Policy Insights
87
July 2020

Counterfeit Pharmaceuticals: A Major Threat to Public Health

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African perspectives
Global insights

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Executive summary

The illegal trade of substandard and falsified (SF) medical products (also known as counterfeit pharmaceuticals, medicines or drugs) is a global challenge. It poses a serious threat to the health of populations and for sustainable development of health systems because it undermines efforts to improve access to genuine medication. If a person takes an incorrect drug, it could harm their health or even cause death. The demand for counterfeit drugs is highest in impoverished, developing countries, where most people are unable to afford or access lifesaving drugs through legitimate channels.

This policy insights examines the challenge of SF medical products in a global and an African context, highlighting the challenges posed to healthcare systems. It also discusses the difficulty of assessing the damage that counterfeit drugs cause, since they affect mostly the poor and illiterate. The paper highlights efforts that have been made to curb counterfeit drugs as well as innovations enabled by technological advancements.

Introduction

The illegal trade of SF medical products is a serious threat to the health of populations and for the sustainable development of health systems.[1] It under-mines the efforts of governments, pharmaceutical companies and non-governmental organisations (NGOs) to improve access to authentic medication. Inequalities in access to wealth and healthcare have enabled a new area of expansion of counterfeit drugs.[2] Counterfeit drug trade aims to defraud customers or to reproduce a generic form of a brand name drug that is permitted in certain countries. One of the world's largest and most rapidly growing criminal enterprises is the trafficking of counterfeit goods. Technological advancements have facilitated the production and distribution of larger quantities of counterfeited goods in shorter periods of time and have made it easier for counterfeiters to profit without detection.[3]

Counterfeit drugs put at risk goal number 3 of the Sustainable Development Goals, which focuses on access to universal healthcare services and safe, effective, quality and affordable essential medicines. The trading of these drugs also threatens public health and safety, erodes the tax base, reduces jobs, and inhibits corporate innovativeness and profitability. It is against this background that this policy insights seeks to highlight the proliferation of counterfeit pharmaceuticals.

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1 Robin Cartwrigh and Ana Baric, *The rise of counterfeit pharmaceuticals in Africa*, https://enactafrica.org/research/policy-briefs/the-rise-of-counterfeit-pharmaceuticals-in-africa.

2 Carla Djamila Reis, Eduardo Jorge Tavares and Jailson Jesus Martins, *Illegal market of medicines in Cabo Verde: Characterisation for Action*, (Research Article, Journal of Pharmacovigilance, Cape Verde, 2015), https://www.researchgate.net/publication/283655166_Illegal_Market_of_Medicines_in_Cabo_Verde_Characterization_for_Action.

3 Roy S Fenoff and Jeremy M Wilson, *Africa's Counterfeit Pharmaceutical Epidemic: The Road Ahead*, (Michigan State University, Michigan, 2009), http://a-capp.msu.edu/wp-content/uploads/2018/05/PAPER-SERIES-Africas-Counterfeit-Pharmaceutical-Epidemic_The-Road-Ahead.pdf..

Understanding substandard and falsified medical products

The lack of a universal definition makes it difficult for countries to exchange vital information about counterfeiting and to understand the issue on a global scale as the statistics have a local bias. As such, the WHO proposed a definition of branded or generic counterfeit medicines that are deliberately and fraudulently mislabelled with respect to their identity and/or source.[4] In 2017, WHO member states adopted the term SF medical products to refer to medicines of this type.

Some counterfeit drugs do not have the active ingredients that the label claims, while others have the wrong ingredients or incorrect quantities of the correct ingredients. The WHO estimates that between 1% and 10% of drugs sold around the world are counterfeits and that 16% of counterfeit drugs contain the wrong ingredients, while 17% contain the wrong levels of necessary ingredients. Medicines in their original form are designed to be targeted and aggressive; active ingredients are measured in order to be effective. If therapeutic levels of a drug cannot be reached, then an effective treatment cannot be achieved, making counterfeit drugs dangerous.[5] Fake drugs are also dangerous because they are made in unhygienic conditions.

Counterfeit pharmaceuticals in a global context

The pharmaceutical industry is worth nearly $1 trillion in drug sales annually, making it highly profitable. The WHO estimates that counterfeit medicines constitute more than 50% of the global drug market, with a significant portion being experienced in developing countries.[6] The US Food and Drug Administration estimates that more than 10% of medicines in the world are counterfeit. It has also been found that groups which distribute counterfeit medicines thrive mostly in countries where

- anti-counterfeiting laws are weak;
- the pharmaceutical regulatory agencies are underfunded and understaffed; and
- legal sanctions are ineffective.[7]

There has been a drastic increase in the incidence of counterfeit drugs in developed countries. Statistics from 2005–2010 show that there was a 400% increase in incidents in

4 Beverly D Glass, *Counterfeit drugs and medical devices in developing countries*, (Dove Medical Press Limited 3, no 5 (2014): 11-22.
5 Terri Chowles, *The Counterfeit Medication Epidemic*, https://ehealthnews.co.za/counterfeit-medication-epidemic/.
6 Glass, *Counterfeit drugs*.
7 Pharmaceutical Security Institute, *The Challenge*, https://www.psi-inc.org/about.

