Conclusion. Rationalizing drug markets in the Global South: re-making medicines essential

Maurice Cassier, Carine Baxerres

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Ever since medicines began to be considered not only commodities but also essential goods to protect populations, the question has been how to rationalize drug markets in the interest of public health. In this conclusion, we draw on our research and past experience to propose areas for reflection and tools for governing pharmaceutical markets that can be used by public authorities and civil society.

In the history of pharmaceutical policies, the purpose behind the idea of "rational" measures is to introduce therapeutic usefulness criteria to organize the market, reduce the proliferation of pharmaceuticals with no significant medical interest, and rely on evidence-based medicine rather than marketing to decide whether therapies are indispensable or a priority (Halfdan Mahler's report, April 3, 1975).[2] As early as the early 1960s, several governments in so-called "developing" countries (Ceylan, Peru, Colombia) drafted and applied restricted lists of "basic medicines" to organize accessibility to them and reduce market crowding (Greene, 2016; Garcia, 2020). India and Brazil, two Global South countries that are significant in pharmaceutical geopolitics, changed their industrial property laws in 1970 and 1971 respectively to authorize the growth of a generics market and to lower drug prices (Cassier, 2008). Several newly independent countries committed to policies of local pharmaceutical production—by private or in some cases public entities—to manufacture copies that cost less than trademarked drugs and to reduce their dependence on the supplies of such products; examples include India, Morocco, Egypt, Ghana, Tanzania, and others. In the late 1970s, the World Health Organization (WHO) developed a model list of essential medicines, which has been revised 20 times since 1977[3]—every two years—to help countries establish national lists adapted to their priority health needs. In 1997 the AIDS epidemic spurred South Africa to pass a law promoting the supply and use of generic drugs (Pelletan, 2019). Recent history is not lacking in mechanisms and experiments to develop and regulate pharmaceutical markets, with varying degrees of success and inclusiveness.

Jeremy Greene (2011) draws our attention to the plasticity of the concept of essential medicines and its circulation between the countries of the Global South and North. In our view, the essential nature of therapeutic agents has been redefined by several factors: a new geopolitics of medicines, improvements in the certification of generic drugs, the intervention of patients into intellectual property debates, the creation of regional common markets between South countries, the industrialization of traditional remedies, and new convergences between the North and the South on transparency in health product prices. This is evidenced by the geography of the signatories to the draft resolution adopted by the World Health Assembly in May 2019, entitled "Improving the transparency of markets for medicines, vaccines, and other health products," between the "Pharmerging" countries (South Africa, Brazil, India, Kenya, Egypt), and the countries of Southern and Eastern Europe (Italy, Spain, Greece, Portugal, Russian Federation) among others.[4]

[1] The second part of the title is inspired by the work of Jeremy Greene (2011), discussed in this chapter.
[2] WHO Archives Essential Drugs A28-11: Reports 1975–1990.
[3] "The selection of Essential Drugs," report from a WHO expert committee, 1977, 40 p. See https://apps.who.int/iris/handle/10665/41272?show=full, accessed November 2020.
[4] "Improving the transparency of markets for medicines, vaccines, and other health products." Draft resolution proposed by Andorra, Brazil, Egypt, Eswatini, Greece, India, Italy, Kenya, Luxembourg, Malaysia, Malta,

What follows is a summary of seven areas of reflection on policies and tools for regulating drug markets.

1) Using Essential Drug Lists

Short lists of "basic medicines" or "essential medicines" were designed as tools to rationalize pharmaceutical markets and drug use in a way that is beneficial to public health. It is useful to recall the WHO Director General's objectives before the 28th General Assembly of Health on April 3, 1975. One was for developing countries to boost the efficiency of their medicine expenditures, burdened by excessively high prices, to avoid selling medications that have been withdrawn from the market in their country of origin because they are dangerous or lack efficacy, or something many of us have since forgotten, "the export of expired products to developing countries not in a position to perform quality control." Other objectives were ensuring the availability of treatments whose production was halted because they were not considered sufficiently profitable, and ensuring that the essential drugs selected are available at "reasonable prices" (Halfdan Mahler's report, cited above).

The criteria for selecting medicines for inclusion in the Essential Medicines List (EML) are crucial here to govern the pharmaceutical market to benefit public health in terms of safety, therapeutic usefulness, and product accessibility. EMLs must be formulated using International Nonproprietary Names (INNs), provoking the wrath of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), which views this as a declaration of war against its brands. The principle of a limited list of 220 products in 1977—all in the public domain due to expired patents—is also denounced by industry actors who argue for the dynamics of markets and innovation.

