Policy Brief

February 2022

Fighting substandard & falsified (counterfeit) medicines in SADC

Rethabile Molapisane & David R. Katerere

TUT Platform Chair, Pharmaceutical &Biotech Advancement in Africa (PBA2)

Southern African Academy of Pharmacy (SAAP)

Who is this aimed at

- Medicine regulatory authorities in the SADC region
- Policy makers and legislators of SADC member states and SADC Secretariat
- Pharmaceutical companies and health care workers

Key messages

- Substandard, unauthorised and counterfeit medicines (SFs) are an ongoing concern in the region and COVID-19 has exacerbated the situation.
- Anti-counterfeit policies at institutional, country and regional level will help to combat of SFs.
- Stakeholder collaboration is key in securing SADC medicine supply chain and ensuring access to safe essential medicines.
- Regional collaboration between regulators, law enforcement and policymakers should be enhanced because counterfeiting of medicines is a cross border or transnational crime.
- Public awareness and education about counterfeits, their sources and the dangers associated with their use should be considered part of public health promotion and messaging.
- Resources should be mobilized and provided to regulators and researchers for regular market surveillance studies.

Key findings

- Absence of a pharmaceutical anti-counterfeiting strategy makes implementation of law enforcement efforts ineffective.
- Weak penalties for being involved with the sale, distribution or manufacture of SFs are not harsh enough to deter criminals.
- Inadequate resources in human capacity, forensic intelligence profiling, budget constraints and shortage of testing and quality assurance laboratories is a major hurdle in the law enforcement against proliferation of SFs.
- Poor national inter-agency collaboration and regional collaboration makes information sharing and planning of combat campaigns difficult and sporadic. Often there is duplicity of function due to competing mandates between governmental agencies.
- Poor Post Market Surveillance and reporting of SFs creates gaps in the system in monitoring of the market.

Executive Summary

The problem of counterfeit medicines and vaccines is a serious public health concern and needs urgent interventions. COVID 19 has created a favourable environment for the proliferation of substandard and falsified health products and medicines because of shortages and reduced access to medicines which have resulted from the pandemic. In addition, there has been an increase in online sales of medicines from unregulated suppliers which lie outside traditional and conventional pharmaceutical supply chains.
The regulation of pharmaceuticals and health products in many SADC member states is by way of Medicines and Related Substances legislation, most of which was enacted in the 1960's and 1970's, and has not been regularly reviewed and amended. Thus it lacks harmonization with other Acts and it does not explicitly allude to "pharmaceutical crimes" nor include specific medicine counterfeiting provisions. In addition, it does not regulate online sales of medicines and health products.

Background

Counterfeit medicines, also known as Substandard and Falsified" (SFs) are medicines which are deliberately and fraudulently mislabelled with respect to identity and/or source (WHO, 2017). The definition also includes medicines have failed to pass the quality measurements and standards set for them. A systematic review showed Africa to have a higher prevalence of substandard medicines at 18.7% of the samples tested while the prevalence was much lower in Asia at 13.7% and 14.4 % in other regions[4]. Shortages caused by the COVID-19 pandemic, the promotion of unconventional treatments by social media, and the increased use of the internet to buy goods have all served to accelerate the trade on SFs in the SADC region and elsewhere. There were reports of seizures of illegal chloroquine in Cameroon, Niger and the Democratic Republic of Congo (DRC) [5], and water for injection marketed as COVID-19 vaccines was seized in South Africa. Operation Pangea XIII action against online SFs found 2,000 online links advertising COVID -19 related products sold online (INTERPOL, 2020). These products included substandard and fake Personal Protective Equipment (PPEs), screening medical devices and hygiene products like sanitisers.

The trade in counterfeits is driven in part by increased demand and the high cost of medicines and vaccines, weak penalties for offenders compared to the profitability of the business, lack of resources and capacity to implement existing laws, non-existent post market surveillance systems and poor stakeholder collaboration and information sharing locally and regionally[1].

