health care in Cotonou revealed that when pharmaceutical drugs are needed, 26% of respondents said they had used informal (generally female) vendors even though they preferentially obtain supplies from official pharmacies (65%).[28] As we had observed previously, such vendors were omnipresent in the city, in a variety of forms: in shops and stalls, as roving street vendors, set up along roadsides, and selling from homes or in neighborhood markets (Baxerres, 2013) as well as near construction sites (Kpatchavi, 2012).

The reality of the informal market was significantly different in rural and semirural areas of the Mono department where we worked. Informal sellers were qualitatively more present, since formal distribution actors were much less represented than in urban areas. For example, in Lobogo, where we conducted a quantitative study of 580 households, people reported that they obtained their medications in almost equal proportions from the health center pharmacy (39%) as from informal vendors (35%). Only 23% of purchases were made from private pharmacies and warehouses. In addition, these saleswomen in rural settings appear to have quite a bit more influence on what their customers purchase than vendors in urban areas do. They advised their clients on what medicines to buy 30% of the time; in contrast, in Cotonou, this was true for less than 6% of purchases (Baxerres, 2013). This can be seen in an excerpt from an interview with a middle-class mother: "I said that my child had started a fever. She asked me what

fever, how long ago it started, and I told her three days. She asked what I had been doing at home for three days. I told her I was giving para [paracetamol] and other medicines, that's why I waited to see if there would be any improvement, but since there wasn't any, that's why I brought him. So she sold him the drugs (…), she said she was going to sell him the deworming and I said I already have some. (…). She sold me a lot… she sold me a lot of medicine that looks like para… she sold me a lot of medicines, including the malaria drug with the drawing of mosquitoes" (interview, January 4, 2015).

Apart from self-imposed rules and standards and the trade licenses that those who work in these locations pay to market management companies, these legions of informal sellers are not regulated by any institutional entity. Their activity is completely unregulated. According to Joseph Nyoagbe, then head of the Pharmacy Council of Ghana, the massive development of the informal drug

Figure 3.4 Stall of an informal saleswoman in semirural Benin.

Source: © IRD/Anani Agossou, février 2015

market in French-speaking West African countries can be explained by the fact that there is no system of private pharmaceutical distribution below the level of pharmacies in these countries[29] (interview conducted during a previous study in July 2007 in Accra). We will see in the next two sections that although Ghanaian pharmaceutical regulatory authorities exercise real control over pharmacy practices, informal practices in both retail and wholesale activities continue to flourish in that country as well.

Informal practices among Ghanaian retailers

Although all the OTC medicine shops operating in the locations we surveyed in Ghana are licensed by the Pharmacy Council, several of their practices fall outside the scope of the legislation presented earlier (Act no. 489 and Act no. 857).

First, the people who receive the license and participate in the continuing education are not necessarily the ones who actually work in the stores on a daily basis, something Pharmacy Council agents are not fooled by: "If you are doing the training (…) how would you be very sure that this man who is participating is actually sitting in the facility? (…). The majority of those people who have their names on the licenses are not there" (Pharmacy Council Head of Education and Training, Accra, June 3, 2016). In fact, many of these are family businesses involving multiple family members: husband, wife, children, including middle and high school students who work after school, and sometimes even more distant family members (such as an uncle, cousin, or nephew). Stores that are not family businesses generally see a succession of employees one after another, who may or may not work alongside the owner.[30] These employees are rarely "Medicine Counter Assistants,"[31] although this is more often the case in urban areas. More commonly they are referred to simply as "shop attendants." Another phenomenon occurs when the official owner dies or transfers their license, yet the license remains in their name and continues to be renewed for several years. Finally, some OTC medicine shop owners open multiple stores, using the identity of other people to obtain the authorization, which is not allowed.