For the WHO, the development and implementation of an EML adapted to health needs assumes that countries have a national pharmaceutical policy as well as the tools, institutions, and experts to select, import, potentially locally produce, and distribute these medicines. The WHO adopted an Action Programme on Essential Medicines in the late 1970s to assist countries with this task, and in 1978 that organization deployed a specific action in the "African region" that proposed African countries subscribe to the WHO quality system, train prescribers, and draft an initial list of 40 medicines to encourage pooled purchasing for the countries of the region (report of March 26, 1979, WHO archives).[5] In the 1990s, WHO economists would disseminate guidelines proposing centralized procurement, financing options for essential medicine purchasing either by creating an international fund or through the marketplace using the cost recovery system,[6] and conditions for local production (Dumoulin, Kaddar, & Velasquez, 1991).

African states generally adopted the EML in the 1980s, in the context of the economic crisis, the introduction of the Bamako Initiative's cost recovery system in 1987 (Blaise, Dujardin, de Béthune, & Vandenbergh, 1998), and contraction in public health expenditures. As Cassandra Y Klimeck and Georges Peters (1995), economists focused on pharmaceutical policy in Africa, have noted, "for this reason, the [essential medicines] system has become a symbol of scarcity for health care providers and inhabitants in some countries" (p. 49). EMLs then began to target obtaining cheaper supplies by using generic drugs. Ghana and Benin, like many

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Portugal, Russian Federation, Serbia, Slovenia, Spain, South Africa, Spain, Sri Lanka, Uganda. See https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_ACONF2Rev1-en.pdf, accessed November 2020.

[5] WHO Archives E19 445 3F J1 1979.

[6] The 1987 Bamako Initiative imposed user fees in sub-Saharan Africa to compensate for the lack of government funding (Dumoulin & Kaddar 1993; Ridde, 2005).

African countries, established EMLs in the late 1980s: 1987 in Benin and 1988 in Ghana. In the French-speaking countries of Africa, central purchasing offices for essential medicines were set up to obtain supplies of generics,[7] at which point we see the use of the category of "Essential Generic Medicines" (EGM) (Crozier, 2017). In these francophone countries, the devaluation of the CFA franc in 1994 accelerated the use of EGMs.

Picture ccl.1 – Benin and Ghana Essential Medicines List

Comparative studies of EMLs reveal variations from the WHO list. We find that essential medicines are selected in consideration of the country's current prescription practices, and that drugs recently added to the WHO EML (e.g., new hepatitis C antivirals) are adopted by fewer countries than those that had been on the list previously. Countries with lower national wealth also tend to omit more of the essential medicines on the WHO list (Persaud et al., 2019). A major change that occurred in the early 2000s in the WHO's selection of essential medicines is the listing of new patented therapies, including antiretrovirals (ARVs) for HIV/AIDS, which Médecins Sans Frontières (MSF) had been demanding. To what extent are EMLs in middle- and low-income countries likely to incorporate these patented essential medicines, with their much higher prices?

With regard to the registration of new therapeutic classes in the WHO EML, we found that Ghana and Benin have included almost all ARVs for HIV/AIDS and artemisinin-based combination therapies (ACTs) for malaria. However, the same is not true for the new molecules that have arrived since 2012 to fight drug-resistant tuberculosis: while Benin's list includes bedaquiline it does not include delamanid; Ghana's list does not include either one. Only a few of the new hepatitis C antivirals that have come on the market since 2014 and were quickly registered on the WHO EML appear on Benin's 2017 EML (two generics for sofosbuvir), but all are absent from Ghana's 2017 EML. Finally, new cancer compounds included on the WHO list are under-represented in both countries. These departures from the WHO list are partly explained by the funding options for these therapeutic classes: ARVs and ACTs (with ACT prices much lower than those of ARVs), are largely funded by the global donor market (Global Fund), while the new hepatitis C antivirals and new anti-cancer drugs are patented compounds that fall outside these markets and are thus largely inaccessible. The share of donor funding is lower for anti-TB drugs than it is for AIDS and malaria drugs, hence the greater price sensitivity of governments to these new molecules. Ghana's EML reminds us of the selection criteria it adopted: in addition to product safety and usefulness, it includes two economic criteria relating to cost: "the drug with the lowest cost, calculated on the basis of the whole course of treatment"; and local production, "the drug for which economically convenient manufacturing is available in the country."[8] EMLs are thus clearly embedded in countries' economies.

We report several limitations to the application of EMLs. Although creating such lists can help determine which drugs may be reimbursed by health coverage, their application is hampered by the limitations of such health coverage in low-income countries, even one like Ghana that has rolled out universal health coverage (Antwi, 2019). The share of government health spending is lower than direct household payments and has tended to stagnate or even

[7] The first purchasing centers were created in francophone countries (Benin, Burkina Faso, Chad, Mali, Niger, and Senegal). In 1996, they joined forces through the African Association of Central Medicine Stores for Generic Essential Drugs (ACAME), which today comprises 22 countries throughout West and Central Africa, the Indian Ocean, and the Maghreb, and whose number continues to grow (there were 19 members in 2010). They are still overwhelmingly French-speaking. See www.acame.net, accessed December 2020.

