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Counterfeit and Substandard Medical Products: Zambia's Legal Response

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ABSTRACT

The presence of counterfeit and substandard Medical Products is a problem of growing concern in African countries, and Zambia has not been spared. Their use causes medical complications among patients and in some cases, death. They also add to the challenges faced by an already burdened health care system. This article explores Zambia's regulatory framework for the control of Counterfeit and Substandard Medical Products. This study examining the extent to which the Zambian law, namely, the Medicines and Allied Substances Act, protects the general public from Substandard and Falsified Medical Products. Further, it identifies the challenges faced by the Zambian regulatory authority for pharmaceutical products, the Zambia Medicines Regulatory Authority (ZAMRA), in controlling of the import, manufacture and sell of Counterfeit and Substandard Medical Products. The study adopted a qualitative research approach through a systematic review of literature. This was done by following a key word search on literature that is relevant or related to regulation of counterfeit and substandard products. The study found that the Medicines and allied Substances Act has empowered ZAMRA to protect the Zambian public from counterfeit and substandard medical products. However, it faces various challenges which include an insufficient availability of financial resources and low staffing levels. The study recommends that the Zambian government should provide incentives and policies to support investment in the pharmaceutical industry, It recommends for an increase in the financial and human resources availed to ZAMRA, in order to solve the challenges that it faces.

Key Words: Counterfeit Products, Medical, Regulation, Substandard Products, Zambia.

1. INTRODUCTION

The presence of Counterfeit and Substandard Medical Products on the pharmaceuticals market is a matter of growing concern in low- and middle-income countries. In Africa, their presence on the market is propelled by the high presence of infectious diseases, which has increased demand for medicines (Ozawa *et al.*, 2018). A study conducted in 2023 revealed that as of 2017, forty two percent (42%) of all the fake medicines reported to the World Health Organization (WHO) are from Africa (Tegegne *et al.*, 2024). Due to budgetary constraints, a large portion of medicines that African governments are able to purchase are generic, and the shortage or non-availability of analytical laboratories makes it difficult to detect counterfeit or substandard drugs (Glass, 2014). Zambia has not been spared from the presence of Counterfeit medications. For example, in 2023, forty-two thousand (42,000) health kits were recalled from government hospitals and health centres because they contained an antibiotic that did not pass quality control tests (National Assembly of Zambia, 2023).

Counterfeit medicines are defined as medicines that have been deliberately or fraudulently mislabelled with respect to their identity and/or source (World Health Organization, 2018). Similarly, the *Medicines and Allied Substances Act (2013),* has defined counterfeit medicine as medicine which is deliberately or fraudulently mislabelled or misrepresented with respect to its identity or source. This definition extends to medicines which have wrong ingredients, an insufficient

amount or excess active of an ingredient, or fake packaging. Substandard medications are authorized but they fail to meet either their quality standards or specifications, or both(World Health Organization, 2018). A similar definition is provided in the *Medicines and Allied Substances Act (2013),* which defines substandard medications as products whose composition and ingredients do not meet approved quality specifications, and may be consequently ineffective and often dangerous to a patient.

Both counterfeit and substandard products are not only harmful to patients, through various medical complications that may arise from their consumption, such as resistance to drugs, prolonged illnesses, but they may lead to death as well (Moshoeshoe, Enslin and Katerere, 2022). In addition, the effects of their use becomes a burden on the health care system of a country (Chabalenge *et al.*, 2022). For example, a study conducted in 2022 revealed that the consumption of counterfeit and substandard malaria medicines led to an additional cost of one hundred and forty one million dollars (U$ 141,000,000.00) on Zambia's health care system (Moshoeshoe, Enslin and Katerere, 2022), which is already burdened with other administrative and financial challenges. African countries generally have poor regulatory and quality assurance systems for pharmaceutical products, and this leaves them prone to online pharmacies that sell counterfeit and substandard medical products (Long *et al.*, 2022).

