Combatting Substandard and Counterfeit Medicines in the Nigerian Drug Market: How Industrial Pharmacists Can Rise Up to the Challenge

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Abstract

Substandard and counterfeit medicines (SCMs) are a major public health threat in Africa. In Nigeria, the manufacture and distribution of substandard and counterfeit medicines in the drug market are booming, despite the efforts of law enforcement agencies to crack down on criminal syndicates over the years. The current situation has been exacerbated due to factors tied to unregulated open drug markets, lack of counterfeit detection technology, poor local pharmaceutical manufacturing capacity, and porous cross-border monitoring and surveillance systems. However, industrial pharmacists have a key role to play in combatting the production and circulation of SCMs in the Nigerian drug market. In this commentary, we examine the prevalence of SCMs in Nigeria and proffer feasible recommendations that industrial pharmacists can leverage to ensure its effective containment.

Introduction

Substandard and counterfeit medicines (SCMs) are a major public health threat in Africa. The World Health Organization (WHO) estimates that over 280,000 children die annually because of taking substandard medicines as treatment for pneumonia and malaria in sub-Saharan African countries [1]. There is no consensus on a common definition of substandard and counterfeit medicines as existing definitions differ by country. However, the definition by Ziance in 2008 stands out. Ziance defined counterfeit medicines as products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product [2]. Counterfeit medicines include drugs that contain no active pharmaceutical ingredient (API), an incorrect amount of API, an inferior-quality API, a wrong API, contaminants, or repackaged expired products [2]. Some counterfeit medications may even be incorrectly formulated and produced in substandard conditions [2]. To further understand the extent of harm caused by substandard and counterfeit medicines, the scenario illustrated by Chambliss *et al.,* 2012 [3] is worth exploring.

"Imagine that a patient is prescribed chemotherapy to treat a life-threatening tumor. A pharmacist dispenses the prescribed medication and counsels the patient without realizing that the tablets did not contain an active ingredient. In this scenario, not only is the patient not receiving the prescribed medication but the physician and pharmacist are evaluating treatment outcomes based on the patient's response to a placebo."

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In Nigeria, the manufacture and distribution of substandard and counterfeit medicines in the drug market is booming, despite the efforts of law enforcement agencies to crack down on criminal syndicates. Although adulteration, falsification, and illicit manufacture of drugs is not a new threat, recent advances in industrialization and commerce have exacerbated the complexity of the problem. While Nigeria has made tremendous progress in reducing the circulation of SCMs from 40% in 2001 to 17% in 2005 [4], this issue continues to be a major challenge, particularly with regard to medicines of great public health importance, such as antimalarial drugs. In 2011, 64% of antimalarials circulating in Nigeria were reported to be substandard [5]. The continued presence of highly unregulated open drug markets in Nigeria's major cities has been a major contributor to the prevalence of counterfeit drugs [6] where medicines are hawked and sold freely on street corners, bus stops, kiosks, and stalls [6]. In Nigeria and other countries, these markets are well-known as outlets and conduits for substandard and counterfeit medicines [6,7]. Notable open drug markets in Nigeria include those located in Kano (Sabon-Gari market), Lagos (Idumota market), Onitsha (Head-bridge market) [6] while other not-so-known open drug markets are found in Abia (Ariaria Market, Aba) and Rivers (Mile 1 and Mile 3 markets). The Idumota market in Lagos has been described as one of the world's largest markets. Manufacturers sell directly to merchants at the market, who then export to other parts of West Africa and Central Africa [7]. Preventing counterfeit medicines from entering Nigeria is very difficult, partly because more than 70% of drugs in Nigeria are imported [8]; these are mainly from India and China, which are two of the world's biggest sources of counterfeit medicines [6]. Unfortunately, in Nigeria, detecting these counterfeit medicines is equally difficult, because many of them pass through the unregulated open drug markets, thereby creating opportunities for counterfeits and substandard medicines to enter the legitimate supply chain. Indeed, the open drug markets represent a major source of medicines to many licensed pharmacy outlets,

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hospitals, medicine wholesalers, and retailers in Nigeria [6]. As long as the open drug markets remain operational, combatting substandard and counterfeit medicines would be increasingly difficult.