What are the impacts of SFs?

SFs have many negative impacts on patients, SADC member states and companies operating in the region. These include

- ***Public health threat resulting from*** endangering patients' lives by either prolonging illness or resulting in disability or death. This also further contributes to the poverty burden due to loss of income in poor communities (Kelesidis & Falagas, 2015).
- ***Drug resistance and treatment failure may result in longer hospital stay and the need to use more complex and expensive*** *medicines.*
- ***Loss of public trust*** *in the health care system because there is a perception that* treatments are not working.
- ***Loss of revenue for*** pharmaceutical companies and reduced tax revenue for member states.

[1] An exploratory assessment of the legislative framework for combating counterfeit medicines in South Africa (biomedcentral.com)

Why is an anti-counterfeiting policy needed?

Anti-counterfeiting policy\ies at company, member state and SADC levels will highlight the issue of SFs and create a bulwark against counterfeiters. It will provide a structure and system for improved monitoring, tracking and tracing medicines through the supply chain from raw materials all the way to dispensary shelf. Such policies will also create better in-country and regional co-ordination and create more efficient use of resources.

What is an Anti-Counterfeit Policy?

It is a document that gives directive on the prevention of counterfeiting. Anti-counterfeiting measures are used to deter, detect and control counterfeiting activities. Different packaging related approaches include the use of smart covert and overt technology, track and trace systems as well as code authentication (Soon & Manning, 2019). There are key elements ensuring effective implementation of a policy which are strong leadership, stakeholder engagement, resource mobilisation and monitoring and evaluation (Mthethwa, 2012).

Why might governments want to implement such a policy?

What are the benefits of implementing an Anti- Counterfeit Policy?

- Government creates conditions that foster stakeholder collaboration.
- The pooling of resources will create maximum potential value which can lead to more efficiency, and better stewardship of public funds towards a common goal of combating SFs.
- Increased visibility and education on the dangers of counterfeit medicines will improve treatment outcomes, prevent deaths and harmful adverse reactions and save the pharmaceutical industry and government from financial losses associated with the illegal trade of SFs.
- The Public will have access to information about SFs and how to identify them and report them to the NMRA.
- There will also be a better climate for private public partnerships with Pharma and all stakeholders in combat efforts.
- Better transparency will be cultivated as all stakeholders will be mandated to disclose counterfeiting of medicine incidents.
- Academic institutions and health care workers will be forced to include counterfeiting of medicines in their educational curricula.

Do intergovernmental organisations support national-level adoption of anti-counterfeiting policies?

Yes. The WHO has been spearheading combat strategies since the Declaration of Rome on the 8th February 2006 (Mackey, 2013). This has led to the setting up of the International Medicinal Product Anti-Counterfeiting Taskforce (IMPACT), in partnership with several organisations in both trade and industry such as the German Pharma Fund, and the World Customs Organisation (IMPACT, 2008). They created a blueprint which has been successfully adopted globally at national level. The five key areas in IMPACT's blueprint were to re-inforce legislative and regulatory infrastructure, communication aimed to raise awareness, regulatory implementation, enforcement and technology (Siddiqi et al., 2009).

Where have anti-counterfeit polices been adopted?

A number of countries, and regions have also adopted anti-counterfeit policies or laws. Kenya implemented an anti-counterfeit law in 2008 (Kenyan Ministry of Health, 2008). A review by the East African Community (EAC) led to an initiative to harmonise laws within its member states, as a result Kenya passed its "Anti-counterfeiting Act" in 2008. The Act in section 23 empowers regulatory officers with policing powers from a

wide pool of sectors and departments like customs, police, trade and industry and health as “inspectors” to enforce the law (Forzley, 2012).