We observed several OTC medicine shops, both rural and urban, engage in other unauthorized activities, delivering health-care services in addition to medicine distribution (offering injections, infusions, diagnostic microscope tests, occasionally even "hospitalization"), in a room either directly adjacent to the store or located nearby. Some open a drug sales business after retiring as a health worker (nurse, midwife), but this is not always the case. Surprisingly, although Ghanaian health authorities appear to have cracked down on the illegal practice of medicine—evidenced by the fact that our field studies show far fewer informal health structures or health workers even in semirural areas than in the less-regulated 1990s (Senah, 1997)—Pharmacy Council agents do not seem focused on curtailing the health-care practices of these OTC medicine shops (Arhinful, Sams, Kpatinvoh, & Baxerres, 2018). Also outside the legal framework of their activities, some OTC medicine shops act as wholesale supply outlets for their counterparts in the neighborhood and sometimes even for nearby public health facilities (health centers

and community-based health planning and services [CHPS] compounds),[32] particularly in rural or semirural areas where access to formal wholesalers is more difficult.

The biggest criticism leveled at OTC medicine shops is that they sell drugs from therapeutic classes well outside their legal purview. Antibiotics are undoubtedly of greatest concern, given the current more-than-critical issue of resistance. But other prescription drugs (Classes A and B) are also involved (to end pregnancy or treat anxiety, hypertension, diabetes, asthma, etc.).[33] In short, OTC medicine shops follow the law of supply and demand to sell what their customers want, think they need, and can afford.

Despite these criticisms, this system does have strong points. OTC medicine shops must account for their practices to Pharmacy Council inspectors, who are more numerous and more efficient than their Beninese counterparts.[34] An OTC medicine seller explained: "The Pharmacy Council does check on us. They don't give you the date that they are coming. It is impromptu. If they see an inappropriate item, they will take it. (…). Sometimes they could lock the shop and take the key to their office for a few days" (field diary, semirural area, July 24, 2015).[35] Ghanaian FDA inspectors are also supposed to inspect these businesses. In addition, OTC medicine shops distribute drugs purchased from authorized wholesalers. Finally, and we will come back to this in Chapter 10, OTC medicine shops play a key role in Ghana as first-line care providers—just as Beninese informal sellers do in rural areas—because of their very high geographical accessibility, their long business hours, and the close social proximity of their vendors (Agblevor, Missodey, Arhinful, & Baxerres, 2016).

Informal practices among Ghanaian wholesalers

However, in our opinion, the informal practices found among wholesalers in Ghana pose the greater risk to public health. These practices question the validity of the very weak application of the pharmacist monopoly in that country.

As we have seen, unlike Benin, a businessman or woman can open a wholesale company in Ghana and import medicines without being a pharmacist but must employ a pharmacist. Of the 25 wholesaler owners we interviewed, 9 were pharmacists. The other 16 either had no specific training (generally the case for the older owners) or had studied marketing, accounting, business, or administration; one had completed 3 years of science studies (chemistry, geology, botany). Quite often, when the owner is not a pharmacist, the "superintendent pharmacist," i.e., the person through whom the facility obtained its authorization to open, is not actually present or is only occasionally present at the wholesale facility. These individuals usually work in teaching positions, government departments, or for other pharmaceutical establishments. They often agreed, for a fee, to provide their license to obtain authorizations from the Pharmacy Council but are not regularly present in the stores, merely stopping by from time to time.

A wholesale company employee explained these business practices this way: "The pharmacists [in the two branches they have] don't come that often, maybe

once in a week or even at times once every month" (interview, Accra, September 19, 2015). An employee of another company stated: "Everyday he [the pharmacist] comes here, but he is working somewhere else as well, but every day he comes here" (interview, Accra, August 21, 2014). Again, another study participant told us: "We have a pharmacist. He doesn't come… he doesn't come here at all… we just pay him his money. He just comes for his money" (interview, Accra, November 30, 2015). This is especially true of small companies that would have real difficulty paying the salary of a full-time pharmacist.

The most influential companies on the market, which cannot afford to violate the law, do employ pharmacists who are permanently on site. But the fact that they are employees, and therefore subordinate to the owner, changes or at least influences the dynamic. Our observations showed that their activities are often limited to taking inventories of current or missing stock, or products that must be acquired at advantageous costs. As expressed by the then Pharmacy Council Head of Education and Training: "Sometimes I ask myself, if we are to actually enforce the laws on regulation, then the poor pharmacist will be finished, because there will be so many issues that the pharmacist cannot explain (…) you regulate the pharmacist…. Will the pharmacist be able to check the others? How? The pharmacist doesn't own the pharmacy. He is an employee" (interview, Accra, June 1, 2016).

