



Commentary

Falsified and substandard medicines trafficking: A wakeup call for the African continent

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ABSTRACT

While great effort is being placed on reducing disease burdens in Africa, the circulation of falsified and substandard medicines in the continent are reversing the hard-won gains. This commentary provides insights on the high (and increasing) burden, impact and threat that falsified and substandard medicines pose to the region's development. The proposed recommendations, such as a coherent multi-sectorial and government-led strategy, call for a fundamental rethink of approaches towards strong regulations, policies, legislations, community-based approaches, collaborations and investments, which all must be scaled up before this the situation gets out of control. These recommendations are of paramount importance and have the potential to ensure access to genuine medicines and also to avert therapeutic failure and intoxication from dangerous substances. In addition, there will be added benefits to the economic, social, health and well-being of the region. Concerted efforts towards medicine regulations have enormous potential to contribute towards averting many preventable deaths and reducing disease burden in the region. A paradigm shift is necessary to ensure quality medicines reach patients at community and healthcare facilities to prevent this silent epidemic in Africa.

1. Introduction

Every year in Africa, millions of people die from preventable causes due to falsified and substandard medicines. Globally, improving access to essential medicines is fundamental in the effort to reduce mortality and morbidity [1]. In Africa, the proliferation of falsified and substandard medicines is a public health emergency that can no longer be ignored [2]. This issue threatens to undermine progress towards achieving the Sustainable Development Goals (SDGs) in the region.

Following many issues and concerns regarding definitions and use of the terminology, in 2017 the World Health Organization (WHO), through the World Health Assembly, provided this definition: falsified medicines or medical products are the ones that deliberately/fraudulently misrepresent their identity, composition or source, while,

substandard are the ones which are authorised but fail to meet their quality specifications or their standard, or both [2].

This commentary provides an insight on the high (and increasing) burden, impact and threat that falsified and substandard medicines pose to the African region. We also propose recommendations that have enormous potential for governments, policy makers, legislatures, development partners and communities, which must be supported by political commitments and resources, to promote health and contribute to the economic, social, health and well-being of the region.

2. The pharmaceutical market in Africa and fate of falsified and substandard medicines

The African region represents one of six WHO regions and includes

Abbreviations: SDGs, Sustainable Development Goals; WHO, World Health Organization; CDs, Communicable diseases; NCDs, Non-communicable diseases; US\$, United State Dollars; PwC, PricewaterhouseCoopers; CGMP, Current Good Manufacturing Practice; AU, African Union; AMA, African Medicines Agency; PPMVs, Patent and Proprietary Medicine Vendors; PMSs, Patent Medicine Sellers.

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14% of the world's population spread across 47 countries. The African region is the second most populated region with 95% of the population aged <60 years [3]. The region also faces a high (and increasing) burden of communicable diseases (CDs) and non-communicable diseases (NCDs) [3]. Africa's pharmaceutical market is growing in every sector, with a net value worth of US\$28.56 billion in 2017, which has increased from a value of US\$5.5 billion a decade earlier [4]. This increase has been driven by many growing forces, including more healthcare facilities, affordability, thriving business environments, urbanisation, and favourable economic and political will. However, Africa's pharmaceutical market has also been fuelled with many challenges, including the global public health crisis of falsified and substandard medicines. Reliable research and information on the true picture and impact of falsified and substandard medicines in the region is scarce.

Falsified and substandard medicines exist in every region of the world; however, Africa bears a significant burden of this problem worldwide [2]. The African region also has the highest prevalence of poor-quality medicines, with an 18.7% prevalence of falsified and substandard medicines amongst low-and middle-income countries worldwide [5,6]. The market for falsified and substandard medicines has been estimated to be worth US\$65–200 billion each year globally [3]. Similarly, the World Custom Organization reported that approximately US \$200 billion worth of fake and potentially harmful medicines are sold every year around the world [7].

