

## **Fake Drugs: Health, Wealth and Regulation in Nigeria**

By Gernot Klantschnig and Chieh Huang

**Abstract:** In recent years, international organisations have warned of the lethal trade in fake drugs particularly in Africa. This article assesses how and why fake pharmaceuticals have become a problem in Nigeria and how successful the state has been at regulating it, based on archival, official and interview data. While we show that the early roots of this trade can be found in colonial times, its expansion and growing policy concern were driven by crises in the Nigerian pharmaceutical industry and the healthcare system in the 1980s. In contrast to dominant explanations, we argue that the rise of fake drugs in Nigeria was closely linked to these national crises and related global trends towards market liberalisation and the commodification of health. In this unfavourable context, policies to regulate fake drugs remained limited as they only addressed the symptoms of a more fundamental political and economic problem: the shift from public health towards private wealth and profit-making.

Fake pharmaceutical drugs have recently become a major policy concern for international organisations. The World Health Organisation (WHO) set up a global programme on poor-quality drugs in 2006 and has focussed particularly on African countries (IMPACT, 2011). In 2010 the UN Office on Drugs and Crime (UNODC) followed suit and highlighted counterfeit drugs for the first time as a major threat in its *Global Crime Threat Assessment*, alongside cocaine trafficking, maritime piracy and human trafficking (UNODC 2010). Interpol also joined these efforts three years later by signing a pioneering agreement with pharmaceutical corporations to extend its campaign against so-called ‘pharmaceutical crime’ (Interpol 2014). Within these last fifteen years, the issue of fake pharmaceuticals has become a key concern for international health and law enforcement cooperation, as well as in national policy debates, especially in the global South.

Nigeria has been a key actor in these debates, spearheading the issue internationally. It has gained a reputation as a forerunner in the fight against ‘fake drugs’ and its main regulatory agency, the National Agency for Food and Drug Administration and Control (NAFDAC), has often been portrayed as a regulatory model by international organisations (OECD 2016; Nigeria News Agency 2013). It has also been a place where the problem of ‘fake drugs’ was particularly accentuated. Already in the 1990s, Nigerian drug exports were banned in neighbouring states due to quality concerns and during the early 2000s it was claimed that more than 60 percent of pharmaceuticals available in the country were fake (NAFDAC 2013). Widely reported scandals, such as the 1990 paracetamol poisoning and the 2009 *My Pikin* teething syrup poisoning have led to great concern among policy makers, the industry and the public (Alubo 2001; Punch 2009). Despite the immense policy concern, the rise of ‘fake drugs’ has not been sufficiently studied in Nigeria and, thus, this article examines how and why they became a problem from a historical and political economy perspective.

The literature has proposed several explanations for the rise of fake medicine in countries of the global South, however, they have mostly been speculative and few of them based on empirical research (OECD 2016). First, one of the most dominant explanations, especially in policy circles, has been that poor-quality drugs are widespread because users are poor and uneducated and thus do not appreciate the risks involved in consuming such drugs (Nigeria Ministry of Health 1989; Adjei and Ohene 2015; Warsi 2016). This rather simplistic demand or ‘need-driven’ thesis has been successfully refuted by ethnographic research, which has emphasised users’ agency and knowledge about potentially dangerous drugs (Van der Geest and Whyte 1988). A second major explanation has seen criminal or ‘greed-driven’ entrepreneurs behind the expansion of the ‘fake drug’ trade. NAFDAC has claimed that ‘drug barons [are] increasingly directing their resources into the less risky and more lucrative drug counterfeiting business – creating international syndicates and making drug counterfeiting more global, sophisticated and militarised’ (NAFDAC 2013, 4).<sup>1</sup> They essentially claim that organised criminals have taken control of this trade (IMPACT 2011; Interpol 2014; OECD 2016), although there is still little evidence for

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<sup>1</sup> Similar statements were made in interviews with Nigerian officials, for instance: Interview with Director General, NAFDAC, Abuja, 20 October 2010.

this as this article will show.<sup>2</sup> Third, it has also been argued that the state in the global South is too weak and unable to regulate the trade and especially the distribution of poor-quality drugs. State authorities are either out-manoeuvred by powerful and at times criminal entrepreneurs or the state is seen as too underfunded and inexperienced to regulate a highly complex sector such as pharmaceuticals. This slightly more evidence-based explanation has gained much support in international organisations, as well as in some academic studies on the topic (UNODC 2013; OECD 2016; Dukes, Braithwaite and Moloney 2015, 167-8). We will assess this argument in more detail in the context of the regulatory impact of the Nigerian state in this article.

In response to these existing explanations, this article places the often-unsubstantiated claims about the rise of ‘fake drugs’ into their historical and political context. Conceptually, the article builds on the few empirical studies available on the topic, in particular policy-driven and epidemiological studies on pharmaceuticals in West Africa (WHO 2005; Bate and Hess 2010; Newton et al 2012). A limitation of this policy literature is its technical approach to ‘fake drugs’, seeing these substances and their control within a political vacuum. To remedy this ‘depoliticisation’ (Ferguson 1996), the article draws on work by critical criminologists, who have explored the political dynamics behind the problematisation of certain social harms as well as the neglect of others (Braithwaite 1984; Dukes, Braithwaite and Moloney 2015; Hilyard and Tombs 2007). Such an approach is especially pertinent in the study of ‘fake drugs’ as the categorisations of ‘fake’ or ‘criminal’ are highly contested and fluid.