[8] EML, Ghana, seventh edition, 2017: https://www.moh.gov.gh/wp-content/uploads/2020/07/GHANA-EML-2017.pdf, accessed September 2020.

decrease in recent years. Households account for 40% of health spending in Ghana and 45% in Benin.[9]

In African countries, although cost recovery has reduced shortages (Dumoulin & Kaddar, 1993), economists and public health specialists have nonetheless pointed out the impact of this mechanism on social inequalities in health and the difficulty poor populations have accessing treatments (Klimeck & Peters, 1995; Ridde, 2005). The market logic that underpins cost recovery may also hinder the adoption of a limited list of essential drugs, since sellers prefer a wider range of products and those with higher margins (Dumoulin & Kaddar, 1993). High drug prices, especially for the new patented molecules on the WHO EML, are major barriers for populations. Even though sofosbuvir is listed on Benin's EML to treat hepatitis C, its price is still quite high despite the fact that the country is eligible to receive generics from the licenses distributed by Gilead to generics manufacturers for low-income countries.[10] In Ghana, experts are encouraging the government to procure generic versions of the drug (Tachi, 2018).

Under such conditions, specific intellectual property arrangements appear necessary so that generic forms of innovative essential medicines can be made available, while simultaneously extending international and national public funding and universal health coverage to acquire these products. For health coverage to be viable, action must be taken on drug prices.

2) Promoting local production

Local production has been an aspect of essential drug policy since the 1970s (Velasquez, 1991). As regards local production, a meeting between the WHO and the African region in Brazzaville in 1980 recommended inter-country or regional initiatives to avoid market fragmentation.[11] The creation of quality control laboratories was discussed in conjunction with local production, and a few countries, such as Burundi, Zaire, and Rwanda, requested technical assistance. The WHO handbook on the economics of essential drugs published in 1991 by Jérôme Dumoulin, Miloud Kaddar, and Germán Velasquez points out that although the impact on prices is unclear, local production will ensure a secure supply; however, they note that the establishment of local production must take into account the uncertainties of obtaining raw materials and machinery. The international pharmaceutical industry was very reticent about these initiatives to promote local industry: recall that it withdrew its investments from the African region in the 1990s in the context of structural adjustment policies that reduced markets (Peterson, 2014).

In this book, we studied the local production policy in Ghana immediately after independence that established manufacturing plants, turning to direct investment from foreign firms and negotiating technology transfer agreements (Pourraz, 2019). Some African states encouraged the establishment of a pharmaceutical industry using the public or private sector (Mackintosh, Banda, Tibandebage, & Wamae, 2016; Chorev, 2020). Through a study of the emergence of pharmaceutical production in three East African states—Kenya, Tanzania, and Uganda—Nitsan Chorev demonstrates that international development aid cannot replace State intervention to support markets (by reducing taxes on imports of raw materials, allowing a certain higher price margin for locally produced medicines in tenders, encouraging local

[9] WHO Global Health Expenditure Database: https://apps.who.int/nha/database, accessed September 2020.
[10] Chronic hepatitis C treatment expansion. Generic manufacturing for developing countries, Gilead Sciences, 2014: https://www.gilead.com/~/media/Files/pdfs/other/HCV%20Generic%20Agreement%20Fast%20Facts%20102214.pdf, accessed in September 2020.
[11] WHO archives E19 445 3F J1 1979.

manufacturers to produce essential drug kits) and to promote technological training and gradually raise manufacturing standards. International aid and government pharmaceutical policy must complement each other to create markets and organize technology transfer. Conversely, Jessica Pourraz (2019) described the failure of a dozen industrial projects in Benin due to the lack of a national policy geared towards local production. International aid can also produce adverse effects if local producers are unable to compete with Global Fund-subsidized drugs, as in the case of Ghanaian firms that produced ACTs in the early 2010s.

There is a debate about the value and viability of producing drugs locally versus importing them from the large manufacturing countries in the Global North or Asia that largely dominate the market. Economists and political actors alike[12] point to the high cost of capital in Africa (Chaudhuri, Mackintosh, & Mujinja, 2010), the shortage of industrial pharmacists, the near absence of bioequivalence laboratories to test generic drugs, the problem of harmonizing standards for drug certification and registration, and the fragmentation of markets. The COVID-19 crisis has revived discussions on local production in a context marked by disruptions in the supply of active ingredients and drugs from China and India.