Europe alone[8]; however, the incidence of counterfeit drugs is much higher in developing countries. Trading with counterfeit pharmaceuticals is 25 times more profitable than that of heroin[9], motivating criminals to expand their operations in this illegal business. The counterfeit medicines market is growing fast - its estimated value was $200 billion in 2018, making it the most profitable sector in illegally copied goods in 2018.[10] Between 2000 and 2006, the illegal medicines market increased by 800%.[11] The prescription drug market is also large and lucrative – up to $900 billion worldwide annually.[12]

Because counterfeits are manufactured at a much lower cost (no research and development costs) than genuine medicines, they are much cheaper[13], making them attractive to people who cannot afford genuine, expensive medicines. Legitimate pharmaceutical manufacturers are heavily impacted by counterfeit drugs as they lose approximately 40% of their sales to counterfeiters.[14] India and China are the leading counterfeit drug manufacturers, with over 50% of the global supply of counterfeit pharmaceuticals having Chinese origin.[15] A drastic escalation in the number of pharmaceutical producers in these two countries makes it harder for their governments to regulate the production of counterfeit drugs. India is well known for its low-cost manufacturing base which makes it vulnerable to counterfeit drugs. It is estimated that there are more than 8 000 small units (local syndicates) that are manufacturing counterfeit pharmaceuticals in India, making it almost impossible for regulators to catch them. Without adequate surveillance and appropriate penalties for these unlawful activities, regulators do not have the tools to enforce quality standards and to take counterfeit pharmaceuticals off the market.[16] China, through its government, state-owned companies and private businesses, entered Africa on its own terms – thus, without any involvement with international organisations operating in health, education and poverty reduction.[17] This made it easy for counterfeiters to enter the market, jeopardising the health interests of vulnerable populations on the continent.

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8 Glass, *Counterfeit drugs*.

9 Silas Webb, *A bitter pill to swallow: the problem of, and solutions to, Sub-Saharan Africa's counterfeit pharmaceutical trade*, The Journal of Global Health , November 1, 2014, https://www.ghjournal.org/a-bitter-pill-to-swallow-the-problem-of-and-solutions-to-sub-saharan-africas-counterfeit-pharmaceutical-trade/.

10 Cartwright and Baric, *The rise of counterfeit pharmaceuticals*.

11 Carla Djamila Reis, *Illegal market of medicines in Cabo Verde: Characterization for Action*. Journal of Pharmacovigilance 3, no. 5 (2015): 1-6.

12 Health Research Funding, *20 Shocking Counterfeit Drugs Statistics*, https://healthresearchfunding.org/20-shocking-counterfeit-drugs-statistics/.

13 WipoTec, Falsified medicines directives- preventing drug falsification, https://www.wipotec-ocs.com/en/serialisation-pharma/falsified-medicines-directive/?gclid=CjwKCAjwzJjrBRBvEiwA867bysRzoCSxh05iXtzDYkXPx4ciden0AQ1wMM80pKCjp9Rkwrm0BQ4fyBoCIIwQAvD_BwE.

14 A Seiter, `*Health and economic consequences of counterfeit drugs*', Clinical Pharmacology & Therapeutics 85, No 6 (2009): 576-578.

15 Fenoff and Wilson, *Africa's Counterfeit Pharmaceutical Epidemic*.

16 NP Ullekh and ET Bureau, *Fake & sub-standard drugs: India, China may be worst offenders*, The Economic Times, June 16, 2013, https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/fake-sub-standard-drugs-india-china-may-be-worst-offenders/articleshow/20608101.cms?from=mdr.

17 Kathleen McLaughlin, *Fake Fake drugs from China: What's stopping a cure for malaria in Africa?*, https://www.theatlantic.com/china/archive/2013/06/fake-fake-drugs-from-china-whats-stopping-a-cure-for-malaria-in-africa/276750/.

Counterfeit drugs increase health inequality between the global north and south, in terms of access to quality healthcare

Counterfeit drugs increase health inequality between the global north and south, in terms of access to quality healthcare.[18] The undesirable side effects and no therapeutic value of counterfeit drugs in the global south, particularly Africa, cause people (located predominantly in rural areas) to question the credibility of modern medicines and pharmaceutical industries. They then opt for traditional medicines instead. This hinders the process of developing modern health care facilities and the use of modern medicines, limiting potential access to legitimate pharmaceuticals.[19] This resistance from the global south to adopting modern medicines from the global north further exacerbates the inequalities in access to and use of modern medicines.

