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SEVENTY-SECOND WORLD HEATH ASSEMBLY

Member State Mechanism on Substandard and Falsified Medical Products

Letter from the Executive Board

Greetings delegates,
Let me be the first one to welcome you to the World Health Assembly.
Considering the fact that the background ground just gives you a direction to the agenda, delegates are encouraged to further expand the realm of their knowledge by breaking the agenda into matters that actually matter and provide solutions that can actually be taken into consideration.
Delegates are requested to be respecting other opinions and be as diplomatic as possible in this manner. All the delegates in the committee have as good a chance as veterans.
It is our honor to look over the proceedings of the committee and hope for a non-political debate .please feel free to contact us on our mails as mentioned below. All the best.

Warmest Regards,

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Introduction to the Committee

The World Health Organization, as part of the United Nations (UN), has expertise to coordinate international public health matters. Within its constitution, its mission “is the attainment by all peoples of the highest possible level of health.” With health as its prime concern, the WHO defines health as “a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.” Its prime concern is to, generally, promote the health of all peoples of the world and to, specifically, combat diseases—especially critical infectious diseases.

The public widely recognizes some work performed by WHO. The WHO responds to natural and human made disasters by providing emergency aid, funds medical research, conducts immunization campaigns against fatal diseases, and improves housing, nutrition, sanitation, and working conditions in developing countries.

The WHO is probably best known for its immunization programs and smallpox eradication. Currently, it is working with other health organizations to treat tuberculosis, malaria, SARS (severe acute respiratory syndrome), and HIV/AIDS (human immunodeficiency virus/acquired immunodeficiency deficiency syndrome).

However, the WHO also performs work that is less familiar to the public. It charts statistical health trends and issues warnings about possible health problems. The WHO is also responsible for assigning a common international name to drugs. WHO standards are used for measuring air and water pollution. WHO personnel work with agencies, foundations, governments, non-governmental organizations, and private sector groups to address the world's health needs.

Headquartered in Geneva, Switzerland, the WHO consists of one hundred ninety three Member States (along with two associate Member States). It is governed through representatives within its World Health Assembly. A thirty-four-member Executive Board, elected by the World Health Assembly, supports the WHO. In addition, six regional committees focus on health concerns within Southeast Asia, the Eastern Mediterranean, the Americas, Africa, the Western Pacific, and Europe.

- The World Health Organization is a specialized agency within the terms of Article 57 of the Charter of the United Nations,The objective of the World Health Organization shall be the attainment by all peoples of the highest possible level of health.

In order to achieve its objective, the functions of the Organization are:

(a) to act as the directing and coordinating authority on international health work;

(b) to establish and maintain effective collaboration with the United Nations, specialized agencies, governmental health administrations, professional groups and such other organizations as may be deemed appropriate;

(c) to assist Governments, upon request, in strengthening health services;

(d) to furnish appropriate technical assistance and, in emergencies, necessary aid upon the request or acceptance of Governments;

(e) to provide or assist in providing, upon the request of the United Nations, health services and facilities to special groups, such as the peoples of trust territories;

(f) to establish and maintain such administrative and technical services as may be required, including epidemiological and statistical services;

(g) to stimulate and advance work to eradicate epidemic, endemic and other diseases;

(h) to promote, in co-operation with other specialized agencies where necessary, the prevention of accidental injuries;

(i) to promote, in co-operation with other specialized agencies where necessary, the improvement of nutrition, housing, sanitation, recreation, economic or working conditions and other aspects of environmental hygiene;

(j) to promote co-operation among scientific and professional groups which contribute to the advancement of health;

(k) To propose conventions, agreements and regulations, and make recommendations with respect to international health matters and to perform such duties as may be assigned thereby to the Organization and are consistent with its objective;

(l) to promote maternal and child health and welfare and to foster the ability to live harmoniously in a changing total environment

(m) To foster activities in the field of mental health, especially those affecting the

harmony of human relations;

(n) To promote and conduct research in the field of health;

(o) to promote improved standards of teaching and training in the health, medical and related professions;

(p) to study and report on, in co-operation with other specialized agencies where necessary, administrative and social techniques affecting public health and medical care from preventive and curative points of view, including hospital services and social security;