Furthermore, while much of the existing ethnographic work has been concerned with micro dynamics, in particular local drug use, we will draw on this work to provide insights into the functioning of informal drug markets (Van der Geest and Whyte 1988, Fassin 1985, Baxerres and Le Hesran 2011, Peterson 2014, Patterson 2014). A few of these works have also touched on the political nature of pharmaceutical markets and their control. For instance, Fassin and Patterson’s work on the pharmaceutical trade in Senegal has shown how the trade is firmly in the hands of the politically powerful Mouride Brotherhood (Fassin 1985; Patterson 2014). Our approach will similarly stress these political dynamics by historicising concerns about ‘fake drugs’ in Nigeria and state responses to them.

In order to historically reconstruct the trade and the politics of ‘fake drugs’, we have worked with a range of difficult to access data and settings. The main sources of data used were Nigerian state archives, government documents and news reports, as well as almost 100 interviews with individuals engaged in the semi-legal supply of pharmaceuticals and their control. This included interviews with manufacturers, importers, wholesalers, pharmacists as well as individuals involved in the regulation of drugs, who were able to provide insights that could not be gained from the scant documentary evidence. Interviews were conducted during four fieldtrips – in Lagos, Ibadan and Abuja – between 2010 and 2015, and they were also

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<sup>2</sup>A related, yet more evidence-based argument has been made by scholars of corporate crime, who have highlighted the criminogenic nature of the pharmaceutical industry more generally and beyond Africa (Braithwaite 1984; Dukes, Braithwaite and Moloney 2015).

supplemented with ethnographic observation in two of Nigeria's main pharmaceutical wholesale markets (Lagos, Idumota) and (Ibadan, Agbeni).<sup>3</sup>

Based on this conceptual and empirical framework, the article is structured as follows: To define the scope of the article, we will first scrutinise the meaning of 'fake drugs' and the wide range of terms adopted by different policy actors. In addition to the contested meanings of 'fake drugs', we will point out the methodological limits of available data and studies on Nigeria. After laying this groundwork, the article will trace the origins and evolution of the illegal trade in pharmaceuticals and how the debate on 'fake drugs' emerged. It will focus on the distribution and control of pharmaceuticals because this area has been largely ignored in existing research and also because the political dynamics of the trade in pharmaceuticals and 'fake drugs' have been most pronounced in this area.<sup>4</sup>

The article's argument is that the trade in 'fake drugs' has its historical roots in the unregulated colonial trade in pharmaceuticals, while the expansion and policy concern about 'fake drugs' were only triggered later by crises in the local healthcare system and the pharmaceutical industry. These crises were closely linked to global trends of market liberalisation and the commodification of health, which intensified in the 1980s. While the emergence of 'fake drugs' was driven by this complex set of domestic and global historical factors, Nigerian attempts to regulate 'fake drugs' remained limited in this unfavourable context. In fact, regulatory work on pharmaceuticals only addressed the symptoms of a more fundamental political and economic problem: the shift from public healthcare towards private wealth and profit-making.

### **Defining 'fake drugs'**

The potentially lethal effects of fake pharmaceutical drugs and their contribution to wider health and social problems, such as antimicrobial resistance to life-saving medicines, has been proven by criminological and medical research and is not in doubt (Dukes, Braithwaite and Moloney 2015; Interpol 2014; Newton et al 2006; Davies 2013). However, the definition of 'fake drugs' and the extent of their availability remain highly contested. There is a range of drugs that fall into the category of 'fake drugs' and conflation of these types of drugs and the problems associated with each of them has helped to contribute to the poor understanding in academic and policy circles. Various terms have been used to describe the problem: counterfeit, fake, falsified, fraudulent, substandard, expired, unregistered drugs etc.

On the global level there has until now been no common definition, in fact the terminology has had a tendency to become more diverse, the longer the issue has been debated. Governments in developing countries and in developed ones have found no common ground due to the contentious issue of intellectual property that is linked to these debates. For the opponents of the term 'counterfeit drugs', the focus has been

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<sup>3</sup> We also conducted fieldwork in Southern China in 2013 and 2014 on the sourcing of drugs for the Nigerian market. For more details on the Chinese dimension of the trade in pharmaceuticals and fake drugs, see Klantschnig (2014).