In 2014, about 60 Pfizer medicines and products counterfeited around the world made their way into hospitals and pharmacies in 46 countries, including the US, Canada and England.[20] As a result of Pfizer's own investigative work, about 50 – 60 convictions were made that year. In the same year, 237 people were arrested worldwide and 10 603 websites that were selling counterfeit medicines were shut down, compared to 2 414 websites in 2015. Websites are usually managed by syndicates based in foreign countries, making it difficult for authorities to catch them.[21] From 2017 to 2018, the Pharmaceutical Security Institute (PSI) found that there was a 25% increase in pharmaceutical crime incidents and, over the past five years, incidents increased by 102%. The PSI also found that 961 counterfeiting incidents involved either customs seizures or police/health inspector raids. Between 2017 and 2018, seizures increased by 63%. Figure 1 shows the incidents per region. The regions with the most incidents are the ones that are effectively identifying pharmaceutical crime through law enforcement activity and inspections by drug regulatory agencies. Regions with low incident totals have weak enforcement and inspection programmes, inadequate regulatory structures and, in certain instances, SF medical products often go undetected.[22]

The trade in counterfeit drugs uses complex distribution networks, making it hard to create a distinct criminal profile that identifies producers and sellers. Those producing and distributing these drugs are diverse in terms of their roles, involvement and level

18 Webb, *A bitter pill to swallow.*

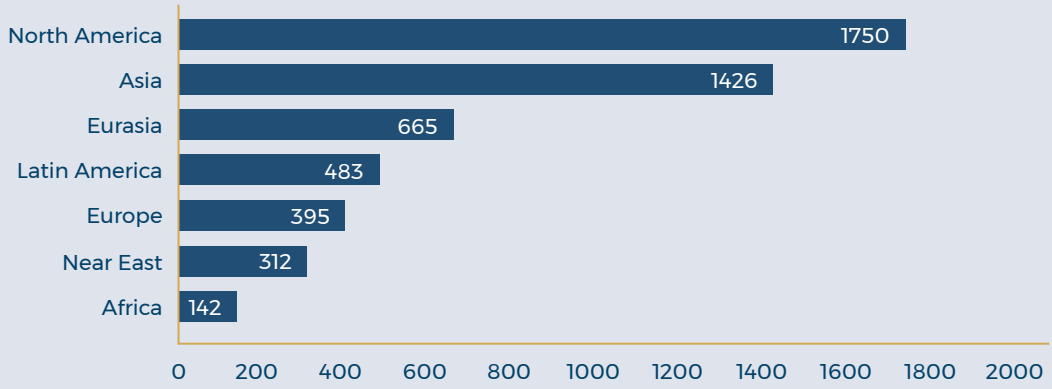
19 Elaine Tai, *Counterfeit medicines in Kenya*, Pfizer Global Health Fellows Program essay, (2011) https://www.pfizer.com/files/responsibility/global_health/elaine_tai.pdf.

20 CBS News, 60 Minutes, *The fight against counterfeit drugs*, March 13, 2011, https://youtu.be/6Djftj0bwus (Online video from CBC News – found on YouTube).

21 Medical Brief, *Counterfeit medicines flooding SA*, August 11, 2015, https://www.medicalbrief.co.za/archives/counterfeit-medicines-flooding-sa/.

22 Pharmaceutical Security Institute, *Geographic Distribution*, (2019), https://www.psi-inc.org/geographic-distribution.

Figure 1 Pharmaceutical crime incidents reported by regions of the world



NOTE: Totals exceed 4405 incidents because a region is included if it is the 'origin, point of seizure or transit, or destination' of illegal pharmaceuticals

Source: Pharmaceutical Security Institute, Geographic Distribution, (2019), https://www.psi-inc.org/geographic-distribution

of organisation. This makes them hard to identify, as the flow of these drugs involves numerous people and organisations from different parts of the world. They include pharmacists, doctors, criminal groups, pharmaceutical companies and corrupt government officials.[23] For example, 80% of the counterfeit drugs that are consumed in the US come from overseas through a complicated web of suppliers and distributors who are increasingly vulnerable to counterfeiters. Thirty-six million Americans are estimated to have bought fake medicines from internet pharmacies. Counterfeit drugs have also become a tool to fund terrorist activities since the current international framework is not equipped to protect the international pharmaceutical industry from terror organisations.[24]

Under the provisions of the Trade-Related Aspects of International Property Rights, medicines are treated as ordinary consumer products, which they are not.[25] Patents expire approximately 20 years from the date of approval[26] and they prohibit competitors from manufacturing or distributing 'multisource or generic medicines',[27] which are usually the only form of legitimate medication easily accessible in developing countries. Although patents were made with the objective of allowing inventors to regain their investment

23 Fenoff and Wilson, *Africa's Counterfeit Pharmaceutical Epidemic*.

24 Douglas Cannon, *War through pharmaceuticals: how terrorist organisations are turning to counterfeit medicine to fund their illicit activity*, Case Western Reserve Journal of International Law 47 (2015): 344-345.