Here we list five important elements to be considered in this debate.

First, in order to combine industrial policy and public health interests, prioritizing investments in the manufacture of medicines on the essential drug lists is key.[13]

Second, a viable pharmaceutical industry cannot be constructed without both a technological and a regulatory infrastructure. The priority must be on training a sufficient number of industrial pharmacists, creating bioequivalence laboratories for the region, and strengthening the staff and equipment of regulatory authorities.

Third, it is essential not only to create investment funds to finance the industry, as proposed in the Abidjan Declaration in 2019, but to drastically reduce the cost of capital to the extent of offering zero or even negative interest rate loans to encourage industrial investment (Cassier, 2018).

Fourth, West African countries do not seem to be taking advantage of the flexibilities offered by the World Trade Organization (WTO) to the least-developed countries to copy new therapies free of charge and free of patents. If these flexibilities were applied, by revising the Bangui agreements[14] for example, a window would open for local African production; note that Indian manufacturers have had to comply with pharmaceutical patents since 2005.

And finally, it is important to recall that the WHO's essential medicines policy included the use of traditional pharmacopoeia. The policies for certifying herbal mixtures as well as R&D projects to isolate new active substances should be extended (see Chapter 8 on Ghana's policy in this area).

3) Crafting standards for "essential" quality

[12] For example, see the "Abidjan Call for the Industrialization of West Africa into Poles of Excellence," in February 2019: http://lists.healthnet.org/archive/html/e-med/2019-02/msg00020.html, accessed September 2020.
[13] Here we may draw inspiration from the Product Development Partnerships encouraged by Brazil's Ministry of Health to produce a list of "strategic" drugs (Cassier & Correa, 2019).
[14] See the recommendations of the International Treatment Preparedness Coalition (ITPC): "Intellectual Property and Access to Medicines in Côte d'Ivoire, Senegal, and Nigeria," March 2019, Pauline Londeix and Fouad Boutamak, 60 pages. See http://itpcwa.org/uploads/fr/ressources/brochures/5cc2ff434f6ce.pdf, accessed November 2020.

The issue of substandard or falsified medicines (per the categories adopted by the WHO) or "counterfeit" and "fake medicines," has polarized public debate and the political scene since the early 2000s (Baxerres, 2015; Quet, 2018). Benin has been a singular site for this debate since the Call of Cotonou issued by French President Jacques Chirac in 2009. In her research on pharmaceutical markets in Nigeria, Kristin Peterson (2014) analyzed the abrupt change that took place under structural adjustment policies in the 1990s, namely the shift from a market dominated by trademarked drugs, sometimes produced by multinational firms that had set up shop locally, to a market dominated by generic drugs "of varying and often low quality" (p. 5), some of which the author states are sold on "unofficial" markets. Nitsan Chorev (2020) also notes that the liberalization of markets with structural adjustment policies has further enabled the arrival of "substandard" drugs. She reminds us that multinationals also used to sell substandard drugs in Africa.[15]

At the same time, Nitsan Chorev observes the implementation of more restrictive regulations in both manufacturing and importing countries. India's major pharmaceutical companies are using the WHO prequalification system (see Chapter 6) to guarantee the quality of the generic drugs they make to treat AIDS and malaria, raise their production standards, and dominate the global donor market.[16] "Second-tier" Indian firms are also improving their standards as those of importing countries rise. African manufacturers are benefiting from technology assistance programs to raise their production standards, and some firms, for example in Kenya, are succeeding in getting their ARVs prequalified. Others, such as Danadams in Ghana (Pourraz, 2019), may not be able to pursue the prequalification process to its conclusion, but even so are raising their manufacturing standards. Ghana's Food and Drugs Authority (FDA) decided in 2012 to establish a program to help local firms apply Good Manufacturing Practices (GMP) (see Chapter 1).

This raising of standards creates a hierarchy of firms and markets, with firms that achieve prequalification and thus access to the global donor market, i.e., the large Indian manufacturers, in one tier, and most African firms that have only national certifications so are confined to national or regional markets in another. As we saw in the first section of this book, there are also significant disparities between the regulatory means in African countries, e.g., between Ghana's FDA with 50 pharmacists in 2016, and the Directorate of Medicines of Benin, which had only 6, including 2 civil servants and 4 contract workers (Pourraz, 2019). Africa also has very few laboratories authorized to conduct bioequivalence testing, so firms must subcontract this work to the Middle East or India.