<sup>4</sup> For medical anthropologies dealing with the consumption of pharmaceuticals in African countries, see Van der Geest and Whyte (1988) and Whyte, Van Der Geest and Hardon (2002).

too often on drugs produced in contravention of patent laws – laws which have been designed to protect the interests of originator drug corporations in western countries (Dukes, Braithwaite and Moloney 2015, 228-253). For instance, the French pharmaceutical giant *Sanofi* – a corporation at the forefront of current efforts to combat ‘fake drugs’ in Africa – recently claimed: ‘In the case of drug counterfeiting, it can mean the difference between life and death for a patient’ (BBC News 2013). In contrast, the Indian government in defence of its growing generic drug industry has been the strongest opponent to the term ‘counterfeit’ and defining the problem as an intellectual property issue, as this could make the production of generic drugs potentially more difficult (UNODC 2010). International health NGOs dependent on the supply of cheap generics have been similarly opposed to this use of the term and its restrictive ideas on patents (Médecins Sans Frontières 2011).

International organisations have not been in agreement either. The WHO initially distinguished between *falsified drugs*, i.e. ‘deliberately and fraudulently mislabelled with respect to identity and/or source’ and *substandard drugs*, i.e. ‘genuine drug products which do not meet quality specifications’ (UNODC 2010, 184). In the case of both types of drugs, the WHO placed its emphasis on drugs’ adverse health effects rather than the politicised notion of intellectual property. In contrast, the UNODC, focuses on ‘fraudulent drugs’ – highlighting the criminal nature and intent of the individuals selling these drugs. More recently, the WHO has begun to promote the awkward consensus acronym SSSFC, i.e. substandard/spurious/falsely labelled/falsified/counterfeit medical products, which has only further highlighted the terminological disagreements and the conflicting political interests behind the different definitions (UNODC 2013).

In Nigerian official and media discourse there has also been a strong tendency to conflate different types of drugs. The Nigerian legal definition of fake and counterfeit drugs deviates significantly from the WHO’s, as it includes falsified and substandard drugs as well as substances that are not properly registered (WHO 2005). Thus, anything not registered by the state can be labelled ‘fake’, although the drug itself might not be of poor quality or harmful to the user. This broad legal definition also makes the notion of ‘fake drugs’ very negotiable and politically potent (Klantschnig 2014). In the last five years, for instance, the government has placed a stronger emphasis on deliberately and criminally falsified medicines, which has been in line with international initiatives by Interpol and the UNODC. But this emphasis was also for domestic political reasons, as it has helped to dramatise an otherwise hidden health problem and distract from the ineffective regulatory state, for which the availability of substandard drugs most often stands for.

In Nigeria as in the rest of Africa, negative health-related effects emanate from both falsified and substandard substances but the latter type of drugs has often been ignored. It is these two types of drugs that this article will concentrate on, but also make reference to related categories of expired, falsely labelled, degraded and unregistered drugs.<sup>5</sup>

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<sup>5</sup> We follow Paul Newton’s definition of these terms here: ‘falsified (fraudulently manufactured with fake packaging and usually no or a wrong active pharmaceutical ingredient); substandard (products resulting from poor manufacturing with no intent to deceive, usually with inadequate or too much active pharmaceutical ingredient); and degraded (good-quality drugs that are degraded by poor storage after leaving the factory)’ (Newton et al 2012, 488-489).

Furthermore, without an internationally and even domestically consistent definition of ‘fake drugs’ it has been difficult to estimate the actual availability of these substances and their health effects. Most existing official and independent studies have used different definitions, and some have been quite explicit about the inconsistency of terms and estimates available (WHO 2005, 7). This inconsistency across different organisations and even within has also meant that the data on the availability of ‘fake drugs’ is hardly ever comparable across time and statements about the effectiveness of government policy based on such data are highly dubious (NAFDAC 2013, 6).

Another methodological shortcoming of the available research on ‘fake drugs’ is that most studies conducted have been geographically restricted, for instance to one area of Lagos, and yet they attempt to make claims about the national market (Bate and Hess 2010; Newton et al. 2012). On the other hand, larger-scale studies with a more national approach, especially conducted by national control agencies, are much less clear on the methodology adopted and hence problematic (NAFDAC 2010, 6-7).

Due to the weak epidemiological evidence available on the topic, studies on the share of ‘fake drugs’ in Nigeria’s market should only be seen as indicative. The earliest larger-scale study commissioned by the Ministry of Health in 1988 found that more than 30 percent of chemically tested drugs were substandard and 4 percent of all samples were seen as dangerous to the user, as they contained wrong ingredients or were contaminated (Nigeria Ministry of Health 1989). In 2005 a WHO study found that 36 percent of drugs were substandard, whereas 17 percent of tested drugs were counterfeit, i.e. they had deliberately falsified packaging or contents (WHO 2005). Finally, in 2010 NAFDAC conducted the largest exercise in testing drug quality until today and found less than 7 percent of tested drugs were counterfeit or substandard. However, the failure rate for antimalarials was significantly higher at 20 percent (NAFDAC 2013, 6-7).

Overall, it is hard to ignore the methodological problems of studies on the availability of poor-quality drugs in Nigeria and beyond. While the numbers are ‘very poor’ (Jerven 2013), they still seem to tell a story of a reduction in ‘fake drugs’ in the market over the last ten years. In part, this reduction can be explained by the changing definitions for ‘fake drugs’ used – definitions that have become slightly more specific over time. Also, as more drugs have been registered by NAFDAC and fewer unregistered have been in circulation, the share of ‘fake drugs’ by definition was also destined to decline. Government control efforts have also played some role in the reduction of poor-quality drugs on the market, as this article will argue in its last part on regulation.

