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## **Recalibrating African health laws to combat substandard and falsified medical products: Beyond COVID-19**

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### **Abstract**

The multi-faceted problem of substandard and falsified medical-pharmaceutical products remains a loose cannon and a constant threat to the enjoyment of the right to life of the people of Africa. Studies show that one out of every ten medications in circulation within the continent is either substandard or falsified. Sadly, amid the scourge of COVID-19, an upward surge in the volume of substandard and falsified medical-pharmaceutical products in the region was reported. Investigations conducted within the period attributed the prevalence of substandard and falsified medical products in the continent to weak regulatory legal frameworks among other factors. This piece draws from the empirical studies and judging from the transnational nature of the problem of substandard and falsified medical products, canvases for the harmonization of legislative action by African states to aid in curbing the menace of substandard and falsified medical-pharmaceutical products.

**Keywords:** Substandard, falsified, medical, pharmaceutical, COVID-19

### **Introduction**

Epidemiologically, science is yet to discover medications that can effectively treat viral diseases including the novel Coronavirus disease 2019 (COVID-19) which hit the world sometime in late December 2019 <sup>[1]</sup>. For now, the best approaches to managing viral diseases remain containment, vaccination and use of drugs to treat or mitigate the effect on infected persons <sup>[2]</sup>. Consequently, the first response to the outbreak of COVID-19 by national governments at different levels (subject to local peculiarities) was the issuance of emergency laws and or orders to suppress the spread of the virus, and to protect individual and public health. On the strength of the emergency laws and orders, national governments imposed measures ranging from partial lockdown to full lockdown (restriction of movements within and outside national boundaries to essentially permitted movements) coupled with either outright ban on congregating and or regulation of mode and conduct at gathering (maintenance of physical/social distancing, use of protective face mask and so forth).

In many African states, the outbreak of the COVID-19 pandemic exposed the deficiencies and frailty of the existing health care systems. For instance, the Nigerian health care system (like most African nations) before the outbreak of COVID-19 was in a state of doldrums, lacking critical infrastructure and heavily dependent on importation for virtually all her medical supplies like drugs, needles and syringes amongst others <sup>[3]</sup>. A study conducted by United Nations Office DC reveals that “70% of medicines and 99% of medical devices and equipment used in Africa are imported”, with a substantial fraction from China and India <sup>[4]</sup>. The period following the outbreak witnessed a shortage of medical supplies as a result of the emergency measures on international movement and trade <sup>[5]</sup>. Managing the resultant gargantuan problem under the prevailing infrastructural and medical supplies deficits was further exacerbated by the endemic nagging albatross of substandard and falsified medical products reported to be on the increase within the period <sup>[6]</sup>. The malevolent issue of substandard and falsified drugs has been a persisting challenge world over particularly in Africa <sup>[7]</sup>. Over the years putting an end to the endemic problem has been a major challenge and it has now assumed a more threatening dimension given the need to effectively manage contagious diseases like COVID-19 <sup>[8]</sup>.

Generally, from the perspective of a lawyer, the most efficient elixir for the eradication of any crime (including the monstrous issue of substandard and falsified medical products) is having in place a robust legal framework accompanied by an efficient enforcement regime; the concern here is with the latter.

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Though the issue of substandard and falsified medical-pharmaceutical products is a transnational phenomenon, however, the engagement of legislation to combat the issue within Africa has mainly been through individual states' solo efforts; though some African states have entered into bilateral and multilateral agreements like the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (MEDICRIME Convention) <sup>[9]</sup>. Thus, most African States have at least one or more domestic laws regulating medication <sup>[10]</sup>. Juxtaposed with the prevalence of substandard or falsified medical products in the continent, this piece queries the efficacy of using domestic laws to curb the menace. In other words, should the regulation of substandard and falsified medical products be left to individual states' domestic laws or international law, or both?