(q) To provide information, counsel and assistance in the field of health;

(r) To assist in developing an informed public opinion among all peoples on matters of health;

(s) To establish and revise as necessary international nomenclatures of diseases, of causes of death and of public health practices;

(t) To standardize diagnostic procedures as necessary;

(u) To develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products;

(v) Generally to take all necessary action to attain the objective of the Organization

- Territories or groups of territories which are not responsible for the conduct of their international relations may be admitted as Associate Members by the Health Assembly upon application made on behalf of such territory or group of territories by the Member or other authority having responsibility for their international relations. Representatives of Associate Members to the Health Assembly should be qualified by their technical competence in the field of health and should be chosen from the native population. The nature and extent of the rights and obligations of Associate Members shall be determined by the Health Assembly.

The delegates are advised to be completely thorough with the mandate to provide viable solutions that actually are beneficial for the committee

Introduction to the agenda

For the purpose of this document and the classifications below, Authorized medical products means medical products in compliance with national and regional regulations and legislation. NRRAs
can, according to national or regional regulations and legislation, permit the marketing or distribution
of medical products with or without registration/license.

(a) Substandard medical products

- Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both. When the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition, or source, then the medical product should be considered "falsified"

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(b) Unregistered/unlicensed medical products

- Medical products that have not undergone evaluation and/or approval by the NRRA for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

- These medical products may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin.

(c) Falsified medical products

Medical products that deliberately/fraudulently misrepresent their identity, composition or source. Any consideration related to intellectual property rights does not fall within this definition.
Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.

- "Identity" shall refer to the name, labeling or packaging or to documents that support the authenticity of an authorized medical product.

- "Composition" shall refer to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by NRRA.

- "Source" shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.

- Medical products should not be considered as falsified solely on the grounds that they are unauthorized for marketing in any given country.

- Globalization of the market in active pharmaceutical Ingredients and finished medical products brings with it the urgent need for effective International collaboration, cooperation and coordination to ensure global access to safe, quality, efficacious and affordable medical products.

- Medical products can be manufactured in one part of the world, packaged in another and supplied to a third. An inter-regional surveillance and monitoring system is now key in protecting patients and health systems worldwide from SF medical products.

- The exponential increase in internet connectivity and mobile telecommunications has opened up a global marketplace for suppliers and consumers of medical products.

- Thoroughly understanding the global threat posed from SF medical products to better inform Member States in preventing them from reaching patients, detecting them quickly when they have penetrated the supply chains and responding to them proportionately and consistently are the key elements of capacity building and regulatory strengthening at a national and regional level.

- WHO will continue to conduct a range of activities with Member States and stakeholders to minimize the risks from SF medical products, including developing policy, identify good practice, data collection and analysis and issuing alerts, to better inform decision making in investing to secure supply chains and build regulatory capacity.

The need for a member-state mechanism

In accordance with the Constitution of the World Health Organization and a number of World Health Assembly resolutions relating to the quality, safety and efficacy of medicines, specific resolutions began to emerge relating to what was then known as counterfeit medicines.

WHA 41.16 (1988) requested WHO to initiate programmes for the prevention and detection of export, import and smuggling of falsely labelled, spurious and counterfeit or substandard pharmaceutical preparations, and to cooperate with the Secretary General of the UN in case provisions of the International Drug Treaties are violated'.

WHA 47.13 (1994) requested WHO 'To support Member States in their efforts in combating the use of counterfeit drugs'

WHA 65.19 (2012) requested WHO to establish a Member State Mechanism to address the issue of Substandard, spurious, falsely labelled, falsified and counterfeit medical products.

WHO provides the Secretariat for the Member State Mechanism which has agreed a work plan, priorities and has commenced work in a number of areas

In 2012 the World Health Assembly established the Member State Mechanism to address the issue of SSFFC medical products.

This resolution renewed and re-established a mandate for WHO and the Member States in tackling SSFFC medical products in a transparent and inclusive way, from a public health perspective and expressly excluding considerations of intellectual property rights.

On 29 May 2017, the World Health Assembly agreed to have "Substandard and Falsified (SF) medical products" as the term to be used in the name of the Member State mechanism and in all future documentation on the subject of medical products of this type.