### **Origins of the unregulated trade in pharmaceuticals**

The article’s aim is to place these numbers and claims about ‘fake drugs’ and their control more fully into the historical and political context. Its first task must therefore be to challenge common assumptions in policy circles that the illegal trade in drugs and ‘fake drugs’ itself is ‘new’ (UNODC 2010; NAFDAC 2013, 4). The recent international policy concern is based on such ahistorical premises.

The history of pharmaceuticals in West Africa, their control and the emergence of poor-quality drugs have been written by pharmacists – a key profession in the regulation of these drugs. They have described a history of small-scale pharmaceutical imports for Europeans during pre-colonial and early colonial times and a slow expansion of the trade and pharmacy from the late nineteenth century onwards. Richard Bailey was the first African pharmacist to gain a licence to operate a chemist shop in Lagos in 1887 and only from the 1920s onwards did larger pharmaceutical stores open, such as Nigerian Medicine Stores and the West African Drug Company, which supplied missionary hospitals as well as chemist retail shops. Their numbers increased steadily and a new Pharmacy Ordinance was introduced at the end of the Second World War to register premises (Egboh 1982).

Among today's pharmacists, this pre-independence and early post-colonial period is seen as a time when pharmacists and government regulators were in control of the markets in pharmaceuticals, as well as drug quality. Nigeria's first comprehensive drug policy of 1990 described the colonial system as follows:

The central stores usually held sufficient stocks that could last for at least one year. The stocks were relinquished regularly and drug shortages in government hospitals were literally unknown. ... Within the private sector were a few expatriate companies, which engaged in wholesale pharmaceutical business only. They made regular supplies to the few indigenous pharmaceutical establishments which engaged in retail business. The retail outlets adhered strictly to the law and to the ethics of the profession .... (Nigeria Ministry of Health 1990).

In reality, this trade was never as law-abiding, especially not in colonial times. The colonial health and drug supply system was urban-based and focussed almost solely on Europeans and thus most Africans wanting western medicine had to get it through informal channels (Alubo 2001). In fact, colonial archives provide much evidence for the unregulated trade in medicine, particularly missionary stations that engaged in the first documented smuggling operations (NAI 1926). The government also had serious difficulties to issue licences to all the retailers of medicines. There were reports from various parts of the country in the 1940s about the widespread illegal sale of drugs (NAI 1946; NAI 1948 and 1951). One of them stated:

[T]here are innumerable market women and itinerant vendors selling small quantities of the common brands of medicine and to attempt to enforce a licensing system against such persons would require a special staff and inspectorate. ... It is at least open to doubt, moreover, whether the uncontrolled sale of harmless medicinal preparations in remote parts of Nigeria, where shops and stores are not easily accessible, is in any way harmful. On the contrary, it is arguable that the petty market trader selling such medicines is performing a useful function (NAI 1946).

Thus, as soon as the trade in pharmaceuticals was established, so was the illegal import and distribution of these drugs. Even colonial officials realised that this illegal system was to some degree necessary as the legal system provided little or no supply to the majority of Nigerians. Thus, the roots of the unregulated trade in drugs had its roots in colonial times. However, concerns about the quality of these illegally imported and distributed substances were yet uncommon and they only started to manifest themselves in the 1980s.

### **The rise of 'fake drugs' in the 1980s**

While the unregulated trade in drugs was the precursor for subsequent drug quality problems, the trigger for the growth in the availability and concern about poor quality medicines were two interlinked crises facing Nigerian health care and pharmaceutical manufacturing. Nigeria's healthcare system had expanded steadily from the late colonial period onwards. The 1960s saw the construction of several hospitals across the country and also a growing exposure of many Nigerians to a health system that had formerly been restricted to a small elite (Alubo 2001, 314). Despite the expansion of the medical facilities, hospitals could often not cope with the growing demand for their services. Medical equipment was insufficient and drug shortages became acute from the mid-1970s onwards, so doctors started to ask patients to purchase drugs outside hospitals (Sunday Punch 1976). A way to improve access to medicines was the expansion of the patent medicine dealer system first established in the late colonial period. Patent dealers were licensed to sell so-called first aid (over-the-counter) drugs in areas that hospitals and pharmacies did not cover, particularly in rural areas (Adenika 1998).

The real crisis of Nigerian healthcare began in the 1980s when structural adjustment programmes (SAPs) led to an abrupt reduction of public spending on healthcare and the devaluation of the currency made the import of drugs unsustainable (Olukoshi 1993). In order to make up for the loss of imported western drugs, improvised production of essential medicines became more common, for instance in-hospital mixing of paracetamol, which did not always adhere to strict quality controls (Alubo 2001, 99).

Local drug manufactures could have made up for the loss of imported drugs, however, they suffered similarly from SAP. While the domestic manufacture of pharmaceuticals had increased significantly in the late 1970s, companies still largely relied on imported raw materials, which now became expensive due to the currency devaluation. Western companies with a Nigerian plant started to divest heavily, until almost all of them had left by the mid-1990s. The surviving local manufacturers continued to operate at low capacity and the local industry has been in crisis ever since (Adenika 1998, 173-8; Peterson 2014). The industry's decline has also led to the lowering of standards and the more likely occurrence of poor quality products.