Like other African countries, Zambia is faced with the challenge of providing quality medicines at affordable prices (Blake, 2009). Although some low-cost drugs are effective, others may be substandard in nature, and where regulation is imprecise or arbitrarily applied, a country may be at risk of receiving counterfeit and substandard medicines on its market. In response to these challenges, Zambia has formulated and implemented a regulatory framework for the control of counterfeit and substandard medicines. The *Medicines and Allied Substances Act (2013)* was enacted to provide a legal framework for the quality and safety of medical products. It also provides for the creation of the Zambia Medicines Regulatory Authority (ZAMRA), whose principal function is to regulate the supply and distribution of medicines and allied substances in the country (Zambia Medicines Regulatory Authority, 2024). One of the challenges faced by ZAMRA is the increase in the number of medicines that are recalled because they are counterfeit or substandard (Chabalenge *et al.*, 2022). This has posed a danger to the health of members of the public, as some of the medicines that are recalled, would have already be consumed.

Therefore, this study explores Zambia's regulatory framework for the control of counterfeit and substandard medical products. This is done by examining the extent to which the Zambian law, namely, the Medicines and Allied Substances Act, regulates the supply and distribution of substandard and falsified medical products. Further, it identifies the challenges faced by ZAMRA in controlling the import, manufacture and sell of Counterfeit and Substandard Medical Products. It then makes proposals for reform in the law that regulates pharmaceutical products in Zambia.

2. THE REGULATION OF THE SUPPLY AND DISTRIBUTION OF SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS

An effective medicine regulatory system is cardinal to the development and public health of a nation. Medicine security and safety is a key player in assuring national security productivity, longevity and development (Mukherjee and Goodman, 2023). Unlike other consumer products, medical products directly affect the health and lives of people who consume them. Therefore, it is very important for a national medicine regulatory authority to be efficient and effective in performing its role of ensuring public health through consumption of quality and effective drugs.

2.1 The Zambia Medicines and Regulatory Agency

The Medicines and Allied Substances Act (2013) has provided for the creation of a national regulator for medicines and allied substances; the Zambia Medicines and Regulatory Agency (ZAMRA). Its role is to effectively regulate and control medicines and allied substances that are made available to the Zambian population, and to ensure that they conform to standards that it sets, thereby safeguarding public health (Zambia Medicines Regulatory Authority, 2024).

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In order to control counterfeit and falsified medical products, ZAMRA is empowered to regulate the manufacture, distribution and import of medicines and allied substances (Medicines and Allied Substances Act, 2013). An individual or entity cannot manufacture, distribute or deal in any medicine or allied substance without a pharmaceutical license obtained from ZAMRA. In addition, an individual or entity cannot import any medicine or allied substance without an import permit obtained from ZAMRA (Medicines and Allied Substances Act, 2013). This helps to ensure that medicines that are made available to the general public meet the set standards of quality, safety and efficacy.

2.1.1 Licenses and Permits for Medical Products

According to Section 33 of the Medicines and Allied Substances Act (2013), an individual or entity cannot manufacture, distribute or deal in any medicine or allied substance in Zambia without a pharmaceutical license. A pharmaceutical license may only be granted after prescribed standards and guidelines for the purpose of the manufacture and/or sale, of a particular medicine or allied substance are met through quality control tests conducted by ZAMRA. In addition, Sections 35 and 36 of the Medicines and Allied Substances Act (2013) medicines and allied substances can only be imported in to Zambia or exported out of Zambia after a permit is obtained from ZAMRA. These measures are implemented by ZAMRA as a way of controlling the availability of counterfeit and falsified medicines on the market.

2.1.2 Quality Control and Marketing Authorization

As stated above, pharmaceutical licenses may not be issued for medicines that are manufactured, or imported in to or out of Zambia without quality control tests that verify their safety. Accordingly, Section 54 of the Medicines and Allied Substances Act (2013) provides for the establishment of a national quality control laboratory to be managed by ZAMRA. The primary purpose for the establishment of this laboratory is to verify the safety, quality and efficacy of medicines and allied substances that are manufactured or imported into Zambia (Medicines and Allied Substances Act, 2017).

As a further precautionary measure, Section 54 of the Medicines and Allied Substances Act (2013) an individual or entity is not permitted to sell, advertise, market, manufacture, import, or supply medicines on the Zambian market without a marketing authorization issued by ZAMRA. Marketing authorization is important because it provides a guarantee that medicines are not counterfeit or substandard, and have been evaluated and registered by ZAMRA. This signifies the safety of medicines for use, and helps reduce the availability of counterfeit and falsified medicines on the market(Sorato, Davari and Kebriaeezadeh, 2024).