Health Implications of Substandard and Counterfeit Medicines

Unscrupulous businessmen and women involved in the illegal production, importation, and circulation of SCMs target medicines with a large volume of use for the treatment of diseases. Antibiotics, anti-diabetic agents, antihypertensives, antimalarials, and lifestyle drugs are among the medicines targeted [9]. Undoubtedly, the consumption of these SCMs can result in serious health implications. These health implications include:

- development of resistance (drug resistance or multi-drug resistance or cross-resistance) which can invariably result in treatment failures and consequently, death
- increased out-of-pocket expenditure
- increased burden on the already-overburdened health system, and
- loss of confidence in the health system.

There have been several reported cases of poisoning in Nigeria due to SCMs as a result of contamination. In 2008, a catastrophic event happened in Nigeria in which several children developed acute kidney injury and later died as a result of consuming a supposed teething solution called *"My Pikin"* which was contaminated by the accidental or intentional addition of diethylene glycol (DEG) as a solvent instead of propylene glycol [10]. Similar events occurred when the same DEG was used instead of propylene glycol in South Africa in 1969 and Nigeria in 1990, resulting in 7 and 47 deaths respectively [10]. Also, an investigation on the quality of widely circulated metformin tablets in Nigeria in 2017 revealed that half of the tested medicines failed at least one pharmacopoeia test of bioequivalence [11].

Roles of Industrial Pharmacists in Combatting SCMs

As one of the drivers and key players of the Nigerian drug market, industrial pharmacists can employ several measures and tactical approaches towards combatting the production and circulation of SCMs in Nigeria. In the context of this commentary, industrial pharmacists are those practicing in the pharmaceutical industry either in drug manufacturing, quality control, regulatory affairs, research and development, and marketing. The following measures can be leveraged by industrial pharmacists to combat the manufacturing and circulation of substandard and counterfeit medicines in the Nigerian drug market:

1. Reform and Regulation of the Drug Supply Chain

Unregulated open drug markets in Nigeria have already been described as a major contributor to the prevalence of SCMs [6]. A major source of worry is that these unregulated and unlicensed open drug market dealers also supply medicines to some retail and wholesale pharmacies in the country, as well as some health agencies. This gives these uncontrolled and unlicensed drug sellers the opportunity to falsify and adulterate medicines in attempt to benefit at the expense of public health and lives. In the absence of an on-site counterfeit detection mechanism, there lies a huge tendency that these medicines if contaminated or adulterated can reach patients directly. In response to the increasing threat of SCMs in the Nigerian drug market, a guideline for National Drug Distribution was initiated in 2012 (and launched in 2015) by the Federal Ministry of Health to reform the country's drug supply chain [12]. However, implementation and enforcement have been ineffectual [10]. Through advocacy efforts at the national and regulatory levels, industrial pharmacists can liaise with key stakeholders, law enforcement agencies, and regulatory bodies to ensure proper implementation of this guideline with strict enforcement. This will help to ensure that all medicines in circulation are from a known and reliable source. Furthermore, it will also reduce the demand for medicines from the unregulated open drug markets by the general public.

2. **Adoption of Mobile Authentication Service (MAS)**

In 2010, the National Agency for Food and Drug Administration and Control (NAFDAC) introduced the NAFDAC Mobile Authentication Service (MAS). It empowers consumers to immediately authenticate a medicine for free by following three basic steps: (i) scratching the sticker on the product; (ii) submitting the unique pin to a short code and (iii) getting a response within seconds showing whether the product is genuine or not [10]. A recent study has revealed the wide acceptance of MAS by 53% of community pharmacies in Nigeria [13]. Thus, as the use and acceptability of MAS are generally feasible, industrial pharmacists can play a key role by:

- Educating fellow pharmacists at the community level, the public and their parent company to adopt this technology at a lower cost.
- Monitoring of counterfeit product alerts.
- Conducting various authentication tests to ensure product integrity.
- This cutting-edge technology should be also be adopted by all pharmaceutical manufacturing companies in Nigeria to ensure the use and public consumption of only safe and authentic medicines.