Between 2013 and 2017, the WHO reported that 42% of all fake medicines reported to them were from Africa, with 50% of drugs for sale on internet being counterfeit [2]. In addition, a report by PricewaterhouseCoopers (PwC) found that approximately 1 million patients die annually, with 450,000 preventable malaria deaths, caused from toxic counterfeit pharmaceuticals [8]. This death toll is only the tip of the iceberg, with Africa contributing to almost 92% of the global burden of malaria cases [3]. The growing number of falsified and substandard medicines also constitutes a major hazard to other prevalent diseases in the region, such as HIV, hypertension, diabetes and tuberculosis. Results from a study in ten sub-Saharan African countries show that nearly one-quarter of the available generic antihypertensive drugs were found to be of poor quality, which could lead to deleterious consequences in the population [9]. Similar results were also seen in a study that evaluated anti-tuberculosis drugs in Africa, India and other middle-income countries, with the percentage of substandard medicines being 16.6%, 10.1% and 3.9%, respectively [10].

Falsified and substandard medicines present a huge setback to the global fight against diseases of major public health concern, such as malaria, and other diseases prevalent in the region despite decades of control efforts from multiple angles converging efforts of the regional governments, the WHO, the Global Funds and various international non-profit organisations.

3. Public health impacts and challenges

Ensuring the circulation of safe medicines to Africa's healthcare system is a key challenge. Medicines save many lives; however, many lives are also lost when medicines are unsafe, falsified or substandard. While progress is being made towards improving access to quality healthcare for the African population, the issue of falsified and substandard drugs remains a neglected problem in the region. Falsified and substandard medicines are a major problem in Africa because either (i) there is limited access to affordable, quality, safe and effective medicines or there is poor pharmaceutical governance, and/or (ii) there is weak technical capacity with poor supply-chain management in African healthcare systems [2].

The majority of people in Africa have not benefitted from advances and technological innovations made in medicines, digital health and public health [3]. Many of the effects of falsified and substandard medicines go beyond public health and threaten to impact socioeconomic and global health security. However, most of the burden of these

effects are seen in rural areas, which often lie beyond the reach of regulations, policies and services [1]. The main challenges in tackling the problem of falsified and substandard medicines include inadequate resources, affordability and availability of quality medicines, weak and fragmented health regulations, lack of price controls, limited access to health services and technologies, recurrent disasters, conflicts and disease outbreaks, global supply chain disruptions, poor management of health resources and extreme poverty [2].

While many interventions are being put in place in different parts of the world to improve access to quality medicines, this is not the case in the African region. Technology is a crucial area and one where progress has been made, even if it is slower than hoped in developing regions of the world. In 2019, the European Union (EU) Falsified Medicine Directive made it mandatory for all pharmaceutical companies operating in the region to adopt extensive serialisation procedures and anti-counterfeiting measures on the packaging for all prescription drugs, including tamperproof seals [8]. In Africa, the situation is unsatisfactory, with only batch numbers and expiry dates being recorded for most products (as required by Current Good Manufacturing Practice [CGMP]) in the region. To address these growing problems, all African Union (AU) countries signed a treaty to create an African Medicines Agency (AMA) in February 2019 [6,11]. The AMA will coordinate the regional harmonisation of systems that are enabled by AU Model Law domestication and implementation as part of its mandate [6]. In addition, seven African countries (Congo, Niger, Senegal, Togo, Uganda, Ghana and Gambia) have created a new initiative (the 'Lomé Initiative') to criminalise the trafficking of falsified and substandard medicines with substantial penalties and to ensure access to quality medicines for the African population [7].

Most African countries have policies that support medicine regulation, but only 15% have a legal mandate to perform all the core regulatory functions [6]. It is also illegal in all countries of the region to sell pharmaceutical products, such as medicines on the streets; however, medicine hawking remains a common practice in most African countries and is dominated by cheap, counterfeit and poor-quality medicines [4]. Strategies that have been put in place by some countries in Africa are often not able to adequately address or respond to this challenge.

In many countries, out-of-pocket payments also significantly contribute to the increased prevalence of falsified and substandard medicine circulation in the region [3]. Out-of-pocket expenditure is catastrophic, with <20% of the total health expenditure [4].

The issues created by falsified and substandard medicines are seen in many countries across the African region, which have also experienced violence, humanitarian crisis and armed conflict [1]. This has taken a major toll on human life and disrupted the supply chain of medicines to the region. As a result, efforts to reduce out-of-pocket payments, improve supply chains and strengthen regulatory frameworks have had limited success. Inevitably, inadequate awareness and limited surveillance is also a major challenge that the region is facing.

The Patent and Proprietary Medicine Vendors (PPMV), Patent Medicine Sellers (PMS) and open drug markets in many parts of Africa are a common feature of the informal health sector and sell all categories of medicines; however, little has been reported about the services they offer beyond their legal scope of practice [12]. They offer private health services in shops and operate as wholesale drug merchants, drug traffickers, shop keepers and market traders, with many of their practices reported to be substandard [13].