### **Nature of substandard and falsified medical products**

Appropriate terminology to address low quality or phoney products has been the subject of much discussion. The choice of appropriate terminology in the context of medication is compounded by the desire to project the different competing interests calling for attention. Such interests include the projection of economic interest at the expense of public health, to the protection of intellectual property rights over facilitating equitable access to medicines. Consequently, depending on where the sympathy lies, several related but different terms like 'expired', 'adulterated', 'spurious,' 'substandard,' 'falsified,' 'falsely-labelled,' 'fraudulent,' 'unregistered,' 'counterfeit,' 'fake' or collective terms like 'substandard/spurious/falsely-labelled/falsified counterfeit medical products,' or "counterfeit, adulterated, banned or fake, substandard or expired drug", have over the years been coined and used in the context of substandard or falsified medical products <sup>[11]</sup>. Extrapolating from the angle of public health concern, this article adopts the term 'substandard and falsified' (SF) medical or pharmaceutical products. 'Substandard' medical product refers to a poor quality medical product, containing lesser or more quotients of the required ingredients or a medical product whose active ingredients fall below or above approved quality, standard and or specification. In other words, substandard medical or pharmaceutical products are defective medical products with the problem of under or over-concentration of ingredients, contamination, adulterated, poor quality ingredients, poor stability and inadequate packaging <sup>[12]</sup>. These include excipients and active substances in drugs, vaccines, cum parts and accessories of medical devices; whether manufactured by or with the authority of the property owner <sup>[13]</sup>. Similarly, 'falsified' (illicit, fake, fraudulent or counterfeit) medical products may drugs, vaccines, including the excipients, active substances. It may also be medical devices, including the parts and accessories used along with medical devices, and generally manufactured without the authorization of the patented or property owner, and intended to pass as the original, whether or not it meets with the approved quality. The terms 'medicine(s)', 'medications', 'medical' and 'pharmaceutical(s)' are within this piece semantically employed, having the same import and used interchangeably except where the indicates otherwise.

Suffice to say that while the problem of substandard medical products is primarily a pharmaceutical issue bothering on

quality control in the production and supply process (deliberate or inadvertently). On the other hand, the act of falsifying a medical product is a criminal act; a deliberate act, designed or calculated to mislead users into believing that the falsified product is original. Portentously, whether substandard or falsified, both SF pharmaceuticals are dangerous and injurious to human health. More often than not, the use of SF medications "... contributes to morbidity, mortality, and drug resistance, and leads to spurious reporting of resistance and toxicity <sup>[14]</sup>" To date, these genres of medication have continued to expand both in therapeutic and geographic coverage, profiting no one but the criminal actors <sup>[15]</sup>.

### **COVID-19: A fresh impetus**

Before the outbreak of COVID-19, the issue of SF pharmaceuticals was already a major health concern in African, which has defiled efforts aimed at stemming the tide and to date the illicit trade remains a thriving multibillion-dollar market. Globally, the value of the trade is estimated at between US\$75 billion and US\$200 billion annually <sup>[16]</sup>. The market for falsified anti-malarial drugs alone within the West African sub-region is estimated by the UN Office of Drugs and Crime to be worth over US\$400 million. UNODC reports that the percentage of failed malarial drugs test in Africa is between 12 and 82 per cent and attributes the prevalence of SF medical products in African to inefficient drug regulatory and weak regulations among other factors. Similarly, WHO estimates that over 280,000 children die annually from taking SF medicines as treatment for pneumonia and malaria in sub-Saharan Africa; asserting that one out of every ten medical products in most low and middle-income countries is either substandard or falsified. The organization estimates the prevalence of SF medical products could be as high as 10 to 30% in Africa. The outbreak of COVID-19 was spontaneously accompanied by an upward surge in the demand for pharmaceutical products. Dealers in SF pharmaceutical products cashed in on the gap created by the excess demand and low supply, to infiltrate the market. For instance, within the period, over 30 million falsified medications were seized by Nigerian authorities in just one port of entry <sup>[17]</sup>. Among the seizure was a large quantity of falsified dexamethasone (a drug believed to treat severe COVID-19 symptoms). Within the period, several incidents of this nature were reported across Africa. For instance, In March 2020, a man and his daughter were arrested for administering a fake vaccine in Uganda <sup>[18]</sup>. In April 2020, falsified chloroquine was seized from about 300 pharmacies and hospitals in Cameroon <sup>[19]</sup>. There are indications the most of the SF pharmaceutical products come from outside the continent; China and India as the main provenance economies, while countries like the United Arab Emirates, Singapore Yemen, Iran and Hong Kong (China) serve as transit economies <sup>[20]</sup>. Recently, the National Agency for Food and Drug Administration and Control (NAFDAC), the regulatory agency in Nigeria, sanctioned an Indian drug manufacturer for manufacturing falsified Ciprofloxacin Tablets BP 500mg <sup>[21]</sup>. Some African states like Egypt, Seychelles and Cameroon, have also been identified as provenance economies <sup>[22]</sup>. One major catalyst responsible for this development within African states is the presence of special economic zones. These zones were originally established to attract foreign investments, employments and promote