In this context of healthcare and industry crises, poor-quality drugs became more commonly available. The first more widely reported evidence of poor-quality drugs in Nigeria appeared in the late 1980s (Nigeria Ministry of Health 1989 11-2; Daily Times 1987; The Guardian 1987). The most high-profile case was the paracetamol poisoning of more than 100 children in Ibadan and Jos in 1990 that was due to a falsely labelled poisonous ingredient used in the drug's manufacture. The poisonous chemical was traced to one of Nigeria's major wholesale markets and its origin was said to be the Netherlands (Alubo 2001, 99-100).<sup>6</sup>

The 1990 paracetamol poisoning caused heated debates about the quality of drugs in Nigeria. This debate has been continued from the 1980s until today, in large part due to recurring cases of poisoning from drugs, such as another highly publicised

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<sup>6</sup> At the same time, there were also other reports about the importation of fake medicines, especially from European countries such as Italy (Nigeria Ministry of Health 1989, 12-3).

scandal involving a locally-produced substandard teething syrup, *My Pikin*, in 2008 and 2009 (Punch 2009; Leadership 2009; Punch 2009a). In most of these cases, Ministry of Health officials initially blamed the pharmaceutical industry for their unscrupulous and greed-driven behaviour, while the latter blamed the Ministry for its lack of regulation (Nigeria Ministry of Health 1989, 13-5). Eventually, the confrontation between the two camps was settled by blaming someone else. In the 1980s and also today, the root cause of the problem was said to be Nigeria's drug distribution system, particularly unregistered wholesalers and traders, as well as the unscrupulous importers of drugs among them (Nigeria Ministry of Health 1989, 61-2). However, the growing role of unregistered actors in the distribution of drugs was only the most visible aspect of two interlinked and much broader changes affecting the pharmaceutical market locally and globally: market liberalisation and the commodification of health.

### **The commodification of health and shifts in Nigeria's drug distribution system**

The liberalised nature of the Nigerian pharmaceutical market and the overwhelming role of private actors has been highlighted by previous research (Baxerres and Le Hesran 2011; Peterson 2014). It can be argued here that the seeds of this system were sown in colonial times with the issuing of patent dealer licences and an emerging private and under-regulated market for medicine, which later expanded as a result of SAP and related policies, as described above.

Linked to these processes of market liberalisation has been a trend towards the commodification of health described by anthropological studies on pharmaceutical consumption (Whyte, Van der Geest and Hardon 2002, 86-90). The changes to Nigeria's drug sector since the late 1970s are largely corresponding to this Africa-wide and global trend. First, commodification refers to the individualisation of healthcare and this has become especially pronounced through increased self-medication as the major way to cure oneself of all kinds of health problems. Drugs have become available like any other commodity in markets and sold on the doorstep by hawkers, without any involvement by the state or health professionals. Second, commodification has also meant that health has become a commodity purchased with cash by consumers rather than a right of citizens. The move away from a state-dominated public healthcare and drug distribution system to an almost completely private one has been the most obvious characteristic of this shift.

In Nigeria this has meant that at least since the late 1980s a distinct system of private manufacture, importation and distribution has developed that applies to most types of drugs today, including antibiotics, antimalarials and vitamin syrups. Local manufacture has clearly been on the decline in the country since the late 1980s, as mentioned above. Good manufacturing standards are a key problem, according to interviewed regulators, and the great majority of substandard or even poisonous substances are manufactured negligently, as in the 1990 paracetamol case mentioned earlier (Interview 1, Senior Pharmacy academic, 2013; Interview 3, Senior NAFDAC official, 2015; Interview 4, NAFDAC legal officer, 2015).<sup>7</sup>

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<sup>7</sup> Full interview details are listed after the Reference section of this article.

In contrast to local manufacture, the private importation of pharmaceutical drugs has been an expanding part of the trade, as it is one of the most lucrative parts of the trade. As in the words of one importer:

In this business until you have your own brand ... or you begin to import you cannot make money. The higher the risk, the higher the profit (Interview 16, Drug importer 3, 2015).

In Lagos alone close to 300 pharmaceutical importers were registered in 2012. They import drugs from across the world, particularly from Europe and the US, but recently also from India and China. The types of importers vary and can include the western multinational, big Nigerian importers with a large selection of drugs, as well as smaller entities, for instance one person importing a handful of different drugs (Interview 5, Senior PCN official, 2013; Interview 6, Drug importer 1, 2013; Interview 7, Drug importer 2, 2013). There has in fact been such a growth of imported drugs that their benefits to the consumer have at times been unclear. For instance, the importation of well-selling antimalarials has expanded immensely, although few of the brands on offer differ in terms of their ingredients.