Improving the safety of generic drugs requires the widespread use of GMP and control testing for pharmaceutical equivalence and bioequivalence in drug copies. Bioequivalence has gradually become a "gold standard" in Mexico (Hayden, 2013) and Brazil (Correa, Cassier, & Loyola, 2019); Morocco, which targets exporting to sub-Saharan Africa, established its own laboratory in 2016. However, the cost to access this standard, in terms of clinical trials, represents a barrier for most African laboratories.[17] International technical assistance programs should be combined with national programs to help firms manage this transition. While a few firms are likely to obtain WHO prequalification to access an international market, the majority will supply domestic and regional health needs. In this context, gradual

[15] Cassandra Y. Klimeck and Georges Peters (1995) show that French firms sold medicines in Africa in the 1970s with fanciful and possibly dangerous indications.

[16] Indian companies account for two-thirds of WHO-prequalified drugs (Lantenois & Coriat, 2014).

[17] The Head of the Diseases Control and Prevention Departments of the Kenya Ministry of Health and Public Sanitation, Dr Willis Akhwale, stated "Kenya is also a country which grows and produces Artemisia and artemisinin but, due to the stringent WHO prequalification standards, is precluded from local manufacturer of 'pre-qualified' ACTs," Artemisinin Conference, 2013, Nairobi, Kenya.

compliance with GMP and certification of pharmaceutical equivalence as bioequivalence tests become more broadly used seems to be an acceptable route, particularly for generics included in the EMLs. Regional integration initiatives could facilitate this process.[18]

It is also appropriate to question the notion of "over-quality" raised by some experts. A pharmacist from a French company specializing in the preparation of drug registration dossiers in the United States and Europe and involved for several years in a WHO prequalification request for a factory in Tanzania wondered about this: "It is true that we sometimes have slightly divergent interpretations of the guidelines, and I am less accustomed to WHO prerequisites than the consultant who is a specialist in that, so we worked in tandem to be sure not to create over-quality in an African laboratory, because that is not the goal; the goal is for them to manufacture a drug, risk-free, but we don't want to create over-quality as we sometimes do in Europe; we must do something rational, but not be more royalist than the king, either" (interview, Bordeaux, July 2016). It therefore seems wise to question what is a "rational" or "essential" quality standard that improves the safety of essential generic drugs at a manageable cost.

Keep in mind that the over-quality mentioned by this expert is a strategy to create a barrier to market entry, one that benefits the most powerful firms and excludes manufacturers who cannot advance the required investments, as noted in the conclusion to Chapter 11.

4) Common markets and regional institutions

The regional dimension appears in the WHO essential medicines program as early as the beginning of the 1980s. At a meeting of the WHO African region, there was talk of creating quality control laboratories at the regional or subregional level.[19] In 2013, after analyzing the flow of drugs between Ghana, Nigeria, and Benin, we envisaged a reform of pharmaceutical regulation to harmonize marketing authorizations on a regional scale (Baxerres, 2013). Beginning in 2014, the Economic Community of West African States (ECOWAS) launched a Regional Pharmaceutical Plan (the ECOWAS Regional Pharmaceutical Plan or ERPP) that provides for the harmonization of pharmaceutical regulations, measures to support local production, and the creation of a regional bioequivalence center to be located in Ghana (Pourraz, 2019). In 2015, ECOWAS joined an initiative funded by the World Bank, the Gates and Clinton Foundations, and NEPAD (New Partnership for Africa's Development), which is being rolled out across eight African Economic Communities and was initially implemented in East Africa. NEPAD aims to harmonize drug regulatory practices through the African Medicines Regulatory Harmonization (AMRH) initiative, in particular the adoption of the autonomous agency model. Jessica Pourraz noted several difficulties involved in this harmonization process: between French- and English-speaking countries, between manufacturing and importing countries, and between the drug agency model and the Ministry of Health Pharmacy Directorate model, used until recently in Benin and Côte d'Ivoire (see Chapter 1). Francophone countries fear that the AMRH initiative will eclipse their own efforts

[18] Brazil has successfully gone down this path over a period of about 15 years by gradually harmonizing the standards for "similar" and "generic" products: in 1999, only generics had to show bioequivalence, through clinical trials (in vivo trials), while "similars" had to pass pharmaceutical equivalence tests in the laboratory (in vitro testing) to establish the structural similarity of the molecules and guarantee a qualitative and quantitative composition of active ingredient equivalent to that of the reference drug. In 2014, both types of copies had to satisfy bioequivalence tests (Correa et al., 2019). The certified generic copies are under an International Nonproprietary Name (INN) in Brazil, while the similar ones have a trademark.

[19] WHO Archives, E19 445 3F J1 1979 Africa.

at harmonization, under way since the mid-2000s within the West African Economic and Monetary Union (WAEMU).[20]

The ECOWAS harmonization initiative is based primarily on the use of a Common Technical Document (CTD) to register medicines in the region's 15 countries. ECOWAS plans to establish its own certification system to promote adoption of the new standard by firms in the region. This system, approved by the WHO, is aligned with international standards for manufacturing (GMP) and bioequivalence. The establishment of a regional regulation should boost industrial investment.