economic growth. To provide incentive and attract the desired patronage, the zones are lightly regulated and most times, detached from domestic policing<sup>[23]</sup>. Currently, there are about 237 established special economic zones in 38 of the 54 economies in Africa<sup>[24]</sup>. The result is that some of these zones now provide unregulated venues to package and repackage products, sometimes to conceal their true root of origin and quality<sup>[25]</sup>.

An investigation conducted by the Organization for Economic Co-operation and Development and the European Union Intellectual Property Office (OECD/EUIPO) shows that with high profit margins, low risks of detection and prosecution, weak penalties and trusting consumers, the market of SF medications in Africa is expanding at the rate of 18.7 per cent annually; the highest in the world<sup>[26]</sup>. A similar study conducted by UNODC within the period, reveals an increase in SF medical products in the market caused by the rush for drugs and other medical products required to test, treat and curtail the spread of the COVID-19 pandemic<sup>[27]</sup>. The study reveals that the pandemic has further exposed the inherent weakness in the extant regulatory and legal framework designed to stop the production and dealings in SF medical products. The study warns that the behaviour of organized criminal groups will gradually change over the course of the pandemic, particularly after a vaccine is developed. It predicts a shift from trafficking in personal protective equipment to developing and dealing in the vaccine<sup>[1]</sup>. True to the prediction, regulatory authorities in some West-Africa States have issued statements warning of falsified COVID-19 vaccines in circulation in the region<sup>[28]</sup>. The prevalence of SF medical products pose a serious threat to lives within Africa and calls for concerted legislative action on the part of governments.

### State's responsibility in protecting the right to life

SF pharmaceuticals pose a greater threat to individual patient safety and shared global health security than the diseases they are intended to treat. Studies reveal that SF pharmaceuticals exacerbate the problem of managing any diseases (COVID-19 inclusive), simply because these products prolong treatments and, most times, negatively affect the health and wellbeing of the patients<sup>[29]</sup>. The primary purpose of government is to ensure the security and welfare of the people<sup>[30]</sup>. Since SF pharmaceuticals constitute a threat to life, it is appropriate to determine the extent of states' allocated responsibility in securing the life and health of the people within their territories vis-à-vis ensuring the availability of safe and genuine medical products?

One notable framework for allocating responsibility to states is under human rights law<sup>[31]</sup>. Under both local and international human rights legal instruments states' obligations are built around three underlying pillars. First, states owe a duty to respect and not to violate secured rights. Secondly, states owe an obligation to protect the enjoyment of legally recognized rights from being violated by third parties. And finally, states are to facilitate the realization and enjoyment of the rights guaranteed<sup>[32]</sup>. Juxtaposed with some human rights instruments, the prevalence of SF medical products in Africa violates several aspects of the legislation; the rights to life and health.

At the global level, the right to life is a recognized inherent human right and forms the basis for all other guaranteed

human rights under international instruments like the United Nations Charter, the Universal Declaration of Human Rights among others<sup>[33]</sup>. For instance, in line with the provisions of the International Covenant on Civil and Political Rights, states are principally obliged to protect against arbitrary deprivation of life<sup>[34]</sup>. Similarly, states parties to the International Covenant on Economic, Social and Cultural Rights are required to "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health<sup>[36]</sup>." In actualizing this right, state parties are to take necessary steps to ensure the "prevention, treatment and control of epidemic, endemic, occupational and other diseases<sup>[37]</sup>." These are positive obligations owed by the state to every person within its territory. Thus, the state must provide the enabling environment for the enjoyment of these rights. While these are territorial obligations, states are also obliged to where possible to prevent third parties from other countries from violating the right to life and health within their territories by way of international cooperation, legal or political means in consonance with international obligations<sup>[38]</sup>.