What are the implications of this significant investment by non-pharmacists in the practice of wholesale pharmacy? First of all, wholesalers spend considerable time in the pharmacy sector in Ghana, through their sales representatives, maintaining their business relationships, promoting their products, and keeping abreast of market developments. This will be discussed in Chapter 9. In empirical observations, such activities, related to trade rather than pharmacy practice or health care, take a considerable amount of time. The extent of these commercial activities may be largely due to the fact that products are not sold at the same price everywhere and that wholesalers do not all sell the same products. Our field studies and interviews with wholesalers in Accra highlighted two types of significant informal dealings in addition to these relational (and not informal) activities.

First, their customers include three types of informal actors alongside those actually authorized to obtain supplies from wholesalers (pharmacies, OTC medicine shops, public and private health centers, other wholesalers). These include the few informal retailers mentioned earlier who resell drugs in Accra's city center. Second, informal wholesale vendors from French-speaking countries in the West African region (Benin, Burkina Faso, Côte d'Ivoire, Mali, Togo, etc.), as discussed earlier regarding Benin, represent an important clientele for wholesale companies in Ghana, especially those in the Okaishie market in Accra, both quantitatively (in terms of the number of vendors) and qualitatively (they buy a lot and pay cash). A feature of the Okaishie market is that it is able to accommodate this type of clientele. Finally, the third category of informal wholesale customers is the intermediaries or "independent sales reps" (for representatives), as they were called by an employee of a wholesale company (interview on June 4,

2016, Accra). These are individuals who do not have a formal authorization but who are involved in the pharmacy business by buying products from wholesalers, then reselling them to retailers or even private individuals who need them. They offer their clients extremely flexible services (delivering at very late hours, providing the desired products quickly, finding drugs that are out of stock or hard to access, etc.), which allows them to build up a clientele that prefers using them rather than wholesalers, despite the relatively higher cost. They also provide a service to wholesalers who, through them, can increase their customer base and thus their sales. They help promote products from importers, usually small companies who do not have sales representatives, and sometimes also work for larger wholesalers. These intermediaries take advantage of occasional drug shortages, seen as inevitable in the market, to sell products they had purchased earlier at a higher price during shortages, thus earning higher profits. Anyone can buy medicines from Ghana's numerous authorized wholesalers, especially in Okaishie.[36] Our observations also showed that, in practice, all customers, both formal and informal, can purchase medicines from any therapeutic category they want to from wholesalers. This was easily demonstrated by looking at how wholesale companies create invoices and how client files are compiled in the software: "A man came to buy 20 boxes of Tanzol [an anthelmintic]; for the customer's name, the young woman in charge of writing the invoice wrote 'cash'. She then explained to me that when customers do not come from a pharmacy or chemical shop and are only buying for themselves, they [the staff of the wholesale company] write 'cash'" (field diary, Accra, August 8, 2014).[37]

A second important observed informality is that despite existing inspection and control mechanisms and capacities of Ghana's FDA and Pharmacy Council (see Chapter 1), the fact that informal actors like "independent sales reps" can so easily engage in pharmaceutical distribution suggests that unauthorized products may also enter the system. This has been discussed several times in our research.[38] The work of regulatory authorities is further burdened by the presence of almost 600 formal wholesale companies involved in distributing pharmaceuticals within the country. In comparison, the pharmacist's monopoly and the specific status of "wholesaler-distributors" ensures greater product traceability in Benin's wholesale distribution operations, as noted previously (see Chapter 2).

According to many of our sources, various informalities described earlier are explained by the fact that businessmen and sometimes women run the companies, and therefore "put profit before practices" (interview with the pharmacist owner of a wholesale company, Accra, November 30, 2015) or that "it really is business, money, that determines everything here" (field journal, discussion with a pharmacist employed by a wholesale company, Accra, December 2, 2015). The head of the Pharmacy Council at the time said this about the wholesale companies based in Okaishie: "The philosophy of most of them who are running the business is profit, not practice. They are just trading. So anybody who walks in, they are just pushing commodities onto people. The necessary [things] that they have to do, they will not do… profit, profit, profit…" (interview, Accra, June 1, 2016).

