Challenges in addressing the menace of counterfeit pharmaceuticals in Kenya

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Abstract
This paper examines the hurdles in addressing the existence of counterfeit pharmaceuticals in Kenya. It looks into issues of corruption, dilemmas in the use of anti-counterfeit technology, the proportionality of punishments, and the politics of the counterfeit economy. The brief recommends zero-tolerance policies on trade in counterfeit pharmaceuticals to improve Kenya’s health care system.
Context

Kenya continues to experience the proliferation of counterfeit pharmaceuticals, due to weaknesses in enforcing and implementing existing governing policies. The vice not only places the country’s health system at risk, but also portends significant economic damage. The cost of fake medicines in the country is estimated at KES 9 billion annually in taxes. By 2015, counterfeit medication accounted for nearly 30 per cent of medicines sold nationally. In 2010 and 2019, 9,072 kilograms and over 12 million units of counterfeit medication were seized respectively at the port of Mombasa, which is a notorious entry point for organised criminal groups trading in fake essential pharmaceuticals. Falsified medication consist of harmful toxic substances, hence endangers the lives of citizens. They alter treatment procedures, posing life threatening risks to consumers often leading to death. Additional factors such as neglect in monitoring expiration dates and storage conditions increase the likelihood of potential harmful effects of unlawful medicines.

This brief examines the impediments to a counterfeit-free pharmaceutical environment in Kenya while exploring existing policy enforcement gaps which allow for the proliferation of the sub-standard medicines in the country. It also proposes mitigation measures to secure the country’s pharmaceutical industry.
Key Issues

The following issues are essential in the discussion on securing Kenya’s pharmaceutical market from counterfeit trade.

Corruption

Misuse of public funds has largely compromised the provision of affordable quality health care in public health facilities leading to increased dependency on cheap counterfeit drugs. Reports of corruption and embezzlement of funds amongst key health institutions, such as the Kenya Medical Supplies Agencies (KEMSA) have characterized public service delivery during the Covid-19 pandemic. In 2017, the United States government suspended a USD 21 million aid package intended for the betterment of Kenya’s health system due to corruption-related allegations associated with politically connected individuals and businesses. The situation, coupled with ineffective public service delivery, has contributed to the rise of unregulated and cheap private health care facilities, particularly pharmacies. Many underprivileged Kenyans have opted for more affordable pharmacies as primary healthcare sources thereby creating a ready market for counterfeit drugs.
The use of technology

The country has seen the emergence of new mobile technology applications such as Tambua and Brandmark to assess the legitimacy of medicinal products through merchandise barcodes. They have been in use since 2018 through partnerships between the governing agency, Pharmacy and Poisons Board (PPB), and Cosmos Pharmaceuticals, a business enterprise. Nevertheless, the utilization of this sophisticated technology to identify counterfeit drugs remains a challenge to a majority of Kenyans due to low levels of awareness of the existing technology amongst members of the public and lack of adequate media coverage on the use of such mobile applications. Consequently, many have fallen victim to counterfeit medicines due to their close resemblance to the original products and the fact that they are sold through the same distribution channels as genuine products.

On the other hand, the rise of online platforms promoting the sale of counterfeit medicines and medical products has, however, made it difficult for the use of Tambua and Brandmark to dissuade the public from purchasing counterfeit medicines. Moreover, tracking of these online counterfeit businesses remains a challenge to enforcement agencies due to difficulties in tracing and locating online sellers. It is equally difficult to monitor appropriate safeguards for dispensation of medication and as well as the valid and safe prescription of drugs. There remains a gap in ensuring that as PPB continues to promote Tambua and Brandmark to ascertain pharmaceutical legitimacy, it is not outpaced by competing online platforms promoting use of counterfeit medicine.
Counterfeit pharmaceuticals’ trade thrives in environments with weak enforcement and regulatory systems. Despite the existence of laws to address the gaps, imprisonment terms, fines, and penalties associated with counterfeited goods need to be enhanced. For instance, the maximum imprisonment sentence for a first time offender under Section 35 of the Anti-Counterfeit Act, is five years or a fine not less than three times the value of the prevailing retail price of the goods. Under Section 18 (2) of the Pharmacy and Poisons Act, failure to surrender the certificate of registration pertaining to the delisting of pharmacies guidelines invites a fine not exceeding ten thousand shillings, or a maximum imprisonment term of one year. Section 19, of the same Act which provides guidelines on restrictions to unregistered persons handling pharmaceuticals similarly prescribes lenient punishment for non-compliance. The stipulated punishment of a fine not exceeding thirty thousand Kenya shillings or a maximum imprisonment term of 3 years or both, does not match the seriousness of the crime committed, taking into account the potential harm to human life. This subjugates the latent ramifications, therefore undermining regulations and cultivating an environment for the growth of counterfeit business in the country. Consequently, such offences necessitate more stringent penalties, equivalent to the magnitude of the crime committed to act as a deterrent and limit recidivism.

