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The Public Health Consequences of Substandard Medicines in Nigeria

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ABSTRACT

Introduction: Poor-quality medicines are a serious public health issue, especially in emerging economies and developing countries, and can have a significant impact on the national clinical and economic burden. Although much attention has been focused on the increasing availability of intentionally falsified drugs, substandard medicines are also reaching patients as a result of poor manufacturing and quality-control practices in the manufacture of genuine drugs (either branded or generic). Substandard medicines are common and pose a health risk because they can inadvertently lead to healthcare failures such as antibiotic resistance and disease spread within a community, as well as death or additional illness in individuals.

Conclusion: The potential solutions to substandard manufacturing practices are also discussed. To ensure that only drugs of acceptable quality reach the patient, governments, drug manufacturers, charities, and healthcare providers must work together.

1. Introduction

Counterfeit medicine is on the rise worldwide and it is becoming a problem in both developing and developed countries. Poor-quality medicines can enter the market through substandard production of legitimate drugs due to insufficient quality-control processes during manufacturing, as well as through intentionally fraudulent practices. The relative contribution of the two sources is unknown; however, most cases are likely to be caused by genuine but low-quality drugs[1]. Until now, legislation has focused on the control of intentionally falsified drugs, but low-quality legitimate drugs, i.e., those that have gone through some sort of regulatory procedure, are more common and pose a greater threat to patient health, so both issues must be addressed. There have been several high-profile recalls in recent years, such as the European Medicines Agency (EMA) recall of an active pharmaceutical ingredient (API) produced in India following an inspection of the manufacturing site[2] and in the United States, all products compounded at the New England Pharmacy facility in Framingham, Massachusetts, were recalled following a fatal outbreak of fungal meningitis associated with injectable steroids[3]. The negative consequences of counterfeit drugs are recognized as a major threat to the integrity of public health systems

worldwide, as well as a direct threat to individual health and welfare[4]. Antibiotics, hormones, analgesics, steroids, antihistamines, vitamins, malaria medications, flu medications, and HIV/AIDS medications have all been counterfeited[5]. However, the precise amount of counterfeit medicine is unknown and there is a scarcity of reliable data for both developed and developing countries.

2. Status of Substandard Medicines

The World Health Organization (WHO) recently grouped all categories as "SSFFC": substandard, spurious, falsely labelled, falsified and counterfeit and defines counterfeit drugs as "drugs that have been intentionally or fraudulently mislabelled with respect to identity and/or source[6]. The products may contain incorrect ingredients, may overstate the amount of active ingredients, or may be manufactured under unsanitary conditions. Preparations without active ingredients, toxic preparations, expired drugs relabelled, drugs issued without complete manufacturing information and drugs unregistered with the National Agency for Food and Drug Administration and Control (NAFDAC), are classical examples of counterfeit drugs in Nigeria. According to current estimates from early 2000, 10% of prescription drugs sold throughout the country are counterfeits, fakes, or contaminated, while the figure exceeds 50% in parts of Africa and Asia[7]. Counterfeit drugs are a public health concern in Nigeria and around the world. The problem of counterfeit drugs has been growing in Nigeria, with supplies coming from all over the world. Counterfeit drugs not only deprive consumers of money by forcing them to pay for products with little or no medical value, but they can also result in unresolved health issues and even death[3]. Documents, currency, software, and electronics, among other things, are being counterfeited in Nigeria today. However, no other product has the potential to harm or even kill its consumers in the same way that illegal pharmaceutical products do[8].

2.1 The Alarming Situation of Substandard Medicines

The threat of counterfeit medicines has grown in the last two decades and the current situation in the West African sub-region, including Nigeria, is alarming. According to empirical evidence, there may be more counterfeit medicines in circulation than genuine drugs[9]. One concerning aspect of the counterfeit drug hazard is that the effects of consuming such drugs go unnoticed, except in cases where mass deaths occur. The consequences of counterfeit drugs on patients are difficult to quantify and are frequently overlooked in public health statistics. In Nigeria, there is no reliable data on the mortality and morbidity caused using counterfeit drugs[10].

Nigeria has struggled for decades to reduce the production and circulation of counterfeit drugs due to a lack of infrastructure, political will to properly enforce legislation and standards. Because of the high prevalence of counterfeit drugs as a public health threat, the Pharmaceutical Society of Nigeria (PSN) is putting pressure on the government to take decisive steps to control the prevalence of counterfeit and substandard drugs in Nigeria. The government responded by issuing the counterfeit and fake drug decree No. 21 of 1998, which prohibited the sale and distribution of counterfeit, adulterated, prohibited and fake drugs or poisons in open markets and without a registration license[11].

Furthermore, NAFDAC was established in 1993 to aid in the creation of a drug-free environment by ensuring the effective registration of high-quality drugs[12]. However, in 2001, the agency underwent intense restructuring and reforms under the leadership of Prof. Dora Akunyili as the new Director General of NAFDAC, with the goal of revitalizing NAFDAC's mandate to "protect the health of the nation." As a result, drug failure rates fell to around 16% in 2006 from 2002, and the circulation of counterfeit drugs was reported to have decreased by more than 80% compared to 2001[13].