Conclusion: Is the pharmacist's monopoly evolving?

In France, the pharmacist's monopoly and its various applications are challenged on a regular basis (Fouassier, 2017). Several official reports have been published on the subject in recent years.[39] The mass retail company E.Leclerc has been developing awareness campaigns for its customers since the mid-1980s and is trying to pressure public authorities into allowing it to distribute medicines.[40] Until very recently, the French health authorities, with support from the Order of Pharmacists, which is quite active in these issues (Brutus, Fleuret, & Guienne, 2017), have favored maintaining the monopoly as it exists. Instead, new health-care functions are being proposed for private pharmacists to clearly identify them as being on the public health side of the sector rather than the commercial side: patient support and treatment follow-up, integrating pharmacists into first-line care, and dispensing certain prescription-only drugs.[41] In Europe, in accordance with the principle of subsidiarity, the pharmaceutical monopoly falls within the competence of individual States, which must nevertheless comply with competition law and the principle of free movement of goods for supply. States can therefore no longer prohibit the online or mail order sales of medicinal products not subject to compulsory medical prescription, which is why this has been allowed in France since 2012.[42] The European Commission is generally opposed to monopolies in principle, although it recognizes pharmacists as true health professionals (Debarge, 2017). Accordingly, a trend toward partial liberalization of retail drug distribution seems to have been underway in Europe since the 2000s (Denmark in 2001, Norway in 2003, Portugal in 2005, Italy in 2006, and Sweden in 2009) (Leca et al., 2017).

Changes are also evolving in Benin and Ghana. In Benin, we have seen a kind of "conquest of rural areas" by pharmacists, at least in the south of the country. There has been a greater trend of pharmacists opening pharmacies in villages than in the past.

Figure 3.5 Banner announcing the upcoming opening of a pharmacy in a Benin village.

Source: © IRD/Carine Baxerres, avril 2014

Others set up pharmaceutical warehouses in rural areas and managed them remotely with the help of employees (pharmacy assistants who may or may not have been trained in private pharmacy schools).[43] This was particularly true for four pharmaceutical warehouses in our study area, two of which opened during our research. In Ghana, the coming years may also see a change in the very large number of wholesale companies. The legislation governing their activities is similar in some respects to that in effect in the United States and the United Kingdom (a company can be both a wholesaler and a retailer, there is no obligation to distribute all approved medicines, and activities are not reserved for pharmacists) (Baxerres, 2013; Mahalatchimy, 2017). As in Ghana, these UK and US economic actors are not subject to the binding public service requirements to which wholesaler-distributors in Benin and France are held. The difference is that the US and UK actors have experienced a concentration in the sector that has not yet occurred in Ghana. At the end of 2010, there were only three main actors in "wholesale" distribution, accounting for nearly 90% of deliveries, in both the United Kingdom and the United States (Baxerres, 2013). A similar shift in concentration could begin in Ghana, although we did not observe anything like that; as noted earlier, only a few companies have multiple branches. The one exception was an interview with the pharmacist owner of a wholesale company, who proposed a franchising model that he wanted to set up in the coming years to distribute his products.

Pragmatic changes formulated by the economic actors and regulators seem to be well underway in both Ghana and Benin to address some of the dysfunctions highlighted in this chapter. The results of the Globalmed program were presented to the Ministry of Health of Benin on February 21, 2017; when we suggested there should be a discussion of opening up the pharmacist's monopoly for retail distribution,[44] the Directorate of Pharmacy, Medicine, and Diagnostic Investigations (DPMED) Director General solemnly replied that as French speakers with the pharmaceutical values that accompany a pharmacist's francophone training, it was impossible for them to conceive of businesses such as the OTC medicine shops of Ghana.[45] However, he went on to say that the health authorities should as a matter of necessity ensure that the number of pharmaceutical depots were increased throughout Benin. The problems in Benin's pharmaceutical sector at the time of this writing do not allow us to study the prospects of that statement at this time. Nevertheless, it could be seen as a very sensible way of effectively opening up the retail pharmacist monopoly without appearing to actually alter it. For the Head of the Ghana Pharmacy Council at the time of our research, many of the informalities in pharmacy practice described earlier would be greatly reduced if pharmacists were actually at the head of wholesale companies: "Those who had money were mostly non-pharmacists. It is now that with some level of consciousness we are arousing the conscience of pharmacists, that they should either have the majority shares or set up their own altogether. So gradually it is shifting. (…). What we want to clamp down on is that all steps should be supervised by the pharmacist (…). Now if we are able to reverse this trend, so pharmacists stay longer and are supervising the activities, then it is presumed that access or