In order to protect public health and promote access to affordable, safe, efficacious, and quality medical products, promote through effective collaboration among Member States and the Secretariat, the prevention and control of SF medical products and associated activities.
WHO launched a global surveillance and monitoring system for SF medical products at a workshop held in West Africa in July 2013.

The system allows WHO to offer immediate technical assistance in emergencies, link cases and connect focal points from around the world.

The system also accumulates a validated body of evidence which allows more detailed analysis, identifying the medical products most at risk, weaknesses in systems and vulnerabilities in the supply chain. This analysis provides a more detailed assessment of the scope, scale and harm caused by SF medical products. It also supports evidence based policy and investment in targeted capacity building, and informs more directed post market surveillance and informs the work of the Member State Mechanism.

WHO publishes medical product rapid alerts in cases where there is a serious risk to public health affecting a wide geographic area.

Criteria influencing the issue of an alert include validation that the medical product is SF, evidence of recent or continued circulation, or evidence that adequate steps have not been taken to inform healthcare professionals and consumers or remove the SF medical product from the supply chain.
WHO has a key function in strengthening National and Regional Medicines Regulatory Authorities in preventing, detecting and responding to SF medical products.

This takes the form of issuing guidance and delivering training across a broad range of regulatory requirements including:

- Good Manufacturing Practice
- Good Distribution Practice
- Post Market Surveillance and surveying the market
- Transparency and Good Governance
- WHO Pre- Qualified Medicines
- Quality Safety and Efficacy of Medicines

WHO Global Surveillance and Monitoring System for Substandard and Falsified medical products

WHO Global Surveillance and Monitoring System for substandard and falsified medical products (GSMS)

PROCESS:

- Step 1. Reports of suspected substandard or falsified medical products "submitted by public,health care professionals, industry, supply chain, customs, police, procurers and nongovernmental organizations to the national or regional medicines regulatory authority (NMRA)

- Step 2. Assessment and response by NMRA

- Step 3 NMRA Focal Point searches and reports to WHO's surveillance and monitoring system database

- Step 4. Immediate technical assistance and alerts are issued by WHO when requested and appropriate. Validated reports and data inform policy, procedure, processes, investment and the work of the Member State mechanism

- It provides national regulatory authorities with an interconnected network. This allows them, for the first time, to cross-reference reports of suspect products with those reported from other regions by searching the WHO database and accessing photograph libraries of confirmed substandard and falsified products. It links incidents and countries, which not only assists regulatory authorities but ultimately can have beneficial outcomes for patients

- As the system grows it will provide an ever richer evidence base, allowing countries to pinpoint risk situations more efficiently, and to respond more rapidly to protect their citizens from substandard and falsified medical products. As a case reporting system, the data from the GSMS is representative only of those products detected and reported by the focal points, and cannot be extrapolated to determine the overall magnitude of the problem. Data on prevalence and cost is vital to not only strengthen the public health case to focus interventions and investments, but to meaningfully engage with other multisectoral stakeholders including policymakers.

- An estimated 1 in 10 medical products circulating in low- and middle-income countries is either substandard or falsified, according to new research from WHO. This means that people are taking medicines that fail to treat or prevent disease. Not only is this a waste of money for individuals and health systems that purchase

these products, but substandard or falsified medical products can cause serious illness or even death.