4. Recommendations

Despite all the challenges, African countries have a unique opportunity to improve access to quality, accessible, affordable essential medicines. A coherent government-led strategy is required that includes regulations, policies, legislations, community-based approaches, collaborations and investments, which all must be scaled up before this the situation gets out of control. Strengthening the current dysfunctional

and weak healthcare systems and tailoring them to the needs of each country and each community will complement recommendations herein towards achieving the desired goals and lead to progress in disease control.

Several key elements need to be in place to ensure stronger, long-term, high-level political will and commitment to ensuring regulatory reforms are implemented. It is imperative that a powerful regulatory network is established in Africa that is responsible for authentication at all supply chain junctures, especially smartphone-based anti-counterfeiting apps. Improved networking and information sharing amongst the medicine regulatory agencies across African countries is also essential.

One of the main reasons that falsified and substandard medicines are such a problem is cost. By any measure, healthcare financing in Africa is often piecemeal. The challenge has always been to expand healthcare coverage through insurance services, which has had varying success across the region. Many African individuals trying to access essential quality medicines are also thwarted by the cost to adequately treat common diseases. Unfortunately, 76% of the population in sub-Saharan Africa live on less than US\$2 per day [1]. Two decades ago, African heads of state made a commitment to allocate at least 15% of their annual budget to the health sector [1]. However, out of the 46 member states, only two countries (Rwanda and South Africa) have honoured this commitment to spend 15% or more of their national budget on health [3]. Other African countries should be encouraged to rise to this commitment - it is better to be late than never.

In Africa, government health expenditure is rare; the patient and their family are expected to cover the majority of medical costs. Until recently, few countries in Africa have fully functional insurance agencies for the entire population, which has hampered healthcare efforts. There is a need for the development and implementation of sustainable medicine price control policies and also a requirement for these policies to be enforced when they are in place. Despite some countries' efforts to strengthen investment in medicines production, much remains to be done. Lack of local pharmaceutical companies make it more difficult to provide access to quality medicines and this trend is likely to continue. If progress is going to be made towards curtailing the problem of falsified and substandard medicines, more investment is required in local production to serve as conduits to availability of essential medicines, delivery of quality care and disease prevention [1].

In view of the significant role that non-governmental organisations and civil society groups play in Africa's healthcare delivery, it is highly important that governments strengthen collaborations with these organisations and also create positive environments to achieve the goal of quality, accessible and affordable medicine delivery. Government-led action, with the support of the WHO, AU, World Trade Organization (WTO) and other international agencies, is required to regulate the open drug market, investment in pharmaceutical companies, and promote rational use of medicines, appropriate selection, procurement and effective distribution. This will help the region develop information systems to collect reliable data on medicine dealers and medicines in circulation. It is also important to scale-up awareness and reliable data, which is crucial for deriving timely and evidence-based public health information for planning, development, monitoring and evaluation of policies.

Policy makers should rethink the training, licensure and scope of patent medicine vendors. Unfortunately, currently, the minimum benchmark to operate a patent medicine store in many African countries is only the ability to read and write, even though they sell a broad range of products beyond their expertise. Governments in many countries must formulate policies and enact legislations designed to bridge the gap in the areas covered by PPMVs and PMSs, and set up training, monitoring and evaluation systems towards strengthening and coordinating their activities.

A further key to success is boosting community-based approaches as these form the basis of what is feasible in low-resource settings. Current efforts need to be increased to bring professionals, such as pharmacists

and/or pharmacies, closer to the community in both urban and rural areas [14]. Pharmacies play a pivotal role in the correct use of medicines and they are essential in the successes of providing access to quality, safe and affordable medicines in Africa.

5. Conclusion

While addressing the challenges, major threats and implications that falsified and substandard medicines pose to Africa, it has become evident that governments, stakeholders and development partners must collaborate and reinforce their dedication and commitment towards overcoming this problem. Focussing on strengthening regulations, policies, legislations, community-based approaches, collaborations, investments and training will contribute greatly towards averting many preventable deaths and reducing disease burden in the region. A paradigm shift is required and more needs to be done to avert this silent epidemic in Africa.

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Declaration of competing interest

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