25 Management Science for Health, MDS3, *Managing Access to Medicines and Health Technologies*, Arlington, VA: Management Science for Health, 2012.

26 Zachary Brennan, *Patents vs. Market Exclusivity: Why Does it Take so Long to Bring Generics to Market?*, Regulatory Focus. August 17, 2016. https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/8/patents-vs-market-exclusivity-why-does-it-take-so-long-to-bring-generics-to-market.

27 Management Science for Health, MDS3, *Managing Access*, 2012.

in research and development during the process of manufacturing, this resulted in high prices, making them almost impossible to access for people in developing countries. This is tantamount to a violation of the universal right to quality health, provided for in the 1966 International Covenant on Economic, Social and Cultural Rights.

Drug development is significantly dependent on high revenues expected from high prices of current drugs because the cost of development is continuously increasing.[28] In 2003, drug development cost $802 million, increasing to $1 billion in 2013, an increase of 145% in just 10 years.[29] A recent study by Tufts Center for the Study of Drug Development showed that it currently costs drug developers $2.6 billion to develop a drug. Not only is development and approval costly but it takes a lot of time. Although there is no typical timeframe, data shows that it takes between 10 and 15 years to get clinical approval.[30] These conditions have created market exclusivity that prevents new, and perhaps cheaper, drugs from entering the pharmaceutical market. Market exclusivity makes pharmaceuticals expensive, which limits access by poor and vulnerable people in developing countries to quality medication.

Counterfeit pharmaceuticals pose a health epidemic in Africa

About 85% of the world pharmaceutical market is in developed countries. Yet 10–30% of all medicines sold in developing countries are counterfeit compared to only 1% sold in industrialised nations. In developed countries, one out of 10 medicines might be counterfeit, while in Africa, seven out of 10 pharmaceutical products are estimated to be counterfeit. A report by the WHO in 2003 showed that 200 000 out of approximately 1 million malaria deaths each year were caused by counterfeit anti-malarial drugs.[31] The estimated annual death toll from malaria and tuberculosis attributed to counterfeit drugs was 700 000 in 2009.[32] A WHO survey conducted in seven African countries showed that between 20 and 90% of all anti-malarial medicines failed quality testing.[33] The most common SF medical products in Africa are antimalarials, antiretroviral drugs and antibiotics, and the market for counterfeit drugs continues to grow with the rate of HIV/AIDS in developing countries.[34]

28 Dana Goldman and Darius Lakdawalla, *The global burden of medical innovation*, Brookings, January 30, 2018, https://www.brookings.edu/research/the-global-burden-of-medical-innovation/.

29 Thomas Sullivan, *A tough road: Cost to develop one new drug is $2.6 billion; Approval rate for drugs entering clinical development is less than 12%*, Policy and Medicine, March 21, 2019, https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html.

30 Cancer Research UK, *How long a new drug takes to go through clinical trials*, February 22, 2019, https://www.cancerresearchuk.org/find-a-clinical-trial/how-clinical-trials-are-planned-and-organised/how-long-it-takes-for-a-new-drug-to-go-through-clinical-trials.

31 Fenoff and Wilson, *Africa's Counterfeit Pharmaceutical Epidemic*.

32 Fenoff and Wilson, *Africa's Counterfeit Pharmaceutical Epidemic*.

33 Health Research Funding, *20 Shocking Counterfeit Drugs Statistics*.

34 World Health Organisation, *A study on the public health and socioeconomic impact of substandard and falsified medical products*, (World Health Organisation, Geneva, 2017), https://www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en/.

In developing countries, counterfeit drugs pose a serious health risk, whereas in industrialised countries, the risk arises from lifestyle drugs rather than essential, life extending medication

Counterfeit drugs account for more than 30% of all medicines sold in Africa. In Nigeria approximately 70%[35] of medicines sold are counterfeit. Poor regulations, lax borders, and delayed implementation of policies aimed at improving the pharmaceutical supply chain in the country enable this trade. There is no clearly defined drug distribution channel in Nigeria – almost anybody can be a drug provider even if they are not a pharmacist.[36] Overall, in developing countries, counterfeit drugs pose a serious health risk, whereas in industrialised countries, the risk arises from lifestyle drugs rather than essential, life extending medication. In Africa, countries face pervasive poverty together with widespread infectious diseases, making them more vulnerable to harm from counterfeit drugs. Given the challenging socio-economic environment and the increasing demand for affordable medicines, there has been an influx of counterfeits entering Africa.