It should be noted that while proximity between assessors and industry is likely to promote the application of these standards, the cost of industrial and quality control investments to access them implies that a specific economic program be implemented to equip companies in order to overcome the standards barrier faced thus far by regional firms in terms of WHO prequalification. The number of companies that will be able to access regional and international markets, and the number that will be limited to certifications and strictly national markets, will depend on this support effort.

There is yet another difficulty: this process of harmonizing rules tends to favor countries with the most extensive regulatory mechanisms and the most modern firms, and highlights inter-regional disparities. The harmonization of regional market rules presupposes concomitant cooperation projects to determine the distribution of manufacturing or quality control and bioequivalence laboratories between countries, so as to create a degree of convergence between them. There is also the issue of distinguishing between a regional agency and the national registration bodies. These are classic problems faced by common or single markets. Boris Hauray's work on the process of harmonizing standards and procedures for marketing medicines in Europe prior to the creation of the European Medicines Agency, from the mid-1960s to the mid-1990s, showed the ambivalence and fluctuations in the positions of both States and firms regarding whether to stay with national agencies or to adopt more or less unified and centralized forms of registration procedures at the regional level (Hauray, 2007).

5) Pharmaceutical distribution: a dynamic balance of market offerings and professional control

Our research on pharmaceutical distribution in Benin and Ghana highlighted the asymmetry of market supply between the two countries. In Benin there were 243 community pharmacies in 2015 operating under the pharmacist-owner system, and 165 private pharmaceutical depots under non-pharmacist ownership but under the authority of a pharmacist. In Ghana, there were 2175 community pharmacies, where the managing pharmacist is not necessarily the owner, along with 10,424 over-the-counter (OTC) medicine shops, which are owned and managed by non-pharmacists who must attend post-registration training sessions (see Chapter 3). The asymmetry of supply is also very pronounced in the private wholesaler trade. Even accounting for the population and national wealth differences between the two countries, the disparity in pharmaceutical distribution is unmistakable, and explains the proliferation of the informal market in Benin. The asymmetry is attributable to the differences in pharmaceutical legislation: Benin applies the principle of the pharmacist's monopoly, part of its legal heritage from France, which requires the pharmacist to be the owner of the community dispensary or

[20] It should be noted that ECOWAS is made up of both anglophone and francophone countries (Ghana, Guinea, Liberia, Nigeria, Sierra Leone, Cape Verde, and The Gambia), which do not have the same industrial capacity and therefore carry different weight in the policies advocated, whereas WAEMU is overwhelmingly made up of francophone countries (Benin, Burkina Faso, Côte d'Ivoire, Mali, Niger, Senegal, Togo, and Guinea-Bissau).

wholesale company, which itself has public service obligations (a pharmacist must still closely supervise private pharmaceutical warehouses); whereas in Ghana, community pharmacies and private wholesalers are open to capital investment, consistent with that country's heritage of British law, a practice moderated by pharmacist control in the sale of prescription drugs in pharmacies and by the theoretically compulsory presence of a pharmacist at private wholesalers. The freedom to raise and mobilize capital for distribution in the two regimes is quite different.

At the end of our analysis of these issues, we consider solutions put forward by local actors to correct the imbalances that arise in each system. In Ghana, this would involve limiting market excesses in both the retail and wholesale sectors: OTC licensees or pharmacists in wholesale companies are present in a wide variety of sectors, despite inspections by regulatory authorities. The proposals aim to strengthen professional control, in particular by associating it with participation in the ownership of wholesale companies. In Benin the aim would be just the opposite: to liberalize retail distribution in order to attract more candidates to open pharmaceutical depots, whose numbers have been declining, and thus shift the boundary between the formal and the informal (the multitude of vendors). We believe liberalization of retail distribution—like what we find in Ghana—combined with a closer supervision of wholesale distribution—as is the case in Benin—would be an appealing prospect for taking advantage of the economic dynamics generated by the market while governing them to meet public health needs and local realities. This is not the path that was adopted in Cambodia, where the inverse is true: retail distribution is under a pharmacist's monopoly and wholesale distribution is liberalized.