Based on interviews, the importation of falsified drugs focuses exactly on the drugs that 'sell fast' and well in the Nigerian market (Interview 2, Drug manufacturer, 2013; Interview 7, Drug importer 2, 2013; Interview 8, Drug distributor, 2013). The importers of such drugs work closely with people involved in the legal trade, for instance, in 2009 a shipment of falsified antimalarials was intercepted in Lagos, which was a collaboration of a Nigerian businessman and a Chinese drug exporter. The job to falsify drugs was outsourced to an employee of a Chinese drug manufacturing company, packaging experts and also a person arranging the shipping for the batch from China (UNODC 2013, 42; NAFDAC 2013, 8; Punch 2009). In fact, the import of falsified drugs works not too differently and quite closely with its legal counterpart.

There are also many more importers of unregistered medicines, whose products fall into the government's 'fake drug' category, although their products are not necessarily harmful to users. Some of these importers ship foreign-registered drugs into the country, which are popular among some Nigerian consumers. During fieldwork in Nigeria's wholesale markets many of these unregulated products were openly available and sometimes imported by the wholesaler directly with the help of friends abroad. Many of these illegal imports are vitamins or traditional Chinese medicines popular among the Nigerian middle class but they can also include drugs originally intended for the foreign market, such as UK-registered cancer drugs uncommon or expensive in Nigeria (Interview 6, Drug importer 1, 2013).

Manufacturers and importers will most of the time distribute their drugs through the major wholesale markets, such as Idumota market in Lagos, Bridgehead market in Onitsha or Agbeni in Ibadan. These markets are essentially the nerve centres of Nigeria's drug trade, where everyone will want to be represented and even where large pharmaceutical corporations which officially deny their involvement in the so-called 'open market' will have their products sold (Interview 2, Drug manufacturer, 2013; Interview 7, Drug importer 2, 2013).

These wholesale markets have often been blamed for being the reason for the widespread availability of ‘fake drugs’, as drugs are stored under inappropriate conditions, sold without licences and to consumers without prescriptions. Several individuals selling unregistered, expired, falsified and substandard drugs have been arrested in these markets. A few of the shop owners have also been prosecuted for the illegal importation of drugs, as there is a desire among many of them to move up the supply chain. However, this is made difficult by law, as importers need to be a qualified pharmacist or they have to hire one for that purpose (Interview 9, Drug wholesaler 2, 2013; NAFDAC News 2013).

While these wholesalers are at the centre of Nigeria’s pharmaceutical trade and the debate about ‘fake drugs’, they are in an intricate legal position. The majority of them sell drugs without having a licence and they are selling drugs that they should not sell, even if they had a licence. However, in the drug market everyone relies on them. Retail pharmacies, drug patent dealers, hawkers and even state hospitals will buy their drugs in these ‘quasi-illegal’ wholesale markets, as there are no alternative suppliers with a similarly wide range of drugs available.<sup>8</sup>

In order to defend themselves in this intricate legal and political position, in particular against state agencies trying to regulate them and against licensed pharmacists competing with them, wholesalers in Idumota and other major markets in Nigeria have also formed powerful associations, such as the National Association of Patent and Medicine Dealers (NAPMED). One of NAPMED’s major aims has been to improve the reputation of its members who are often blamed for Nigeria’s ‘fake drug’ problem. Ironically, NAPMED’s motto is ‘Health is Wealth’, the same as the slogan of the major association of Nigeria’s pharmacists. Both these associations, as well as most of their members interviewed were always eager to stress that their involvement in the trade was not primarily for profit but for nobler purposes such as the ‘health of the nation’ or to ‘save lives’ (Interview 10, Drug wholesaler 3, 2013; Interview 11, Drug wholesaler 4 and 5, 2013; Interview 17, Senior PSN official, 2015).

In addition to attempting to improve their reputation, these associations have been an important player in confrontations between wholesalers and their economic and political rivals, such as regulatory agencies and pharmacists’ associations. Some of these confrontations have been fought out in court and have been highly publicised. Less visible but similarly important have been these associations’ role in promoting ‘self-regulation’ among members, as discussed below. In essence, with the increasing number of its members and their growing economic clout, these associations have helped to give wholesalers more political clout in the pharmaceutical market (Interview 10, Drug wholesaler 3, 2013; Interview 11, Drug wholesalers 4 and 5, Ibadan, October 25, 2013).

### **State regulation and criminalisation**

The nature of the pharmaceutical market, well-represented interests of some economic actors and state agencies’ weak capacity have shaped regulatory policy in Nigeria.

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<sup>8</sup> For a discussion of the concept and ramifications of ‘quasilegality’ in the field of drugs, see Carrier and Klantschnig (2017).

The limits of regulation appear largely in line with what the literature has said about the failures of drug regulation in weak developing states, although there are also some significant successes in our case that contradict these arguments (UNODC 2013; OECD 2016; Dukes, Braithwaite and Moloney 2015, 167-8).