At the African level, one legal document that has and continues to influence various national governments and sets the agenda for the recognition of a plethora of rights as enforceable human rights within the continent is the African Charter on Human and Peoples' Rights<sup>[39]</sup>. The Charter is Africa's fundamental human rights instrument regulating virtually all manner of rights including the rights to life and health<sup>[1]</sup>. Normatively, the Charter provides the template and the minimum benchmark for the protection of human rights in Africa<sup>[40]</sup>. In facilitating the ease of enforcement, article 1 of the Charter requires State parties to "... recognise the rights, duties and freedoms enshrined ..." in the instrument and to "adopt legislative or other measures to give effect to them." In compliance, most African nations have in one way or the other made the charter an integral part of their constitutional system. Others like Nigeria have explicitly domesticated the Charter<sup>[41]</sup>. Domestic courts have come to recognize the rights of Africans to rely on the provisions of the Charter. The Nigerian Court of Appeal in *Ohakosim v. C.O.P., Imo State*<sup>[42]</sup> while holding that the appellant was entitled to apply to the court for leave to seek redress for the alleged infringement of his rights as guaranteed by the Constitution of the Federal Republic of Nigeria 1999 and by the African Charter, observed that

"By virtue of the African Charter on Human and Peoples' Rights (Ratification and Enforcement) Act ... the African Charter on Human and Peoples' Rights constitutes part of the laws of Nigeria and must be upheld by all law courts in the country. Indeed, Nigeria has given due recognition to African Charter on Human and Peoples' Rights by enshrining most of the Rights and obligations guaranteed therein in Chapter IV of the 1999 Constitution<sup>[43]</sup>."

Among other human rights, the Charter secures the right to life of persons within the territorial jurisdiction of state parties. It expressly provides that "Every human being shall be entitled to respect for his life and the integrity of his person. No one may be arbitrarily deprived of this right<sup>[44]</sup>." Commenting on the extent of state parties' responsibility under Article 4, the African Commission on Human and Peoples' Rights (the Commission), an administrative cum quasi-judicial body created by the Charter to promote human and peoples' rights and ensure their protection in the

continent, monitor the enforcement of the Charter, observed that a state may be involved in the violation of this right within and outside her territories if the state has possession of the jurisdiction or exercises effective control over the territory where the victims are affected or engage in conduct that could reasonably be foreseen to result in arbitrary deprivation of life<sup>[45]</sup>. The states thus have obligations to act responsibly with regards to the protection of lives by controlling activities within their territories and beyond where the activities may affect or threaten the sanctity of life within territories under their control<sup>[47]</sup>. Given the prevalence of SF medical products in Africa, this approach is significant as it effectively places on state parties the responsibility of protecting their territories from the products inimical to the enjoying of the right to life.

Specifically, the Charter in unambiguous terms recognizes the right of every individual to the enjoyment of good health and every other right that contributes to health. Article 16 (1) states “Every individual shall have the right to enjoy the best attainable state of physical and mental health.” The Charter imposes a duty on state parties to “take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick”<sup>[48]</sup>. In discharging the responsibility, a state party is required to protect the physical health of the individual and family<sup>[49]</sup>. These are very ambitious provisions; imposing obligations to put in place preventive measures to prevent and contain diseases (including endemic, epidemic and pandemic diseases) by state parties in the interest of individuals, family and public health; and to regulate treatment (curative) measures. In essence, the latter obligation requires state parties to regulate the production, distribution and sale of genuine medical products. In amplifying this latter obligation, the Charter makes it the responsibility of the state parties to ensure access to proper medical treatment and medication and holds them accountable in the event of a breach<sup>[50]</sup>.