2.1.3 Surveillance of Medicines and Allied Substances

Once authorization for the sale or distribution of a particular medicine is granted, its continued safety for use or consumption is ensured through the surveillance conducted by ZAMRA. The surveillance conducted detects and responds to incidences of substandard and falsified medical products (Hamill *et al.*, 2021). Surveillance is also conducted through the presence of inspectors at airports, boarders and points of entry, whose primary role is to ensure that medicines and allied substance that are imported in to, or exported out of Zambia comply with the regulations set by ZAMRA.

3.0 CHALLENGES IN THE IMPLEMENTATION OF MEASURES TO CONTROL COUNTERFEIT AND SUBSTANDARD MEDICAL PRODUCTS

ZAMRA is constrained from the execution of its mandate by financial and human resource constraints. According to Section 8 of the Medicines and Allied Substances Act (2013), it is funded by the government, and from fees it collects, and any grants or donations that it may receive. The funds are limited and may not ably meet the needs of the regulator, thereby hampering its activities.

In addition, shortage of available human resources and tools have led to reduced presence of inspectors of medical products at entry points in to the country. Findings of this study revealed tut of the seven designated ports of entry for the movement of pharmaceuticals, only two inspectors were available to carry out inspections leaving the other designated ports vulnerable and exposed to potential smuggling of counterfeit drugs. This challenge is escalated by existence of

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geographical borders that, are porous, with loose control systems. This creates a leeway for illegal entry of counterfeit and falsified medical products in to the country.

4.0 RECOMMENDATIONS

4.1 Investment in Pharmaceutical Industry

As alluded to above, the high cost of medical products is a contributory factor to counterfeit and falsified products in African countries and Zambia is not an exception. This compels entities and governments to import cheap generic drugs as an alternative, which may, in some instances be counterfeit or substandard. In order to curb this problem, it is recommended that the government formulates measures that will attract local and foreign investment in the domestic drug manufacturing industry, to reduce the cost of the medicines, and improve their availability for members of the public.

4.2 Sensitization and Awareness Campaigns

Sensitization programs and campaigns may assist people with the skills to distinguish medical products that are original form counterfeit products. Public awareness is one of the cheapest means of curbing the prevalence of counterfeit drugs. Some pharmaceutical companies for example sponsored television programs such as 'drug scope' to enlighten the general public on effects of fake drugs, diseases and the need to obtain drugs from registered pharmaceutical stores.

4.3 Stakeholder Engagement

Fighting counterfeit drugs requires collaborations and corporation of key stakeholders, which include the Drug Enforcement Commission, the Anti-Corruption Commission, Immigration Officers, The Ministry of Health, and the general public. Though the mandate of medicine regulation is the responsibility of ZAMRA, efforts of all players and key holders will be beneficial and make the work objectives of ZAMRA much easier as the ultimate benefit is conferred on the citizens of Zambia. According to a report issued from a survey conducted in South Africa, it was noted that there where challenges experienced in information sharing and collaboration among the various agencies. This affects the contribution of these supporting agencies which affects the fight against counterfeit drugs.

4.4 Capacity Building

In order to overcome the challenges that arise from the restriction in the availability of funds or human resources by increasing its human resource or staffing levels. Improvement in staffing levels will further lead to effective enforcement of regulatory authority as weak enforcement has been indicated to be caused by inadequate human resource and tools to ensure a strong system of enforcement.

5.0 CONCLUSION

Counterfeit and substandard medicines are a matter of concern in developing African countries such as Zambia. Their presence on the Zambian market is as a result of high demand for affordable medicines and allied substances by the public. In order to control counterfed and substandard medicines in the country, the Zambia enacted the Medicines and Allied Substances Act (2013). It provides mechanisms that are designed to ensure the quality and safety of medical products. ZAMRA has the legal mandate to ensure the quality and safety of medicines through the issuance of Licenses and Permits for Medical Products, quality control, market authorization, and surveillance of medicines and allied substances. In the execution of its mandate, ZAMRA is faced with a number of challenges. These include the shortage of human and financial resources, and the porous geographical borders which are adequately controlled, thereby allowing the smuggling of counterfeit and substandard products. These challenges may be overcome through investment in the domestic industry to reduce the cost of medicines and meet high demand for their consumption. In addition, sensitization programs and engagement with stake holders may help control the presence of counterfeit and substandard medicines in the Zambia.

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