- “substandard and falsified medicines particularly affect the most vulnerable communities.Countries have agreed on measures at the global level – it is time to translate them into tangible action.”
- Since 2013, WHO has received 1500 reports of cases of substandard or falsified products. Of these, antimalarials and antibiotics are the most commonly reported. Most of the reports (42%) come from the WHO African Region, 21% from the WHO Region of the Americas, and 21% from the WHO European Region.
- This is likely just a small fraction of the total problem and many cases may be going unreported. For example, only 8% of reports of substandard or falsified products to WHO came from the WHO Western Pacific Region, 6% from the WHO Eastern Mediterranean Region, and just 2% from the WHO South-East Asia Region.
- “Substandard or falsified medicines not only have a tragic impact on individual patients and their families, but also are a threat to antimicrobial resistance, adding to the worrying trend of medicines losing their power to treat”.
- Prior to 2013, there was no global reporting of this information. Since WHO established the Global Surveillance and Monitoring System for substandard and falsified products, many countries are now active in reporting suspicious medicines, vaccines and medical devices. WHO has trained 550 regulators from 141 countries to detect and respond to this issue. As more people are trained, more cases are reported to WHO.
- WHO has received reports of substandard or falsified medical products ranging from cancer treatment to contraception. They are not confined to high-value medicines or well-known brand names and are split almost evenly between generic and patented products.
- In conjunction with the first report from the Global Surveillance and Monitoring System published today, WHO is publishing research that estimates a 10.5% failure rate in all medical products used in low- and middle-income countries.
- This study was based on more than 100 published research papers on medicine quality surveys done in 88 low- and middle-income countries involving 48 000 samples of medicines. Lack of accurate data means that these estimates are just an indication of the scale of the problem. More research is needed to more accurately estimate the threat posed by substandard and falsified medical products.
- Based on 10% estimates of substandard and falsified medicines, a modelling exercise developed by the University of Edinburgh estimates that 72 000 to 169 000 children may be dying each year from pneumonia due to substandard and falsified antibiotics. A second model done by the London School of Hygiene and Tropical Medicine estimates that 116 000 (64 000 – 158 000) additional deaths from malaria could be caused every year by substandard and falsified antimalarials in sub-Saharan Africa, with a cost of US$ 38.5 million (21.4 million – 52.4 million) to patients and health providers for further care due to failure of treatment.

- Substandard medical products reach patients when the tools and technical capacity to enforce quality standards in manufacturing, supply and distribution are limited. Falsified products, on the other hand, tend to circulate where inadequate regulation and governance are compounded by unethical practice by wholesalers, distributors, retailers and health care workers. A high proportion of cases reported to WHO occur in countries with constrained access to medical products.
- Modern purchasing models such as online pharmacies can easily circumvent regulatory oversight. These are especially popular in high-income countries, but more research is needed to determine the proportion and impact of sales of substandard or falsified medical products.
- Globalization is making it harder to regulate medical products. Many falsifiers manufacture and print packaging in different countries, shipping components to a final destination where they are assembled and distributed. Sometimes, offshore companies and bank accounts have been used to facilitate the sale of falsified medicines

Substandard and falsified medical products:

The Consequences

Far too many people in the world still have no access at all to basic health care.Up to two billion people cannot get medicines that are crucial for their health and many millions more risk being tipped into abject poverty by healthcare costs that they simply cannot afford. As this report shows, constrained access to quality, safe and effective medical products creates a vacuum that is too often filled by substandard and falsified products Despite this huge and continuing challenge, efforts to reduce global inequities in access to health care have succeeded at least partially. Per capita spending on health more than doubled worldwide in the 20 years to 2014, the last year for which comprehensive data are available. In low-income countries, spending on health came close to tripling over those two decades. Although much of that still comes out of the pockets of families who can ill-afford it, the percentage of the health care bill paid by governments rather than families is rising fastest in the poorest countries. One effect of these collective successes is that the market for medicines and other medical products has shown unprecedented growth. Some 15 years ago, global sales of medicines rose above US$ 500 billion for the first time. Since then, sales have doubled again, to approximately US$ 1.1 trillion, with by far the largest growth occurring in middle-income markets (3,4).

Unfortunately, this growth has opened the door not just to quality, safe and effective medicines, but also to medicines, vaccines and other products that do not meet quality standards and that are sometimes positively dangerous.

substandard medical products are made by registered manufacturers. However they do not meet approved quality standards, sometimes because they were poorly manufactured, or badly packaged or transported. In the case of falsified medicines, the manufacturing and packaging are deliberately designed to deceive consumers. These items, masquerading as medical products, may contain amounts of active ingredient that are either dangerously high or ineffectively low. They may contain contaminants (as was the case with the cough medicines in Pakistan and Paraguay), or no active ingredient at all. Sometimes, medicines that have passed the expiry date determined by manufacturers and regulators are repackaged and put back on the market, sometimes pretending to be a completely different medicine. These irregularities can undermine people's confidence in medical systems and endanger health, while eating into family and government budgets.