In Nigeria, drug quality control was promoted since the early 1990s but not seriously implemented until the 2000s. Two specialised state agencies were carved out from the over-burdened Ministry of Health in 1993 to address two very specific issues within the healthcare system. The Pharmacists Council of Nigeria (PCN) was supposed to regulate the profession of pharmacists and licence premises selling pharmaceuticals but instead it has been involved in a series of court battles with pharmaceutical wholesalers and patent dealers who challenged the agency's licensing authority (Interview 1, Senior PCN official, 2013; Interview 10, Drug wholesaler 3, 2013). These confrontations in court and their inconclusive outcomes meant that the PCN was denied any clear regulatory influence over these economic actors. Since 1993 very few licences have in fact been issued and traders have circumvented PCN regulation successfully. Without licences, traders have grown so fast in number that their own association had to take a restrictive self-regulatory stance issuing fewer new memberships and thus trying to reduce the number of new entrants and curtail competition in the market (Interview 9, Drug wholesaler 2, 2013; Interview 12, Drug wholesaler 6, 2013; Interview 13, Drug wholesaler 7, 2013).

From 2001 onwards, the second agency created, NAFDAC, gained more national prominence due to its charismatic and publicity-savvy Director General Dora Akunyili (2001-2008). Compared to other state agencies, NAFDAC's budget rose steadily in the first few years under Akunyili's control. Financially, it was also helped by its own efforts to increase registration of drug and food items, as a share of the registration fees was kept by the agency itself and at times illegally diverted by senior agency officials (Vanguard 2015). Simply based on the appearance of its facilities, such as exceptionally good electricity supplies in all its major offices, NAFDAC has been much better funded than comparable state agencies (Klantschnig 2009, 47).<sup>9</sup>

NAFDAC has also been in a relatively strong financial position because it has nurtured and benefited from close state-business relations. Some of NAFDAC's regulatory initiatives have been funded by the pharmaceutical corporations which it is supposed to regulate. For instance, many of NAFDAC's public events and publications are sponsored by major pharmaceutical corporations interested in good relations with the agency (NAFDAC 2013a). Thus, NAFDAC's close relations with the pharmaceutical industry, which is much more important in this field than support from traditional donor countries, have financially benefited the agency as a whole and some of its agents individually. These close relations have encouraged some corrupt practices and the agency's dependence on large corporations – dynamics familiar from studies on the pharmaceutical sector elsewhere (Dukes, Braithwaite and Moloney 2015).

In terms of regulation, NAFDAC has taken a dual approach to regulate the drug distribution system, which it also sees as the root cause of Nigeria's 'fake drug'

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<sup>9</sup>There have been some recent reports that NAFDAC is facing electricity shortages like most other Nigerian state agencies, even in its Lagos offices (New Telegraph 2016).

problem. First, since 2001 NAFDAC has attempted to ‘enlighten Nigerians’ about the dangers of using poor quality and unregistered drugs, especially through the media. A significant share of the publicity was also very person-centred, promoting Akunyili’s career ambitions. Indirectly, however, these efforts have shown some success at creating greater consumer awareness in Nigeria. Based on anecdotal evidence gained during fieldwork in Lagos and Ibadan between 2005 and 2007, many more Nigerians were aware of the drug-related work of NAFDAC rather than its sister agency dealing with illegal drugs. In urban areas at least, drug users seemed to be very aware of NAFDAC’s message that only registered drugs were safe to consume.

Assuming that the availability of poor-quality drugs in the Nigerian market decreased over the last ten years, as claimed by most drug quality surveys, then this is partly an outcome of the information campaigns and efforts to register drugs. This aspect of regulation can be seen as a success of the work of NAFDAC, quite in contrast to the generally negative appraisals of regulation in the global South in the literature (UNODC 2013; OECD 2016; Dukes, Braithwaite and Moloney 2015, 167-8). In addition, these information campaigns as well as changed consumer behaviour have also led to much stronger self-regulation among the sellers of drugs in Nigeria. During fieldwork in South-Western Nigeria’s major wholesale markets, special efforts have clearly been made to enforce drug quality standards in order to maintain the reputation of these markets among consumers. Pharmaceutical traders in Idumota and Agbeni prided themselves of their own so-called ‘Taskforce’, which regulates the activities of new and established wholesalers (Interview 9, Drug wholesaler 2, 2013; Interview 12, Drug wholesaler 6, 2013).

There has also been a second type of approach, criminalisation, which has been much less conciliatory. NAFDAC has at several occasions taken more draconian measures to ‘sanitise drug markets’ (Interview 14, Senior NAFDAC official, 2013; Interview 15, NAFDAC official, 2013). This has usually meant the arrest of unlicensed smaller-scale dealers of drugs and the seizure of their products. The most drastic measures of this type have been police-assisted closures of drug markets in Onitsha, Lagos and Kano. These have often met with strong resistance from the traders involved and at times there were violent counter-attacks at NAFDAC and its officials, including attacks at Akunyili herself (Daily Trust 2012; Comet 2004).

However, drug markets are usually reopened after a few weeks of closure and the supply of drugs continues. If these measures are seen as ways to eradicate the sale of poor-quality drugs by unlicensed traders, they can be considered unsuccessful. These traders and their products are simply pushed underground for short periods of time. This is in large part due to the inexistence of any available alternatives to the current distribution and wholesale system from where Nigerians could purchase drugs that are in high demand.