The United states, Food and Drug Authority formed the FDA Counterfeit Drug Task Force in July 2003 to prevent the introduction of counterfeit medicines and biologics into the U.S. distribution chain; to facilitating the identification of counterfeit drugs and biologics; to minimise the risk and exposure of consumers to counterfeit medicines; and to reduce unnecessary costs to the prescription medicine distribution system and restrictions on lower-cost sources of medicines (generics) (US FDA, 2009).

What can governments do to combat the manufacture, trade and distribution of SFs?

Governments can incorporate the recommendations in the World Health Organization’s: Counterfeit drugs: guidelines for the development of measures to combat counterfeit drugs. (World Health Organization, 1999).

a) Foster awareness and promote public engagement concerning substandard and falsified medicines.
b) Facilitate information sharing and stakeholder collaboration with multiple agencies and departments involved in the enforcement of against SFs.
c) Promote the development of policies and guidelines for the combat of SFs in line with best practice recommendations.
d) Promote the incorporation of education about SFs in the curricula of schools and academic institutions.
e) Support capacity building for the sustainable development of anti-counterfeiting combat strategies nationally and regionally.
f) Foster strategic alliances with international organisations involved in the combat of SFs globally.
g) Encourage and support further research on counterfeit medicines.
h) Mandate data collection and use risk based assessment systems and trend analysis for combat efforts.
i) Regulate online trade of medicines and pharmacies.

Conclusion

Based on our study, there are gaps in medicine legislation in member states of SADC which allow for the infiltration of counterfeits. We propose that there be anti-counterfeit policies at company, member state and regional level and a law reform process which provides for the incorporation of these policies as well as codifying pharmaceutical crime into the penal code.

References

1. Oyetunde, O. & ilozumba, P. (2013). Mobile Authentication Service: Curbing circulation of fake Medicines and Assessing Consumer's Response. West African Journal of Pharmacy, 24:102-108.
2. Kelesidis, T. & Falagas, M.E. (2015). Substandard/counterfeit antimicrobial drugs. Clinical Microbiology Reviews, 28(2):443-464.
3. Centre for Safe Internet Pharmacies. (2014). Principles of participation for members. https://safemedsonline.org/wp-content/uploads/2014/03/CSIP-Principles-of-Participation.pdf . Accessed 12 October 2018.
4. Jan Mei Soon & Louise Manning. 2019.Developing anti-counterfeiting measures: The role of smart packaging. Food Research International,123:135-143. https://doi.org/10.1016/j.foodres.2019.04.049.
5. “Anti-counterfeiting.” Merriam-Webster.com Dictionary, Merriam-Webster. https://www.merriam-webster.com/dictionary/anti-counterfeiting. Accessed 30 Nov. 2021.