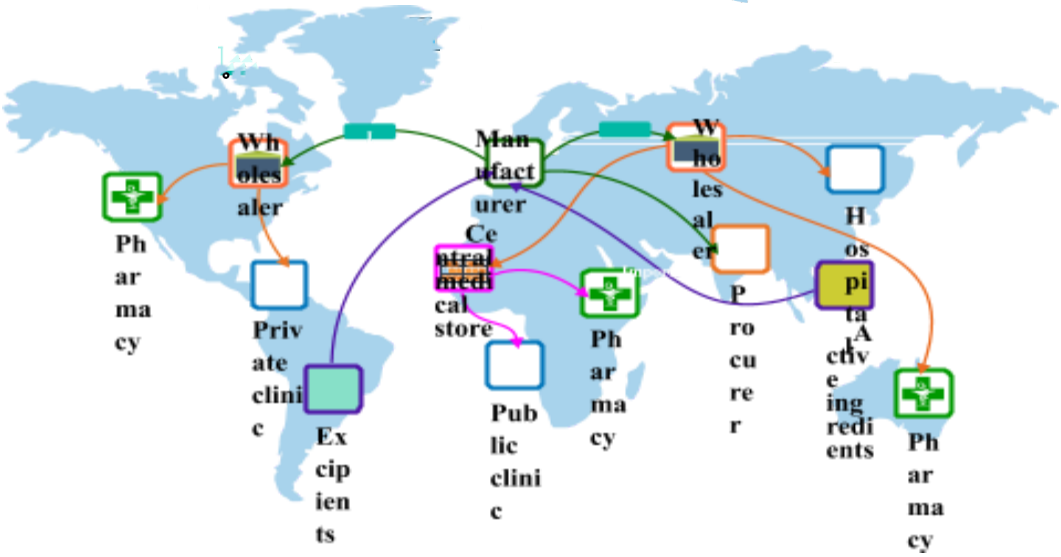
A threat to health:

When medicines do not work the way they should (as is the case with most substandard and falsified medical products), they can prolong illness and the inconvenience, time off work and often the misery that go with it. Doctors and other health workers waste precious time trying out alternative treatments, when all that is really needed is a quality version of the same treatment. In the worst cases, several of which are described in this report, people die, either from untreated disease or because the product itself kills them.

Substandard and falsified medical products in one country can make diseases impossible to treat even in another country that has a very well-regulated medicine market. This is because substandard medicines promote antimicrobial resistance. Antibiotics and other antimicrobial medicines are manufactured and prescribed at doses designed to destroy the pathogens that are causing illness. If a treatment course contains only a fraction of the correct dose, or if it is so badly made that the active ingredients are not released properly, then it is only likely to destroy some of the pathogens, but not all of them. The ones that survive will be the ones that have mutated enough to survive low doses of the medicine. Usually, they do not reproduce very quickly. But with all the more susceptible strains killed by the weak medicines, they have room to multiply and spread to more people. There is clear evidence that resistance to the most important antimalarial medicine, artemisinin, first appeared in a part of the world where at one point between 38 and 90% of the artemisinin medicines on the market were substandard or falsified (5–7). This really is a global problem. In the age of cheap air travel and mass population movements, people who develop resistant infections because of substandard or falsified medicines in one country can easily travel to another country and pass on the mutant infection. Once a bacteria or virus is resistant to a medicine, even a full treatment course will not kill it. So even if the medicines in the new host country are all perfect quality, they will not cure the disease. This not only affects treatments for tropical diseases like malaria. Essential antibiotics are used for routine purposes on every continent, for example to prevent infection in cancer patients whose immune responses are temporarily reduced because of chemotherapy, or to protect against infection during planned surgery. Substandard and/or falsified versions of these antibiotics have also been reported in every region of the world.