3. Boosting Local Pharmaceutical Manufacturing Capacity

With over 115 registered pharmaceutical manufacturers [14], Nigeria still depends on other countries such as India and China for the supply of active pharmaceutical ingredients and excipients. There are concerns that this may create an opportunity for falsified medicines to enter into the legitimate drug supply chain as these countries have already been reported to be two of the world's biggest sources of counterfeit medicines [6]. Thus, industrial pharmacists have a role to play by strengthening and intensifying local manufacturing capacity to avoid foreign dependence which is a potential source of SCMs. Nonetheless, the pharmaceutical industry cannot survive in a country without an enabling environment. Strengthening the country's pharmaceutical

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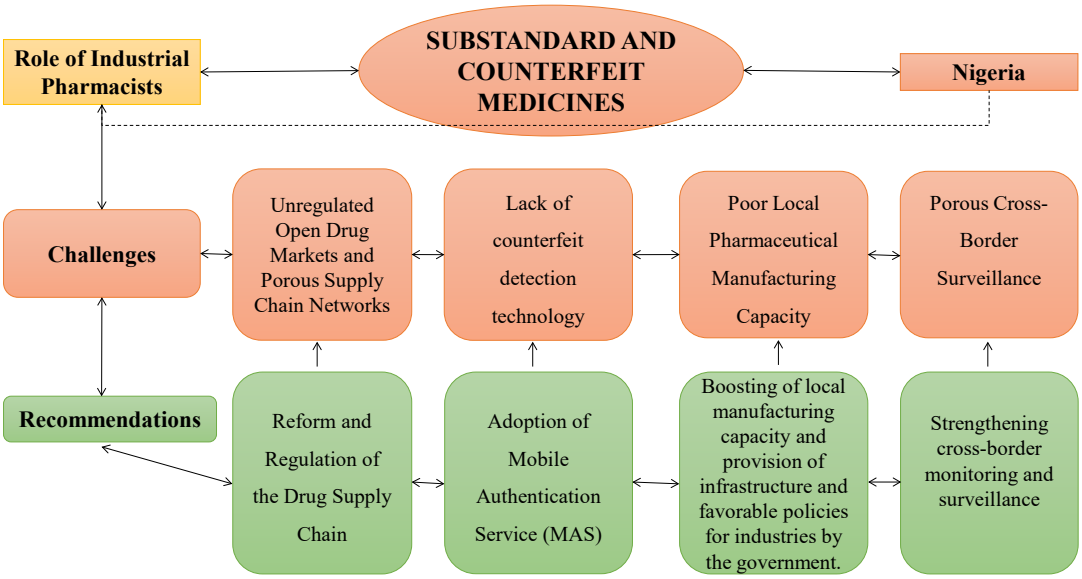
manufacturing capacity will also require more investment, dedication, collective advocacy, and coordinated efforts by the government and private stakeholders.

4. **Strengthening Cross-Border Monitoring and Surveillance**
In a bid to smuggle SCMs into the country, most foreign manufacturers particularly from India rebrand medicines to evade detection by custom officials at the country's borders and ports [15]. Between 2nd and 19th of August 2020, 33 containers of prohibited drugs worth N1.3 trillion ($3.2 billion) were shipped into three different locations in Lagos where it is then redistributed illegally to other parts of Nigeria [15]. Industrial pharmacists at the regulatory level will need to strengthen policy and laws that regulate the importation of drugs at the various channels of entry. Prosecutions should be intensified and targeted at corrupt officials as well as smugglers, illegal distributors and buyers.

The figure below is an overview of how industrial pharmacists can ensure the containment of substandard and counterfeit medicines in Nigeria.



Conclusion

The production and circulation of substandard and counterfeit medicines (SCMs) in the Nigerian drug market is a dynamic and unquantifiable issue. The current situation has been exacerbated due to factors tied to unregulated open drug markets, lack of counterfeit detection technology, poor local manufacturing capacity, inconsistent regulatory oversight, poor monitoring and surveillance systems, and the lack of concerted anti-counterfeiting efforts by various national and multinational regulatory agencies. Although several strategies have been initiated to alleviate the burden of SCMs in Nigeria, industrial pharmacists must not relent in their efforts. They can play an active role in combating SCMs in the Nigerian drug market by reforming and regulating the drug supply chain, adopting Mobile Authentication Service (MAS), boosting local pharmaceutical manufacturing capacity and strengthening cross-border monitoring and surveillance.

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