Despite their limitations, it can be argued that these draconian measures to ‘sanitise’ or disrupt the unregistered trade can be seen as part of the regulatory work of NAFDAC. As Gill (2002) has argued, policing and law enforcement are not too dissimilar from the regulatory work of state agencies and often overlap with them. NAFDAC’s recent emphasis on policing or cracking down on unregistered drugs could thus be seen as part of the regulatory spectrum, as it helps to enforce self-regulation among traders. The threat of closure or disruption to drug markets acts as a

means to strengthen what Gill calls ‘enforced self-regulation.’ Wholesalers and traders’ strong concern over compliance with NAFDAC and even reproducing NAFDAC’s ‘taskforce-style’ of regulation among themselves is evidence of this effect of draconian measures on self-regulation. The same can be said about the adoption of NAFDAC discourse on ‘stamping out fake drugs’ among drug traders.

In general, the effectiveness of this criminalisation-focussed approach is doubtful.<sup>10</sup> On the one hand, criminalising the ‘fake drug’ problem has meant that NAFDAC has received some positive media coverage, it has led to the short-term disruption of the unregulated pharmaceutical market and – to some degree – contributed to a level of ‘enforced self-regulation’ among the traders most anxious about their reputation. On the other hand, the impact of this approach has been limited, as it has diverted attention away from the long-term regulatory problems caused by liberalisation and commodification, in particular the local industry’s continued decline and related poor manufacturing standards leading to substandard drug production. Criminalisation has also closed off or at least redirected policy resources from other approaches of regulation that NAFDAC had been quite successful at, such as expanding product registration and consumer and trader awareness campaigns.

## **Conclusions**

The Nigerian policies discussed need to be understood within the wider context of the public healthcare sector and the pharmaceutical market in Nigeria. With the continued deterioration of public healthcare, there has been a strong shift away from relying on state health facilities towards the privatisation of healthcare and liberalisation of related markets. In the field of drug distribution, this has meant that Nigerians had to acquire their medicines from private sources rather than the state hospitals and health centres prevalent in the 1970s (Baxerres and Le Hesran 2011). Related to the greater role for private actors has been the commodification of health – an Africa-wide and global phenomenon – that was well-illustrated through the Nigerian case study (Whyte, Van der Geest and Hardon 2002). Commodification has led to a greater emphasis on self-medication and health has quite literally become a commodity purchased with cash in ‘open markets’. This has also led to wealth becoming a determining factor for gaining access to quality healthcare and drugs.

The shift away from a state-dominated healthcare and drug distribution system has also meant that Nigerian consumers of pharmaceuticals have been much more exposed to the mechanics of global pharmaceutical markets and their dominant actors: pharmaceutical corporations in the West and more recently also in the East. These corporations’ major incentive, in line with most other actors in the Nigerian market today, has been the accumulation of corporate wealth rather than national health (Gereffi 1984; Braithwaite 1984; Peterson 2014). While the Nigerian debate about ‘fake drugs’ and some of the dominant explanations for the ‘fake drug’ problem have often blamed the unscrupulous activities of domestic market actors, such as unlicensed wholesalers, traders and pharmacists, surprisingly little was said in this

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<sup>10</sup> For a discussion of the experience of such policies in the field of other illegal substances, see Klantschnig (2016) and Carrier and Klantschnig (2012).

debate about the global actors dictating the terms of the pharmaceutical trade, which have a long and documented history of perpetrating serious harms (Braithwaite 1984, Dukes, Braithwaite and Moloney 2015; Whyte and Wiegratz 2016).

Furthermore, this article has also challenged some of the dominant and speculative explanations for the rise in ‘fake drugs’ in the global South. As stated at the outset, this rise had little to do with the ‘uneducated’ nature of consumers or with organised criminals entering the market. In fact, there was little evidence for organised crime in the ‘fake drug’ trade. Instead, our research has shown that the trade in falsified drugs had more in common and many links to the licit trade in pharmaceuticals and its historical evolution. The emphasis on the criminal and fraudulent nature of the ‘fake drug’ problem in policy discourse has instead diverted attention away from the complexity of ‘fake drugs’, in particular the substandard production of pharmaceuticals.

Finally and in contrast to another dominant explanation, it has been argued that the Nigerian state was somewhat successful at regulating aspects of the drug distribution system, especially through NAFDAC’s initiatives to reduce the availability of ‘fake drugs’ in the market. This was achieved through close relations with the industry, particularly through greater product registration, as well as widespread public information campaigns. This relative regulatory success challenged dominant explanations in the literature, which were much more pessimistic about regulation in the global South.

Nonetheless, the agency’s work remained limited, as it only aimed to fix an isolated technical policy problem: the regulation of drug quality. But due to this narrow focus it was destined to ignore the larger political economy issues without which its policies could not succeed, particularly the decaying public healthcare system, the decline of the local pharmaceutical industry as well the unfavourable terms of the global pharmaceutical trade, all of which were not within its control. Thus, while NAFDAC’s regulatory work was relatively successful on a technical level, its impact remained limited in this global and local political context that was characterised by a much more fundamental problem: the shift from public healthcare towards private profit-making and wealth.

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