Furthermore, penalties for counterfeiting in most African countries are minor compared to the danger the crime poses to people. The most common penalty for manufacturing or trading in counterfeit medicines is a fine because governments have poor regulation and weak implementing mechanisms. The business of counterfeit drugs is therefore seen as easy and lucrative. Counterfeit medicines on the market come from all economies, however, most of them come from more sophisticated operations based in countries with developed pharmaceutical manufacturing capabilities.[37]

African countries are bombarded with counterfeit drugs as a result of governments failing to curb the influx of illegal products

Developing countries are the biggest target for the trading of counterfeit drugs because they have insufficient regulations and controls to protect themselves, as well as limited access to healthcare. African countries are bombarded with counterfeit drugs as a result

35 Fenoff and Wilson, *Africa's Counterfeit Pharmaceutical Epidemic*.

36 Chioma Obinna, *Nigeria losing war against fake drugs – Experts*, Vanguard, March 3, 2019, https://www.vanguardngr.com/2019/03/nigeria-losing-war-against-fake-drugs-experts/.

37 OECD & EUIPO, 'Why do countries export fakes? The role of governance frameworks, enforcement and socio-economic factors ', 2019 https://www.oecd.org/gov/risk/why-do-countries-export-fakes-brochure.pdf.

of governments failing to curb the influx of illegal products. Laws and levies added 69% to the cost of legitimate drugs in 2003[38], making it impossible for most Africans to afford medicines from legal sources and further driving illicit drug markets. In addition, government-imposed distortions of the medicines market through taxes, tariffs, price controls and licensing regimes contribute to the counterfeit drug epidemic. The loss of tax revenues is also a big concern in East African countries such as Kenya, Burundi, Tanzania, Uganda and Rwanda. These countries have reported losses of more than $500 million in taxes annually due to counterfeit drug circulation.[39] The often-flawed legal systems of developing countries also contribute to the circulation of counterfeit drugs. The countries also generally lack the resources to invest in technologies to test and identify counterfeit drugs.[40] According to the UN Office on Drugs and Crime, developing countries are an easy target for counterfeiters due to weak supply chain regulations, as well as the absence of track-and-trace technology and enforcement regimes.[41] As internet usage increases in Africa, cybercrime increases, making the continent a hot spot for Internet scams. Online sales of counterfeit drugs have proliferated and this trend exacerbates the counterfeiting problem on the continent. It is estimated that Internet sales of SF medical products account for $75 billion of the total market. In most cases, medicines bought online from illegal sites are found to be counterfeit.[42] Many consumers are unaware of the dangers involved in buying cheaper medicines on the Internet.[43] Counterfeiters use packaging to convince consumers they are buying the real product. Cost is also a deciding factor in poorer communities that choose to buy counterfeit medicines.[44]

There is no global regulatory framework addressing the illicit trade in medical products and the scope for international cooperation is limited. Internationally supported operations also remain selective. For example, South Africa is currently the only developing country that is a member of the Permanent Forum on International Pharmaceuticals (an operational platform) and only three African countries are using the Council of Europe's Medicrime Convention that non-member states can ratify to make their supply chains safer. Various proposals to curb counterfeits in Africa have been tabled, including:[45]

- reducing the number of borders that serve as entry points so that regulations can be more targeted; and
- countries enacting laws that focus on counterfeit pharmaceuticals instead of treating them as breaches of intellectual property fraud.

38 Fenoff and Wilson, *Africa's Counterfeit Pharmaceutical Epidemic*.
39 Wilson and Fenoff, *The health and economic effects of counterfeit pharmaceuticals*.
40 Fenoff and Wilson, *Africa's Counterfeit Pharmaceutical Epidemic*.
41 Cartwright and Baric, *The rise of counterfeit pharmaceuticals*.
42 Ashifi Gogo, *Combating the counterfeit drug trade*, https://youtu.be/4ZIwOoaCPxI (Online video from TedX Talks Boston – found on YouTube).
43 EA Blackstone, JP Fuhr Jr and S Pociask., *The health and economic effects of counterfeit drugs*, American Health & Drug Benefit 7, no 4 (2014):216-224.
44 Medical Brief, *Counterfeit medicines flooding SA*, August 11, 2015, https://www.medicalbrief.co.za/archives/counterfeit-medicines-flooding-sa/.
45 Judith Vorrath and Maike Voss, *The Hidden Dangers of Falsified and Substandard Medicines*, German Institute for International and Security Affairs, no 25 (2019): 1-4.