Proportionality of punishments

Counterfeit pharmaceuticals’ trade thrives in environments with weak enforcement and regulatory systems. Despite the existence of laws to address the gaps, imprisonment terms, fines, and penalties associated with counterfeited goods need to be enhanced. For instance, the maximum imprisonment sentence for a first time offender under Section 35 of the Anti-Counterfeit Act, is five years or a fine not less than three times the value of the prevailing retail price of the goods. Under Section 18 (2) of the Pharmacy and Poisons Act, failure to surrender the certificate of registration pertaining to the delisting of pharmacies guidelines invites a fine not exceeding ten thousand shillings, or a maximum imprisonment term of one year. Section 19, of the same Act which provides guidelines on restrictions to unregistered persons handling pharmaceuticals similarly prescribes lenient punishment for non-compliance. The stipulated punishment of a fine not exceeding thirty thousand Kenya shillings or a maximum imprisonment term of 3 years or both, does not match the seriousness of the crime committed, taking into account the potential harm to human life. This subjugates the latent ramifications, therefore undermining regulations and cultivating an environment for the growth of counterfeit business in the country. Consequently, such offences necessitate more stringent penalties, equivalent to the magnitude of the crime committed to act as a deterrent and limit recidivism.
Interagency collaboration

The challenge of collaboration and coordination among law enforcement key players, such as the Anti-Counterfeit Authority (ACA), the Kenya Bureau of Standards (KEBS) and the Ethics and Anti-Corruption Commission (EACC), encourages this unlawful trade. Agencies mandated with safeguarding the interest of consumers from counterfeit medication have continuously presented inadequacies, in controlling the production and entry of unlawful pharmaceuticals into the Kenyan market. In fact, a 2018, report by the Kenya Auditor General indicates that the Kenya Medical Supply Agency (KEMSA) had supplied expired drugs worth USD 1.5 million to government hospitals in the country. Similarly, institutions including the Ministry of Health (MOH), Kenya Revenue Authority (KRA), Anti-Counterfeit Agency (ACA) and the National Police Service (NPS) have been accused of conflict of interest, undermining their credibility in the fight against counterfeit medicines. The Inter-Agency Anti-I illicit Working Group (AIAIWG) formed in 2018 to strengthen interagency coordination in combating trade in counterfeits is yet to deliver on its mandate. The lack of a comprehensive framework for collaboration coupled with existence of bureaucratic silos and individual institutional weaknesses, have enhanced laxity amongst supervisory bodies in coordinating the fight against substandard medications in Kenya.
Politics of the counterfeit economy

The counterfeit economy is centered around increased reliance on counterfeit trade by the government to sustain revenue flow in times of adversity. Poor economies heavily rely on the sale of substandard goods to sustain cash flows and thus generate revenue for the government. The political advantage of an economy that relies on the sale of counterfeits is that it helps the system cure salient issues of cash flow, unemployment and poverty. The higher the demand for counterfeit pharmaceutical goods, the more the revenue for the government regardless of whether this kills legitimate economies. Therefore, in as much as the major pharmaceutical companies are affected by the existence of counterfeits in the market, the inadequacies of authorities in combating them indicate a silent non-intervention strategy meant to create livelihoods to a population facing such socio-economic challenges like unemployment. This raises the question on political goodwill and the readiness of government to deal with counterfeit pharmaceuticals. As revenue continues to be generated from businesses involved in counterfeits to cushion the economy, the war against counterfeits remains active.
Conclusion

The rise of counterfeit pharmaceuticals in Kenya remains a risk factor to the economy and public healthcare systems. There is need for adequate and prompt policy interventions addressing enforcement of existing laws, corruption in key health institutions and lapses in collaboration among concerned regulatory bodies. The use of technology in identifying fake medicines; the lenient punishments for potential law offenders and the lack of political goodwill highlight pitfalls that have so far minimized efforts to combat the menace. A consumer centred initiative across all relevant stakeholders including government ministries and agencies, parliament and consumers, remains essential in realising a counterfeit-free pharmaceutical environment in the country.

Recommendations

a) The Presidency should remain at the forefront in combating counterfeit pharmaceuticals through regular public pronouncements and participation in anti-counterfeit operations such as destruction of seized goods.

b) The Ministry of Health should institute collaborative initiatives with the Kenya Revenue Authority (KRA), Anti-Counterfeit Authority (ACA), the Kenya Bureau of Standards (KEBS) and the Ethics and Anti-Corruption Commission (EACC), to facilitate the identification of unregulated pharmacies dealing in counterfeit pharmaceuticals. This can be done by empowering the AIAIWG to develop a comprehensive collaborative framework on counterfeit medicines and whistle-blower guidelines for identifying the dealers.
Recommendations

c) The Pharmacy and Poisons Board should collaborate with County Governments to create public awareness on the use of existing technology to identify counterfeit medicines at the pharmacy level.

d) The Parliament of Kenya should:

i. institute amendments to Section 35 of the Anti-Counterfeit Act to enhance the punishments for dealing in counterfeit medicines.

ii. institute amendments to Section 19 of the Pharmacy and Poisons Act to enhance the punishments for non-compliance with registration guidelines.

e) The Ministry of Health in collaboration with the Ministry of Information, Communications and Technology should:

i. Mandate all dealers and manufactures of pharmaceuticals to avail to all pharmaceutical consumer’s information that would help them verify the legitimacy of all the medicines they purchase. This should be displayed on the medicine containers and on a notice board within the pharmacy store.

ii. Promote awareness campaigns targeting vulnerable populations on the negative effects of counterfeit medicine.

iii Partner with relevant stakeholders such as health technology research based corporations to come up with monitoring systems to regulate the sale of pharmaceuticals online.

f) The AIAIWG should enhance its capacity to deal with counterfeits at the local manufacturing hubs and entry points before they get to distribution points.
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