unlawful access or unauthorized access to these types of people and of medicines will be minimized" (interview with Joseph Nyoagbe, Accra, June 1, 2016).

Hybrid approaches like this, which would adapt how distribution functions in both countries, are necessary. They offer new ways to strike a balance between profession and capital, and between public health and commerce, gradually distancing themselves from colonial legacies. Above all, these approaches depend on the countries' regulatory capacities, which in Benin need to be significantly strengthened. These solutions to reconcile the disparate laws of various West African countries are also needed to implement the current initiatives to harmonize pharmaceutical regulation in this region.

Notes

1. Olivier Debarge (2011) classifies the States of the European Union into three categories of retail pharmaceutical distribution legislation: the deregulated model, which includes the United Kingdom; the strictly regulated model, which includes France; and the mixed model.
2. The liberal professions involve intellectual work, performed without any subordination between the person who conducts it and the person on whose behalf it is conducted, in accordance with codes of conduct, the remuneration of which is not intended to be commercial or speculative in nature. These professionals include notaries, architects, lawyers, doctors, and certified accountants. The liberal professions are exercised in a personal capacity, under the responsibility of the workers themselves, who are considered self-employed professionals.
3. See the Introduction of the book for more information on the data collection methodology.
4. Prior to 1973, Law no. 54-418 of 1954 made this monopoly applicable to all French colonies; see Book V of the French Public Health Code applied to the colonies.
5. Since the Bamako Initiative and beginning in 1988 in Benin, the government has been introducing the sale of medicines in public and private nonprofit health centers. Only "essential generic medicines" are eligible, mainly sold under their international nonproprietary name or INN (Decree no. 88-444 of November 18, 1988). In Ghana, medicines are also officially sold in public and private health centers.
6. List of Benin's private pharmacies, updated on September 7, 2015; Directorate of Pharmacy, Medicines, and Diagnostic Investigations (DPMED); Ministry of Health, Republic of Benin.
7. According to Ordinance no. 75-7 of January 27, 1975 on medicines in the then Dahomey, now Benin, medicines are classified by degree of harm into two main categories: nonhazardous products and poisonous substances. The latter are further classified as A (toxic), B (narcotic and psychotropic drugs), or C (dangerous). Although there is no legislation requiring pharmacies to stock all authorized drugs and there are some differences by geographic areas (neighborhood type, urban, semi-rural, rural), overall pharmacies distribute the same drugs at the same prices (sources: oral communication, DPMED, June 2016).
8. See the Ghana Pharmacy Act, 1994 (Act 489).
9. Now Junior High School Certificate.
10. See the Ghana Pharmacy Act of 1994 (Act 489), recently updated by the "Health and Professions Regulatory Bodies Act" (Act 857).
11. See the OTC medicine seller authorization conditions: http://www.pcghana.org/wp-content/uploads/2017/09/GUIDELINES-ON-APPLICATION-FOR-OTCMS-LICENCE-1.pdf, accessed April 2019.