African countries are in desperate need of adequate training for regulatory authorities and corruption prevention, but attention must first be given to the insufficient manpower and resources to combat counterfeits.[46]

Opportunities for growth

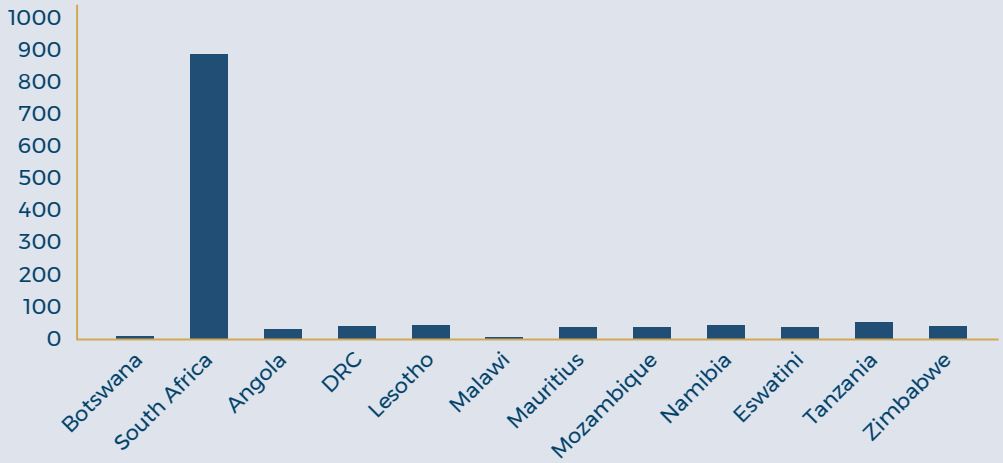
Africa presents a unique opportunity for growth, both for the pharmaceutical industry and its markets. Pharmaceutical companies have new markets to explore and consumers in Africa have access to new and diverse modern medication. Africa comprises many markets, therefore, one of the unique opportunities for growth available to pharmaceutical companies is through integration of global and regional value chains in order to gain access to these markets. While pharmaceutical industries in developed countries have been experiencing stagnation, Africa has been recording high levels of growth on a global scale. To illustrate this, foreign direct investment (FDI) data from the Southern Africa Development Community (SADC) region was analysed. The analysis is primarily based on data from FDI markets which tracks global cross-border investments tabulated by 'capital investment' ($), and 'number of jobs' created. The FDI data is based on the number of investment projects and/or number of new capital injections into existing projects within the pharmaceutical sector in the SADC region. Within the FDI markets database, many of the 'capital investment' and 'number of jobs' figures are based on estimates when data is unavailable.

Figure 2 shows that SADC started attracting FDI in the pharmaceutical sector from 2005 to 2019, with South Africa getting the lion's share of the investments ($892.6 million). The biggest investor in South Africa's pharmaceutical sector is the UK followed by the US. Tanzania and Lesotho recorded FDI inflows way below the South African levels at $49.2 million and $43.2 million respectively. This was followed by the Democratic Republic of Congo (DRC), Zimbabwe and Namibia, with the same capital investment of $39 million each. India has been a consistent investor in the region, with most of its investments destined for Tanzania and Zimbabwe. South Africa is the only intra-FDI investor (Lesotho, Botswana, Eswatini) in the region. Most investment in the region is in manufacturing, followed by research and development (R&D). In South Africa, capital investment in the pharmaceutical sector is almost double the investments in R&D. The growing FDI is an indication that there is potential for growth in these countries.

Figure 3 depicts the number of jobs created per country from the FDI inflows in SADC from 2005 to 2019. South Africa has the highest number of jobs created (4461) for the period under review, which correlates with the high capital investments in that country, followed by Eswatini (414), Angola (376), Tanzania (329) and Lesotho (227). Comoros, Seychelles, Madagascar and Zambia are not shown in Figures 1 and 2 because they have not received any FDI in the pharmaceutical sector for the period under review (2005–2019).