The goal of these solutions is to offset market dynamics with management by the profession. Balancing the two is a delicate task. Requiring pharmacists to hold the majority of shares in a wholesale company, if not all of them, fortifies professional control but reduces sources of capital. In the first section of the book, we saw how pharmacists in some francophone countries (Benin, Côte d'Ivoire) have tried to get around this issue by organizing themselves into public limited liability companies or cooperatives. Note that in the 1960s French law also invented the figure of the "responsible pharmacist" in distribution and production companies in order to dissociate capital formation from professional control.[21]

Liberalizing the creation of private pharmaceutical depots in Benin in order to broaden supply in the countryside necessarily implies some form of oversight by regulatory authorities, which are sorely lacking in pharmacists. The State could also create incentives to encourage the establishment of pharmacies in rural areas. Other forms of regulation and education of informal vendors could also be considered, such as that attempted in Cambodia (see Chapter 4). We propose further strengthening the role of the health professions to counteract self-medication, which is significant in both countries' markets (Chapter 10).

6) Making room for consumers and civil society in pharmaceutical market regulation

Although this book analyzes the power of consumers through self-medication—Chapter 10 refers to "essential" management of health events by families—patients as civil society actors are not very present in our work. This is because we did not investigate HIV/AIDS drugs but focused on antimalarial drugs, and malaria patients are less organized as civil society actors

[21] The concept of "responsible pharmacist" appeared in France through statutes and decrees between 1961 and 1969, with Decree 69-13 of January 2, 1969, clearly establishing a dissociation of capital ownership and pharmaceutical responsibility (Ruffat, 1996; Fillion, 2013).

on the drug policy scene, despite some recent initiatives (Impact Santé Afrique, Civil Society For Malaria Elimination, AIDS Watch Africa).[22]

This is unlike the late 1990s, when patient associations played a major role in structuring the ARV market, and especially in promoting access to generics (Pelletan, 2019; Eboko & Mandjem, 2011). This was particularly the case in South Africa, Uganda, Kenya, and Côte d'Ivoire. Fred Eboko and Yves Paul Mandjem have characterized a plurality of associative models, self-organized by patients or created through initiatives by medical staff or international organizations. Their actions ranged from prevention and patient assistance, to medical staff support (Soriat, 2014), to demands for access to treatment. The South African association "Treatment Access Campaign" (TAC), created in South Africa in 1998, mobilized legal pressure to defend the South African law promoting generics in court, against multinational pharmaceutical companies and alongside the government, and then brought a lawsuit against the South African government that was slowing down the ARV deployment (Heywood 2009). In the end, TAC obtained voluntary licenses from multinational firms for patented molecules that allowed the manufacture of generics. Patient associations are potential partners in drug policy: in her dissertation on the pharmaceutical industry in South Africa, Charlotte Pelletan (2019) described a "health coalition" that involved the Ministry of Health, the generics industry, and patient associations.

In addition to their action on market dynamics and "logistics regimes," to use the expression of Mathieu Quet and his colleagues (2018), who discuss them (see Chapters 4, 7, 8, 10 and 11),[23] patient associations are likely to get engaged in access to essential medicines, pricing, and intellectual property. [24] They may be involved in the management of essential drug purchasing offices and national and international drug supply programs to monitor supply disruptions, similar to the South African associations that never hesitate to take legal action.

Recent initiatives aim to federate patient associations at the regional level, such as the Civil Society Institute for HIV and Health in West and Central Africa, created in 2018, which combines 81 associations.[25] This initiative is supported by the French public agency for technical cooperation, the 5% Initiative. It is a civil society organization mobilized by Global Health actions in support of the Global Fund. At the same time, federated patient associations may also be inclined to involvement in therapeutic activism to demand access to treatment.

Finally, associative movements are a place where the Global North and the South converge for access to treatment. ACT UP has cooperated with many associations in Africa (Broqua, 2018).

7) Pharmaceutical commons and markets

[22] See these organizations' websites: https://impactsante.org/; https://cs4me.org/; https://aidswatchafrica.net/strengthening-youth-leadership-and-engagement-in-the-fight-against-malaria-in-africa/; accessed November 2020.

[23] Mathieu Quet and his colleagues give the example of Southeast Asian patients who go to other countries, via "suitcase" imports, to find products that they cannot get at home because of national or international legislation (hepatitis C treatments, contraceptive or abortive pills).

[24] As an example see Médecins du Monde's campaign "Le prix de la vie [The price of life]": https://leprixdelavie.medecinsdumonde.org/fr-FR/ and the White Paper "Médicaments et progrès thérapeutique : Garantir l'accès, maîtriser les prix [Medicines and therapeutic progress: Guaranteeing access, controlling prices]": https://www.leslivresblancs.fr/livre/sante-medecine/medicaments/medicaments-et-progres-therapeutique-garantir-lacces-maitriser-les.

[25] See https://www.enda-sante.org/fr/content/expertise-france-sengage-aupres-de-linstitut-de-la-societe-civile-pour-le-vih-et-la-sante-en, accessed November 2020.