2.2 Health and Economic Consequences of Substandard Medicines in Nigeria

The problem of counterfeit drugs has embarrassed Nigerian healthcare providers and eroded public trust in the country's healthcare delivery system[14]. Various factors such as incorrect Active Pharmaceutical Ingredients (APIs) or excipients; poor control of drug quantity; manufacturing processes that cause contamination or do not adequately ensure sterility; and inadequate packaging design or quality can all contribute to substandard medication. Any formulation can be considered substandard if the drug content is insufficient (i.e., if it has either too much or too little API compared with the formulation specification), contains impurities (Any substance in the product that is neither the chemical entity defined as the drug nor an excipient, its pharmacological variability and stability (when its generic formulations are different from its originator drug).

Counterfeits, substandard products, and drug diversion have a negative economic impact on the overall pharmaceutical financing and delivery system[15]. Medicines stolen from warehouses and resold on the black market or

outside the country are not available to the patients who need them[16]. The public funds used to purchase these drugs are a waste. Substandard and counterfeit drugs undermine consumer trust in healthcare systems[17]. In the absence of a credible quality-control system, prescribers and patients often exhibit preference for branded, more expensive imported products, which makes implementing a rational drug policy, based on generic essential medicines difficult. The collaboration of relevant federal and state health institutions to enact effective pricing strategies to ensure a uniform distribution of drug prices across facilities, could be a good cost-effective model to guarantee access to quality medicines and overall standard quality of care at all levels[18].

2.3 The Nigerian Pharmaceutical Markets

Nigeria has a large pharmaceutical market, with over 130 existing pharmaceutical manufacturers. Despite the enormous size of these pharmaceutical industries, only 60 are actively producing drugs. This contrasts with the industry's installed capacity of producing between 50 and 75 percent of the nation's drug needs. With a production capacity of less than 30%, much of the country's drugs are imported[19], with most imports coming from Asia. Drug traffickers see Nigeria as an ideal location for their illegal but lucrative trade. According to the literature, India and China are the global market leaders in pharmaceutical manufacturing and the leading perpetrators of drug counterfeiting. A large portion of global outsourcing is contracted to Asian and Indian firms, both for manufacturing and, increasingly, for services[20]. According to a European Commission statistic, India is the source of 75% of counterfeit drugs. As a result, it is not surprising that the majority of counterfeit drugs in Nigeria come from India[21]. This is not to say that the problem is limited to Asia. In many cases, the goods are only mislabelled in locations far from the manufacturing site[22].

2.4 Availability of Substandard Medicine in Nigeria

The Nigerian health and economic systems' lax control has contributed to the circulation of fake and counterfeit drugs in the country. The regulation and control of imported products is a major function of NAFDAC and other regulatory bodies. This is accomplished by stationing inspectors at various airports and seaports. Pharmaceutical registration is a criterion that must be met before any drug can be sold in Nigeria. Substandard medicine is available in Nigeria due to deficiencies in legislation and enforcement, which are a major impediment to combating the problem of substandard medicines[23], insufficiently equipped public forensic laboratories for quality control analysis testing for drugs to handle the volume of imported drugs, vulnerable supply chain of imported medicine can lead to the availability of substandard medicines[24].

According to existing literature, other factors contributing to the prevalence of fake drugs in Nigeria include greed, ignorance, and corruption. Corruption and greed are evident among some unpatriotic officers within the drug regulatory authorities, as well as drug importers and manufacturers[25]. The suspected high level of official manipulation and corruption in the Nigerian healthcare system has a negative impact on the effectiveness of regulatory bodies. It is alleged in many quarters that some unscrupulous law enforcement officers are paid to look the other way while the fake drug trade thrives[26]. It is generally perceived that inadequate drug regulation and weak enforcement of sanctions are driven mostly by conflicts of interest of some officials in the drug regulatory agencies, which encourages drug counterfeiting. Aside from the growing public health threat posed by this expanding and increasingly lucrative crime, evidence suggests that counterfeit and fake drugs provide material support to criminals and terrorist organizations working to undermine national security[4]. Stopping these bogus drug markets, producers, traffickers and illegal traders must be a top public health priority.

2.5 Strategies to curb proliferation of Substandard Medicines

There are several strategies used to combat the spread of substandard medicine. Regulatory measures (e.g., drug registration and WHO prequalification) and onsite quality inspections (which were key components of multifaceted interventions) were suggested as effective measures in reducing the prevalence of counterfeit and substandard medicines in the previous effectiveness review[27]. Previous evidence suggested that using onsite quality surveillance and inspection systems could provide regulators in low-resource settings with an efficient and cost-effective tool for preliminary testing of large drug samples, as well as increase regulatory reach and visibility across the country[28]. Although product authentication systems such as track and trace and RFID are increasingly being promoted as anti-drug counterfeiting measures[29], there is no evidence that they are effective in reducing the prevalence of counterfeit medicines. Pharmacovigilance systems appear to be expanding rapidly in low- and middle-income countries in order to promote drug safety and allow routine post-marketing surveillance of pharmaceuticals at the national

level. Importantly, interventions should be undertaken to strengthen the legal framework and structures for pharmacovigilance activities[30]. In addition, public awareness and education about the dangers of substandard medicines should be implemented.

3. Conclusion

Generic formulations provide low-cost alternatives for many drugs and generic substitution may be required in some countries; however, the quality of these drugs must be regulated. Parallel to the resources invested in combating the problem of intentionally falsified drugs, a global effort is needed to combat the distribution of low-quality medicines caused by poor manufacturing processes and inadequate regulatory oversight. It is critical to have strong, appropriately empowered, and well-funded national drug regulatory agencies in Nigeria.

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