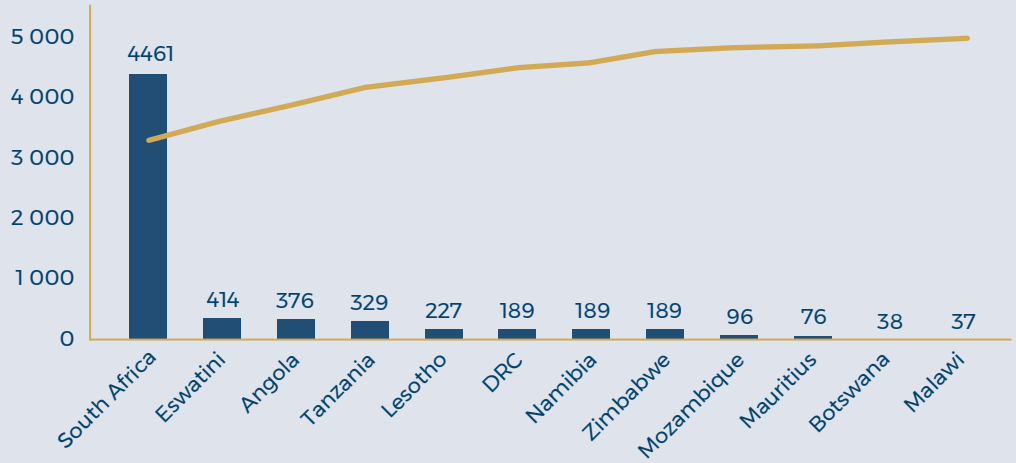
46 Hammond Kwame Adjei and Princess Ohene, *Counterfeit drugs: The relentless war in Africa*, Pharmacy & Pharmacology International Journal 2, no 2 (2015): 1-3.

Figure 2 FDI in the pharmaceutical sector in SADC 2005–2019 ($ million)



Source: FDI markets data

Figure 3 Number of jobs created by FDI in the pharmaceutical sector in SADC 2005–2019



Source: FDI markets data

There has been an expansion in the number of pharmaceutical manufacturers in Africa in Uganda, Kenya and Nigeria that has also resulted in a price reduction for pharmaceuticals.[47] In 2013, the pharmaceutical industry in Africa was valued at $20.8 billion from only

47 Glass, *Counterfeit drugs*.

$4.7 billion 10 years earlier. The value of the industry was estimated to grow further, reaching values of as high as between $40 billion to $65 billion by 2020.[48]

Efforts to combat counterfeit pharmaceuticals

In 2006, the WHO established the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) that comprises all the major anti-counterfeiting players, including international organisations, non-governmental organisations, enforcement agencies, pharmaceutical manufacturers and drug regulatory authorities. IMPACT was created to address the growing concerns about counterfeit drugs, with a focus on legislation and regulation, infrastructure, enforcement, technology and communication. However, developing countries have criticised IMPACT for its lack of accountability to the WHO, which they say has also not been supportive of them. The other critique is that IMPACT has been operating more as a public health discussion forum instead of an enforcement body.[49] Despite the existence of IMPACT, the fight against counterfeit drugs has not been won and not much has been achieved at a global level.

The WHO requires countries to establish a Falsified Medicines Directive[50] (FMD) and, in 2013, it established the Global Surveillance and Monitoring System for counterfeit drugs in Africa. This enables countries to actively report suspicious medicines, vaccines and medical devices, thereby assisting them in improving their reporting on incidents of counterfeit drugs. These directives provide measures to fight medicine falsification and ensure that the trading of medicines is rigorously controlled. There is also the innovative WHO Medical Product Rapid Alert System that facilitates a rapid and accurate response to incidences related to counterfeit drugs that pose eminent danger to international public health and safety.[51]

Generally, there is a fundamental lack of technologies to guarantee product safety and enable traceability. There are, however, four leading `Track & Trace' technological innovations available in the market that can be used to detect the authenticity of medicines, namely:[52]

- *Coding*: All falsification directives should contain an individual product identification number on the packaging. In most cases, an expiry date as well as a batch and serial number on the medicine are also required. Different countries have different coding systems depending on their directives;

48 Tania Holt, Mehdi Lahrichi and Jorge Santos da Silva, *Africa: A continent of opportunity for pharma and patients*, McKinsey & Company, June 2015, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/africa-a-continent-of-opportunity-for-pharma-and-patients.

49 Glass, *Counterfeit drugs*.

50 Pharmaceutical Security Institute, *The Challenge*.

51 Nafiu Aminu et al, *Unveiling the peril of substandard and falsified medicines to public health and safety in Africa: Need for all-out war to end the menace*, Medicine Access 1, no 1 (2017): 149.

52 WIPOTEC_OCS, *Falsified medicines directives- preventing drug falsification*, https://www.wipotec-ocs.com/en/serialisation-pharma/falsified-medicines-directive/?gclid=Cj0KCQiAqNPyBRCjARIsAKA-WFziDxuHry_VOv9cvUjeSx6obm-sR9nh4hkZD6_SY87CRG5l0gCtT4EaAuN9EALw_wcB.