6. Borse, N.N., Cha, J., Chase C.G., Gaur et al. (2021). Responding to the surge of substandard and falsified health products triggered by the Covid-19 pandemic.https://www.usp.org/sites/default/files/usp/document/our-impact/covid-19/surge-of-substandard-and-falsified-health-products.pdf. Accessed 30 Sept 2021.
7. Forzley, M. 2012. Counterfeit hard goods and the public's health and safety: a study of interventions. https://micheleforzley.com/uploads/3/5/4/9/35498635/study_report_v5_9_1_12.pdf. Accessed 20 Feb 2016
8. Johnston, A. & Holt, D.W. Substandard drugs: a potential crisis for public health. British Journal of Clinical Pharmacology. 2014;78(2):218-243.
9. Khader, M. Legal framework: Counterfeit Goods Act. (2015). http://www.worldtrademarkreview.com/Intelligence/Anti-counterfeiting/2015/Country-chapters/South-Africa. Accessed 03 March 2016.
10. World Health Organization. (1999). Counterfeit drugs: guidelines for the development of measures to combat counterfeit drugs. World Health Organization. https://apps.who.int/iris/handle/10665/65892. Accessed 28 June 2015.
11. World Health Organisation. Seventieth-world-health-assembly-update. (2017). https://www.who.int/news/item/29-05-2017-seventieth-world-health-assembly-update. Accessed 29 May 2018.
12. South Africa. Department of Health. Medicines and Related Substances Control Act 101 of 1965. Renamed the South African Health Products Regulatory Authority Act since 2003. (2003). https://www.sahpra.org.za/wp712 content/uploads/2020/02/Government_Gazette_Medicines_and_Devices_Act_Jun_2017-1.pdf . Accessed 15 Sept 2017.
13. Forzley, M. (2016). Counterfeit hard goods and the public's health and safety: a study of interventions. https://micheleforzley.com/uploads/3/5/4/9/35498635/study_report_v5_9_1_12.pdf. (2012). Accessed 20 Feb 2016.
14. World Health Organisation, 2016. Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) medical products. World Health Organization: 2-5. http://www.who.int/medicines/areas/quali.pdf . Accessed 27 April 2017.
15. US FDA., 2020. Drug Quality Sampling and Testing Programs. https://www.fda.gov/drugs/science-and-research-drugs/drug-quality-sampling-and738 testing-programs. Accessed 15 Sept 2021.
16. KENYA. 2008. Anti-counterfeiting Act. Revised 2016. Publisher: National Council for Law Reporting: Kenya. http:/www./kenyalaw.org. Accessed 03 Jun 2016.
17. Donovan, G., Parkin, L., & Wilkes, S. (2015). Special unlicensed medicines: what we do and do not know about them. The British journal of general practice: Journal of the Royal College of General Practitioners. 65(641): e861–e863. https://doi.org/10.3399/bjgp15X688033

18. Siddiqi, S., Masud, T.I., Nishtar, S., Peters, D.H., Sabri, B., Bile, K.M. & Jama, M.A. 2009. Framework for assessing governance of the health system in developing countries: gateway to good governance. Health policy, 90(1):13-25.
19. United States Food and Drug Authority., 2009. Combating Counterfeit Drugs: A report of the Food and Drug Administration. February 2004. http://old.fda.gov/oc/initiatives/counterfeit/report0.html. Accessed: 27 August 2020.
20. Mackey TK & Liang BA. Improving global health governance to combat counterfeit medicines: a proposal for a UNODC-WHO-INTERPOL trilateral mechanism.

BioMedCentral Medicine. 2013; 11(1):233. https://doi.org/10.1186/1741-7015-11-233

21. NAFDAC. Nigeria national Agency for Food and Drug Administration and Control. Laboratory Services Directorate. (2017). https://www.nafdac.gov.ng/about680

nafdac/nafdac-organisation/directorates/laboratory-services-directorate/ . Accessed: 15 Sept 2021

22. MCAZ. Medicines Control Authority of Zimbabwe. Laboratory Services. (2017). https://www.mcaz.co.zw/index.php/how-we-regulate/18-labs/34-laboratory-services.

Accessed: 15 Sept 2021.

23. International Medical Products Anti-Counterfeiting Taskforce. (2008). https://www.who.int/medicines/services/counterfeit/impact-faqwa.pdf. Accessed 12 August 2015.

24. INTERPOL. 2020. Global operation sees a rise in fake medical products related to COVID -19). https://www.interpol.int/en/News-and-Events/News/2020/Global-operation-sees-a-rise-in-fake-medical-products-related-to-COVID-19. Accessed 08 Jan 2021.
25. Nkansah, P., Smine, K., Pribluda, V., Phanouvong et al., 2017. Guidance for implementing risk-based post-marketing quality surveillance in low-and middle-income countries.

In Rockville, MD: US Pharmacopeial Convention. (2017). The Promoting the Quality of

Medicines (PQM) Program. https://www.usp-pqm.org/sites/default/files/pqms/article/risk-based-post-marketing-surveillance-feb-2018.pdf. Accessed 15 Sept 2018

26. Mthethwa, R. 2012. Critical dimensions for policy implementation. African Journal of Public Affairs, 5:37-47.