These are salutary provisions. While the provisions do not in the strict sense guarantee the right to a healthy life (which is primarily conditioned on genetic makeup and social influences), they impose on the state parties an obligation to guarantee access to good healthcare facilities (including pharmaceutical products) and other basic factors required to achieve and sustain healthy living. In essence, the Charter obligates the states to ensure the existence of those conditions that promote healthy living. Consequently, the state parties are to either provide health services and or have in place a robust regulatory framework for the health sector<sup>[51]</sup>.

At the moment there is a paucity of cases touching on the interpretation and application of the Charter, particularly in the domain of the right to health. One of the few reported cases in this regard is *Purohit and Moore v The Gambia*<sup>[52]</sup>, while upholding states’ responsibility to ensure access to healthcare, the African Commission on Human and Peoples’ Rights held that Article 16 of the Charter imposes a positive obligation on states to ensure without discrimination, universal access to medical products and health services by all persons within the state’s territory. It is therefore within the ambit of and incumbent on all African state parties to the Charter and other international legal instruments to fulfil the health obligation imposed by these instruments; which includes ensuring access to genuine medical products and

on the other hand, protecting the region from exposure to SF pharmaceutical products<sup>[53]</sup>.

In essence, having signed and ratified the Charter, state parties undertake to employ available resources to progressively secure the realization of the rights guaranteed. In this wise, state parties are expected to take all reasonable steps to maximize the enjoyment and protection of any right so guaranteed<sup>[54]</sup>. While some states may want to hide under paucity of funds for not vigorously protecting and securing the enjoyment of these rights, it is trite that under international law, non-availability of resources is not an absolute excuse. Repeatedly, most international human rights bodies are disposed to finding states to be unwilling and in violation of their obligation even where they plead paucity of resources<sup>[55]</sup>. To successfully avoid being in breach, a state party in addition to proving paucity of resources must also demonstrate that it has unsuccessfully sought to obtain international aid and is progressively developing its capacity to ensure the enjoyment of the rights. Legislatively, one of the most potent ways of obtaining international aid and capacity building by low-income countries is through conventional international law; treaties, conventions and other agreements among states.

### State of African municipal laws

Africa is said to have the fastest-growing population rate in the world with an estimated 1.3 billion people and from the United Nations projection, this number is expected to double by 2050<sup>[56]</sup>. The continent also has a large infectious and non-communicable diseases burden<sup>[57]</sup>. The combination of these indices portends a flourishing market for genuine pharmaceutical products. Despite poor reporting, available data show that 42% of the detected cases of SF pharmaceuticals in the world are from Africa<sup>[58]</sup>. Amid all these disturbing reports, the irony is that virtually all states in Africa have individual national medical products regulatory agencies (except the Sahrawi Republic)<sup>[59]</sup>; though possessing different levels of expertise, enabling laws, operating policies, standards and capacity<sup>[60]</sup>. These agencies are primarily established to perform core functions like oversight of clinical trials on drugs, licensing of manufacturing establishments, quality control, the inspection of manufacturing premises and distribution channels, imports and export control, marketing authorization, post-market surveillance including and monitoring adverse drug reaction, among others<sup>[61]</sup>. On common trend, is that most of the enabling laws, in theory, give powers to the regulators to investigate and prosecute offences created by it and other related laws<sup>[62]</sup>.

WHO reports that of the 54 national medicines regulatory agencies in Africa, only about seven per cent possess the average capacity to perform their core regulatory function, while over 90 per cent are either incapable of or possess very minimal capacity to perform their core roles<sup>[63]</sup>. The incapacity to perform core regulatory functions by any national health regulatory authority provides the enabling environment for SF pharmaceuticals to thrive. Peddlers of SF pharmaceuticals may find it easier and more conducive to use the territories of incapacitated states to transit SF medications into other countries<sup>[64]</sup>. According to Hooper, in such instances, “containers that get past port surveillance teams are stripped and the medicines broken up into smaller packages, then taken across borders - some go north to

Burkina Faso, others into Ghana and on to Ivory Coast, and others east into Nigeria <sup>[65]</sup>”

These are some of the pitfalls inherent in leaving the regulation of SF medications exclusively to the domain of domestic law. From the perspective of the African Charter, this to a large extent is a dereliction of responsibility and a breach of state parties’ commitment under the African Charter to protect the right to life. Similarly, viewed from the perspective of the Commission’s position in General Comment 3, the consequential use of the territories of incapacitated states as transit corridors to ferry SF pharmaceuticals products into other state parties territories also constitutes a breach of the obligation to protect the right to life the people of Africa.