12. Personal communication with Joseph Nyoagbe, Registrar of the Ghana Pharmacy Council, September 2015, Globalmed annual meeting: "Pharmacy practice development in Ghana: Tracing the evolution through education, practice and regulation."
13. See the list of medicines in each of these three categories: https://fdaghana.gov.gh/wp-content/uploads/2017/06/NEW-DRUG-CLASSIFICATION-LIST.pdf, accessed March 2019.
14. This is the national list of essential medicines established by the Ministry of Health for use in municipal health centers. This list provides for different drugs by health pyramid level (sources: DPMED oral communication, June 2016).
15. See Decree no. 2000-410 of August 17, 2000, implementing Act no. 97-020 of June 17, 1997, establishing the conditions for private medical and paramedical practice and for opening pharmaceutical warehouses in the Republic of Benin.
16. Source: DPMED.
17. It should be noted that, as stated in the introduction of the chapter, the pharmacy sector in the United Kingdom was created by the market using the free trade model, whereas a public health insurance system, the National Health Bill, had been established as early as 1911.
18. Currently, it is said that only 8.4% of individuals are covered, mainly civil servants or employees of large companies. Universal health coverage initiatives are not yet effective despite having been launched in 2011 (Deville, Fecher, & Poncelet, 2018).
19. Nevertheless, we saw in the previous chapter that competition between them manifests in other ways.
20. See the lists as of December 31, 2013, provided by the Pharmacy Council. Most of these 38 companies had two or three branches. The largest retailers had between four and nine branches. All the branches must be licensed by the Pharmacy Council and have a superintendent pharmacist.
21. A list provided by the FDA in 2016 shows 121 such importing companies. But this number may not be reliable, as field studies indicate it is low. FDA agents themselves noted there could be omissions due to malfunctions when extracting certain information from their database (Siamed – FDA database, developed by WHO) (sources: oral communication, August 2016).
22. The price of drugs reimbursed by Ghana's National Health Insurance, on the other hand, is set by that body (Arhinful, 2003).
23. As previously mentioned, after our field studies were conducted, the informal drug market saw unprecedented repression beginning in February 2017 under the first government of the President of the Republic of Benin, Patrice Talon, elected in April 2016. According to our information, informal sales and purchasing practices still exist, but we are not in a position to describe them.
24. By informal market, we mean drug sales and purchases that occur outside the legal and administrative frameworks imposed by the State and by a country's biomedical health system (Baxerres, 2013).
25. The vast majority of these vendors sold a few boxes of anthelmintics (albendazole and mebendazole), often marketed under different trade names; some sold laxatives or antifungal vaginal creams, and some also sold painkillers, antipyretics, or anti-inflammatories. More rarely, some vendors offered a much wider variety of drugs packaged in transparent containers to promote the contents.
26. Because cocoa farming is an important source of income in this region, camps are set up temporarily for several months during the cocoa tree maintenance and harvesting season. Other crops rely on camps during harvesting season (yam, cassava, plantain bananas).
27. These primarily involved manufactured herbal medicines (see Chapter 8).
28. The informal retail medicine trade along the West African coast is mainly performed by women, unlike countries in the Sahel region, for example.

29. Or that such distribution is too constrained, according to our analyses, as in the case of pharmaceutical warehouses.
30. During our research we saw examples of recently hired employees who did not know who the store owner was for several months, since the owner merely managed the business by telephone through the employee who had been working there the longest.
31. The schools that train Medicine Counter Assistants are private, numerous, and varied, particularly with regard to the content of their training, which generally lasts 6 months. With a few exceptions, many of these schools are criticized for the qualifications of their young graduates. A Pharmacy Council agent referred to them as a "gray area." We see this as comparable to the situation in Benin regarding schools that train pharmacy assistants and medical representatives (see Chapter 9).
32. This occurred when these health facilities and regional warehouses were out of stock and the purchasing process was faster through OTC medicine shops.
33. OTC medicine shop owners do not perceive the sale of antibiotics in their stores as a public health problem. At the time of our research, they had apparently not yet been made aware of the issue of antimicrobial resistance. More generally, their view on this subject is "if you decide to sell only over-the-counter drugs, then you end up selling nothing" (field diary, Accra, October 27, 2014).
34. In 2016, 83 people were employed full-time at the Pharmacy Council. Some had worked in its regional offices (two to four people per office). Ghana has 16 regions and at the time of our study, one final region was scheduled to have a Pharmacy Council office (interview with the Head of the Pharmacy Council, June 1, 2016). There are no pharmacist inspectors among DPMED staff in Benin (see Chapter 1).
35. The owner of this OTC medicine shop had to pay a substantial fine in order to reopen his business. We were told of several inspections and store closures. Of course, we also observed methods of circumventing inspections (closing the store following a telephone call warning of the inspectors' visit) or concealing products not supposed to be sold in stores.
36. In our view, this situation is facilitated by a legislative provision (described earlier) that allows companies to open in Ghana that are both wholesalers and retailers, which further simplifies the ability of an individual who does not have a pharmaceutical retailer's authorization to purchase medicines in that country. According to the Director of the Pharmacy Council, this provision has been obsolete in major cities since 1998 (confirmed with wholesalers). But since this expiration is not retroactive, many companies were still operating in this manner at the time of our research (377 at the end of 2013). However, the practice of selling to unauthorized buyers has also been observed among non-retail wholesalers.
37. Later in our observations, the staff of wholesalers in our ethnographic studies were instructed to stop registering customers under the name "cash" in the client software. Other practices were then used, such as giving a fictitious first name and combining it with the term "chemical," or using an employee's first name. During our observations at wholesaler premises, when a new customer was created in the client file, no legal documentation was requested from the customer regardless of whether or not a pharmacist was present.
38. These are medicines sold by wholesalers or independent sales reps that do not have a marketing authorization (MA) in Ghana but do have an MA in other countries, particularly Nigeria (a nearby English-speaking country with close relations to Ghana). It also appears that some drugs that are not yet approved but are in the FDA approval process, or others that are no longer approved, may be sold. Finally, there have been several instances regarding the questionable origins of certain drugs or diagnostic tests, particularly during stockouts of the products in question in the country. For example, during some observations it appeared to us that coun-