In 2016, the chief economist of the French Development Agency (AFD), Gaël Giraud, raised the concept of the commons to apply it to development economics: "A commons is a natural or cultural resource shared by a group, with precise rules of distribution, preservation, and promotion."[26] In the health sector, he mentions the drug pipeline for neglected diseases developed by the Drugs for Neglected Diseases initiative (DND*i*) Foundation (see Chapter 5).

If we apply the perspective of commons to medicines, they should be made into accessible, non-exclusive goods, whose technology must be shared in a collective framework, governed by well-defined communities of actors who ensure that they are extensively distributed, and if necessary, preserved from opportunistic appropriation (Cassier, 2017). They could be distributed free of charge through a public economy or by humanitarian nongovernmental organizations (NGOs), or on a non-exclusive market, at affordable prices and supported by mechanisms for pooling health expenditures that lead to universal access. Here we come back to four conditions that could support the "commons" features of medicines.

In one way, the criteria for selecting essential medicines take the chosen drugs out of the classic commodity framework. The priority is not the profit margin per treatment unit and unlimited market expansion through brands, marketing, and so forth, but rather the cost savings with an associated guarantee of safety and therapeutic efficacy. And this occurs in the context of a designation that, unlike a brand name, is not an exclusive intellectual right but instead and intentionally a common name. Recall that the essential medicines policy recommends caution with regard to pharmaceuticalization:[27] it is not about fostering unlimited growth in the market and consumption, merely introducing some order through limited lists.

We saw earlier that there is a barrier to the dissemination of essential drugs when they are patented (see the new therapies for AIDS, tuberculosis, cancer, hepatitis C, etc. that are listed in the WHO EML). In such cases, the WHO or NGOs propose sharing the patents and authorizing the production of generic drugs for low- and middle-income countries.[28] They also propose using the flexibilities of the WTO's TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreements to suspend these patents temporarily (the "compulsory license").

Chapter 5 returns to the notion of common property in relation to the invention and dissemination of ACTs. It concludes that putting the basic ACT molecules and the formulations developed by DND*i* (ASAQ, ASMQ)[29] in the common domain has helped overcome monopolies, allowed production to become dispersed, and resulted in affordable prices. That chapter also shows how technology sharing requires specific transfer investments to acquire the necessary industrial capacities.

The dissemination of medicines as common goods, accessible by and affordable for the population, also presupposes the extension of various forms of health expenditure pooling mechanisms: markets subsidized by global donors, public spending by States, universal health coverage, mutual health organizations (MHO), distribution by humanitarian NGOs, and so on.

Finally, we come back to a previous point: patient associations and humanitarian organizations can play a key role in defining and managing medicines as common goods, by

[26] "Les communs, un concept-clé pour l'avenir du développement [the commons, a key concept for the future of development]" Paris, October 25, 2016. See https://ideas4development.org/communs-developpement/, accessed November 2020.
[27] See the Introduction, where this concept is explained.
[28] See for example the Medicines Patent Pool created in 2010: https://medicinespatentpool.org, accessed November 2020.
[29] ASAQ stands for the combination artesunate-amodiaquine and ASMQ for artesunate-mefloquine.

demanding modifications to intellectual property rights, promoting the use of essential medicines (MSF), and participating in the actual conception of a drug's therapeutic use value, following the example of MSF and DND*i*. These, too, are actions towards drug market transparency as promoted by the WHO Declaration of May 2019, mentioned at the beginning of this conclusion, and conveyed by associations in the Global North, such as the Observatoire de la Transparence des Politiques du Médicament [Drug Policy Transparency Monitoring Center] in France (Londeix & Martin, 2019), and in the Global South, such as the ABIA Association in Brazil or I-MAK in the United States and India.[30]

The seven regulatory tools and powers that we have just laid out are largely interdependent: drawing up a list of essential medicines can guide a policy of local production and serve as a basis for setting up health coverage; strengthening drug agencies and quality control laboratories strengthens local production and monitoring of pharmaceutical supply and distribution networks; intervention by consumers and citizens is likely to promote the expansion of health coverage and price vigilance to make treatments accessible. These technical, financial, and political instruments and mechanisms could create market governance that is more favorable to public health, patients, and the populations to be protected, and a better balance between the drug's therapeutic use value and the market value. This contrasts with the waves of "commodification" that have occurred since the origin of the pharmaceutical industry, extensively explored in this book at currently at work today.

Picture ccl.2 – Pharmaceutical business in the Global South

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[30] ABIA, or Brazilian Interdisciplinary AIDS Association: http://gapwatch.org/; and I-Mak, Initiative for Medicine Access & Knowledge: https://www.i-mak.org/2018/04/26/tahir-amin-transparency-drug-pricing/

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