One notable consensus from studies conducted by WHO, UNODC, OECD/EUIPO and other international bodies is that the absence of a comprehensive legal framework is responsible for and provide a fertile environment for SF medical products to thrive in low-income countries including Africa. They posit that most extant legal frameworks in the continent are either too weak or inconsistent to effectively curb peddling in SF pharmaceuticals. Specifically, the studies point out that in some cases, the existing law out rightly failed to criminalize issues like “attempt, participation by accessories and the possession and sale of illegally obtained medical products <sup>[66]</sup>.” Similarly, SF pharmaceuticals offences perpetrated via the internet were not envisaged or captured. In some countries, such as Ghana, there is a near absence of medical product sector specialized laws or conflicting regulations coupled with duplication of regulatory bodies <sup>[67]</sup>. Securing convictions under some of the extant laws are sometimes near impossible. Even in Nigeria where the manufacturing and sale of SF medications are statutorily criminalized, instances of successful conviction for dealing in SF medication are rare; however, there are few cases <sup>[68]</sup>.

More worrisome is that in most African countries, statutorily prescribed punishments for offences relating to SF pharmaceutical products can be likened to a slap on the wrist compared to punishment for some other similar offences like drug smuggling which in many cases attract stiffer penalties; long term imprisonment along with a forfeiture of the proceeds of the crime <sup>[69]</sup>. More disheartening is the fact that victims of SF pharmaceutical products in most African countries do not have a statutorily backed civil right for extracting compensation from the perpetrators.

### **Recalibrating the laws**

To rectify the current shortfalls and guarantee the effectiveness of regulatory authorities in dealing with the threat posed by SF medical products, changes will have to be made to extant weak legislative regimes. Below are some proposed approaches.

The core traditional method of controlling conducts or behaviour considered inimical to public health and safety is by providing disincentive through the use of sanctions; legislatively regulating such conduct <sup>[70]</sup>. The foregoing discussion, reveal that at the national level, most African states have legislation regulating pharmaceutical products production and distribution, though most of the efforts have been adjudged too weak to serve as deterrence against the lucrative criminal trade in SF medical products. Legislatively, all states have the sovereign right to make

domestic laws such as unilaterally regulating SF medical products. While the making of domestic law to curb social menace is theoretically feasible, it is not in all cases successful for a plethora of reasons. One of such is where the process of committing the offence sought to be prohibited cuts across states’ boundaries; where the offence is committed transnationally. Under the circumstances, the importing state’s domestic law cannot unilaterally compel other states to enforce the legislation, unless there is an existing bilateral or other international obligation obligating the other state. In other cases, particularly in low-income states, the importing state may lack the resource and capacity to efficiently enforce its domestic law. The experiences of some African states, where SF medical products are imported from neighbouring countries, demonstrate the futility of unilateral regulating of SF medical products <sup>[71]</sup>. The Nigerian experience demonstrates the futility of unilateral regulation of SF medical products. Following the criminalization of the manufacture and sale of SF medications in the country, circulation of SF medications remained unabated, but after neighbouring countries like Cameroon and Niger banned imports of Nigerian drugs, greater efforts were made by Nigerian authorities to curb the trend <sup>[72]</sup>.

On the other hand, engaging international law to combat SF medical crime also has its shortfalls. While there is a presumption that international problems ought to be solved by international law, the proposition is not generally true and for obvious reasons, it also not completely true in the case of SF medical products for some reasons. For instance, despite having signed and ratified the MEDICRIME Convention, there are reports of SF medical products in circulation in Benin <sup>[73]</sup>. To be effective, any international law designed to protect against SF medical products and similar crime, must in addition to regulating the conduct of the state parties, regulate the conduct of private citizens; who ordinarily are not subjects of international law. States generally will not agree to a treaty that encroaches on their sovereignty. It is a general principle of international law that states being sovereigns are the only authority that can directly regulate the conduct of their citizens. Consequently, to be effective in solving the multifaceted problem of SF medical products, in addition to other provisions such treaty must contain a model law prescribing minimum regulatory standards and obligating state parties to shape or reshape their domestic laws in tandem with its provisions.