- *Tamper-evident seal*: This is required by the European Union's FMD for prescription medicines, to prevent subsequent manipulation of the packaged medicine or the concealment of falsified drugs in the original packaging. The product is not to be dispensed if the seal is damaged or opened;
- Aggregation made possible through an integrated camera that captures the codes of medicine boxes. For example, Russian and Turkish directives require aggregation so that each product is traceable throughout the distribution chain. In certain countries (ie. the US), however, aggregation is not required by their directives and, in others (ie. the EU), it is an obligation;
- GS1 international initiatives that design global standards for a variety of industries and allocate Global Trade Item Numbers and other identification numbers for medicines. Their objective is to guarantee international communication via standardised barcodes and identification numbers. South Africa uses this solution.[53] There are currently more than 20 falsification directives worldwide at various stages of implementation and with partly differing requirements;
- Nigeria's Mobile Authentication Service (MAS) launched in 2010 to enable consumers to instantly validate medicines through a text message. MAS provides a scratchable label for each package, which consumers can scratch to get a personal identification number, to send to a toll-free number. Within seconds, the consumer receives a text message that confirms whether the product is genuine or not. This technology has also been deployed in Ghana.[54]

Pharmaceutical companies exporting high volumes of medicines have accepted regulatory compliance as a crucial requirement for operating successfully in foreign markets.[55] The challenge is that the cost to install such technology is high; therefore it is mostly used by developed countries. Developing countries have to find the financial resources to import these technologies, and establish a strong governmental administrative body to implement regulatory compliance. Evidence has shown that sustainable solutions for combating counterfeit drugs need local support as raising the necessary funds to import such technology is not the only challenge.[56]

Various academic institutions have developed models to estimate the impact (ie. deaths per year and $ value) of SF counterfeit dugs. Lack of accurate data on counterfeit drugs, however, makes it hard to estimate the extent of the problem.[57] It is extremely difficult to collect research data on counterfeit drugs due to the illegality of the operations, as a

53 WIPOTEC_OCS, *Falsified medicines directives*.
54 Aminu et al, *Unveiling the peril*.
55 WIPOTEC, *Serialisation: South Africa will join the fight against counterfeiting*, https://www.wipotec-ocs.com/en/news/serialisation-in-south-africa/.
56 World Economic Forum, *How do we combat the problem of counterfeit drugs?*, https://www.weforum.org/agenda/2015/08/how-do-we-combat-the-problem-of-counterfeit-drugs/.
57 World Health Organisation, *1 in 10 medical products in developing countries is substandard or falsified*, https://www.who.int/en/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified.

result, it is difficult to formulate policies to combat illegal pharmaceuticals without quality data. The counterfeit drug challenge is worsening as the gap between research and policy formulation widens. More research is therefore needed globally and in developing countries in order to accurately estimate the threat that counterfeit drugs pose.

> It is extremely difficult to collect research data on counterfeit drugs due to the illegality of the operations, as a result, it is difficult to formulate policies to combat illegal pharmaceuticals without quality data

The WHO has trained 550 regulators from over 141 countries to detect and respond to counterfeit drugs.[58] As of 2017, there have been 20 global alerts and many medical regional warnings issued by the Global Surveillance and Monitoring System, and more than 100 cases have been provided with technical support by the WHO.[59] In an effort to help Africa address the counterfeit medicine epidemic, the US Pharmacopeial Convention has been providing training on medicine regulations.[60] This will also help with information sharing on counterfeit drugs on the continent.

Conclusion and recommendations

Counterfeit drugs are a global threat but the effects are largely felt on the African continent. Africa is home to the world's most vulnerable populations with regards to socio-economic challenges which are further exacerbated by the scourge of malaria, HIV/AIDS and tuberculosis. The existence of these diseases offers a unique opportunity for pharmaceutical industries to expand into the African market, to help meet its demands for inexpensive lifesaving drugs. It has, however, brought with it an influx of counterfeit pharmaceutical imports.

This policy insights makes the following recommendations:

- Lack of quality research on the impact of SF medical products to inform policy should be addressed and countries need to work with international organisations on data collection.

58 Wilson and Fenoff, *The health and economic effects of counterfeit pharmaceuticals in Africa*, (Backgrounder, Michigan State University, United States, 2011), http://a-capp.msu.edu/wp-content/uploads/2018/05/BACKGROUNDER-The-Health-and-Economic-Effects-of-Counterfeit-Pharmaceuticals-in-Africa.pdf).

59 Aminu et al, *Unveiling the peril*.

60 Glass, *Counterfeit drugs*.

- There is a need for public education programmes about the dangers of counterfeit drugs. This is to empower consumers about the dangers and to raise awareness about the technological innovations available to verify the authenticity of pharmaceutical products.
- Regulations to combat counterfeit drugs should emphasise data collection and research to inform effective implementation and enforcement, especially in developing countries.
- In addition to sound regulations, clearly defined supply chains involving legitimate pharmaceutical industries, non-governmental organisations and qualified local distributors are essential to ensure that poor populations have access to affordable and quality medicines.

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Acknowledgement

SAIIA gratefully acknowledges the support of the Swedish International Development Cooperation Agency (SIDA) for this publication.

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