terfeit Coartem had been circulating; this was subsequently confirmed to us at the same time (mid-2015) by studies conducted with the FDA in the framework of the Globalmed research program.

39. Beigbeder C., 2007, *Le "Low Cost": Un levier pour le pouvoir d'achat [Low Cost: A purchasing power lever]*.; Rochefort R., 2008, *Un commerce pour la ville. Rapport au ministre du Logement et de la Ville [A Business for the city. Report to the Minister of Housing and Urban Affairs],* Doc.fr.; Attali J., 2008, *Rapport de la commission pour la libéralisation de la croissance française: 300 décisions pour changer la France [Report of the Commission for the Liberalization of French Growth: 300 decisions to change France],* Doc.fr.; *Rapport de l'Inspection Générale des Finances sur les professions non réglementées de 2013 [Report of the General Inspectorate of Finance on non-regulated professions in 2013]*; Competition Authority, Opinion no. 13-A-24 of 19 December 2013 on the functioning of competition in the distribution sector of medicinal products for human use in cities, p. 168.
40. These awareness campaigns, which were particularly active in 2008, 2009, and 2013, are available from E.Leclerc in the "History and Archives" section of its website: https://www.histoireetarchives.leclerc/photos/les-grandes-campagnes-de-communication/parapharmacie-et-pharamacie-les-campagnes-et-contre-campagnes, accessed February 2019.
41. See the July 21, 2009, law known as the HPST law (hospital, patients, health and territories) (Maurain, 2017), as well as National Assembly Amendment no. AS1487, presented by Mr. Mesnier on March 8, 2019. Great Britain is also experiencing this shift toward a new place for pharmacists in the health system (Mahalatchimy, 2017).
42. See Order no. 2012-1427 of December 19, 2012. The European Union has also recently restricted the scope of the French monopoly by removing products that were initially covered by it, such as pregnancy and ovulation tests or those for contact lens care and use (see Law no. 2014-344 on consumption adopted on March 17, 2014) (Debarge, 2017).
43. Which is legally possible (Article 9 of Order no. 13495 of December 28, 2006).
44. Proposals are regularly made by public health experts to institutionalize informal drug vendor activities (Goodman et al., 2007; Shah, Brieger, & Peters, 2011).
45. There are indeed divergent values in Europe and West Africa regarding the distribution of medicines: either the drug, whatever it may be, is perceived as a dangerous product that requires the supervision of a pharmacy professional (French and Beninese vision), or it is perceived as a basic necessity product that must be widely geographically accessible to potential patients (English vision, shared by a large part of Europe and in Ghana). Sweden is often reported as aligning with the French vision. After authorizing the sale of paracetamol in supermarkets in 2008, Sweden withdrew the authorization in 2015 because of the number of paracetamol-related poisonings, which had increased by 40% between 2009 and 2013 (Guerriaud, 2017).

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