Consequently, there is no “one fits all approach” in the context of protecting individual and public health against SF medical products. It is therefore imperative for an optimal result that both domestic and international law be engaged. For instance, while the production of SF medical products will be more effectively regulated by the provenance or transit states’ domestic laws, international laws would be required to obligate exporting provenance or transit states to cooperate in the control where such products are strictly meant for exports or are being transited. Viewed from this point, there is a need to employ both domestic and international laws in the fight against SF medical products in Africa; the problems of combating SF medical products have both international and domestic dimensions.

From the angle of international legislation, there is a need to harmonize African approach through a carefully crafted treaty criminalizing SF medical products of the nature of the Council of Europe Convention on the Counterfeiting of

Medical Products and Similar Crimes Involving Threats to Public Health (MEDICRIME Convention) <sup>[74]</sup>. However, unlike the MEDICRIME Convention which primary concern is the criminalization of falsified medical products, the provisions of an African MEDICRIME treaty should go some steps further to criminalize substandard medical products whether produced by the patent owner(s) or under a license or outright counterfeit. This is because scrutiny of the convention shows that Europeans are more concerned with protecting intellectual and economic rights. On the contrary, Africa's concern should be the protection of the right to life and health of her citizens. Thus, the scope of the treaty should be wide enough to include both substandard and falsified medications in its net, because both genre medications are dangerous and injurious to individuals and public health.

For effective control of the international chain of distribution, state parties under the proposed treaty should be required to first, regulate and monitor exports of medical products and have in place regulatory bodies with the power to decisively prohibit such exports when found to be substandard or falsified. Secondly, an exporting state party should be required to stop any export of medical products without the consent of the relevant authorities of the importing country. To avoid situations where such products are dumped in transit states, transit countries must be given prior notice of the movement and the opportunity to object to transiting such products through their territories. As an incentive for exporting countries to control medical products exports, there should be a stringent liability regime for allowing wrong or improper export of medical products from their territories. In other words, should the importing country or its citizen suffer any injury or damages, the exporting country will be held liable subject to stated conditions and the right of subrogation in an action against the offender.

To complement the proposed treaty, individual states should subject to local peculiarity enter into bilateral and other multilateral treaties especially with provenance economies outside the continent. From studies, some states have been unanimously identified as major provenance economies of SF medical products. African states should as a matter of public health concern and protection of the right to life, enter into a bilateral agreement for mutual legal assistance or extradition treaties with such states to facilitate effective prosecution. Among others, the agreement should impose prior notification of and consent by the importing or transit nations before medical products are exported.

At the domestic level, first, stiffer penalties for the sale of SF medications should be introduced to deter actors. From the above discussion, the consensus is that the present penalties regime is too weak to provide deterrence. Secondly, following the possibility of abuses of free trade zones in the manner earlier mentioned, it is imperative in the interest of individual and public health that domestic laws relating to policing of free trade zones be reviewed; insertion of provisions that will enable effective policing of the zones by relevant agencies. The desire to attract foreign participation, trade and the employment of locals should not be allowed to relegate to the background the need to protect the right to life and health of the people of Africa. Again, there are reported cases where SF products were officially approved by regulatory agencies within the final consumer countries. Such instances make the insertion of provisions

anti-corruption provisions in domestic laws; imposing well-articulated penalties for infringement. As earlier mentioned, toward achieving a near-uniformed domestic regulatory framework, the proposed African MEDICRIME treaty should obligate state parties to reshape domestic laws where they fall below the minimum stipulated by the treaty.

### Conclusion

One conclusion from the foregoing is that the absence of a robust legal framework is one of the factors militating against the eradication of substandard and falsified medical products. Domestic laws cannot by themselves effectively combat the manufacture, trafficking and dealing in substandard and falsified medical products. To facilitate detection of such products, support local and global surveillances, strengthen regulatory capacity and harmonize pharmaceutical governance in Africa, there is a need for a transnational action through transnational regional law to assist in the fight against substandard and falsified medical products.

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