The Problem with complex supply chains

Nowadays, a tablet taken in Germany may be made in Egypt from ingredients imported from India, Brazil and Spain, packaged in foil that came from China, inserted into a box designed for the United Kingdom of Great Britain and Northern Ireland, and shipped to Liverpool by way of Dubai. A trader in the United Kingdom, taking advantage of fluctuations in the foreign exchange rate, might legally repackage the medicines with information written in German and ship it to Munich. This extraordinary complexity, which is illustrated below in a much simplified way (Fig. 2), involves a high turnover of products



passing through many hands and presents numerous opportunities for mistakes, bad practice and unethical

Restrictions due to lack of money

While substandard and falsified medical products in the unregulated and informal marketplaces are sometimes less expensive than quality, safe and effective medicines, they cost more in the long term Uninsured patients have to dig deep into their pockets a second time to buy effective treatment when a substandard or falsified product fails to work. These patients are often among the very poorest. Insurance companies or national health systems also have to pay twice if medical products fail to work. Further, they face the extra costs of coping with the adverse reactions and drug-resistant infections that substandard and falsified medicines and vaccines can trigger. The legitimate pharmaceutical manufacturers must bear the cost of product recalls, and they may lose out substantially if falsified products undermine consumer confidence in their products.

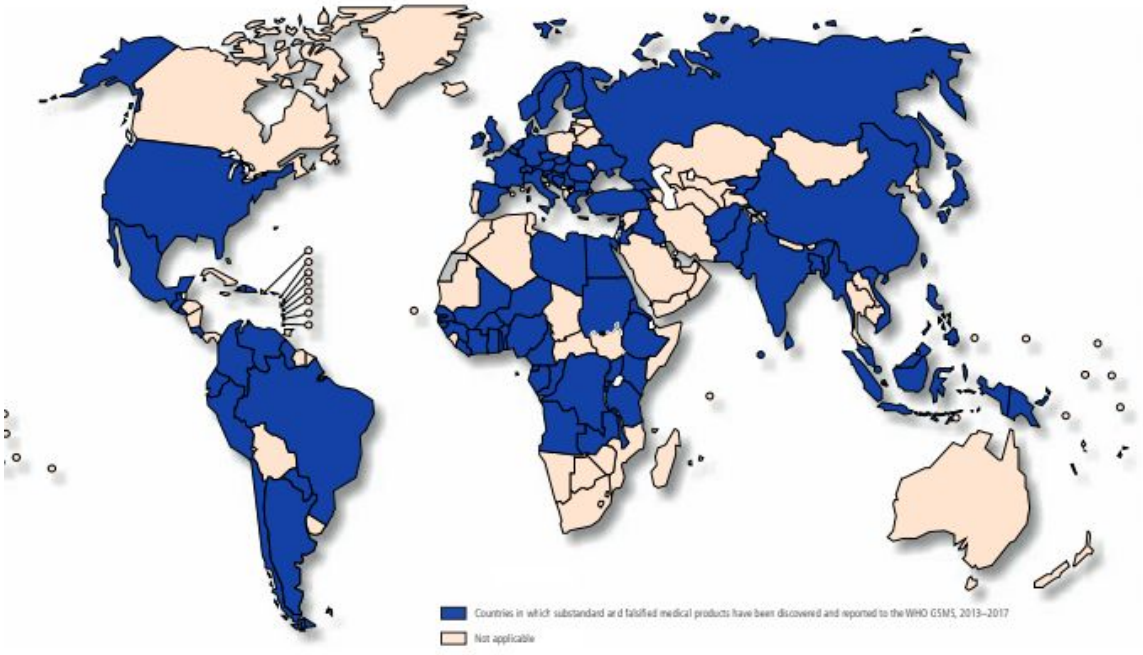
- The people that benefit most from the trade in falsified medicines are criminals. The international policing organization INTERPOL has reported that some organized criminal networks are using profits from falsified medicine operations to subsidize other clandestine activities

Understanding the problem: Analysis of the data

The first question that is asked about the topic is how much, or how many, and the simple answer to that is that this cannot be answered from WHO'S GSMS alone, due to the fact that the system receives reports mainly from focal points in NMRAs who have been trained to identify and report incidents. The Magnitude and overall shape of the problem can be further illuminated through deeper analysis
of the 1500 reports of substandard and falsified medical products reported to WHO's surveillance and monitoring system in its first four years of operation. The question is difficult to answer thought there could be an extensive analysis of all the data available.

The WHO receives data from all over the world, and compiles and processes this data on multiple accounts.

FIG. 3: COUNTRIES IN WHICH SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS HAVE BEEN DISCOVERED AND REPORTED TO THE WHO GSMS, 2013–2017

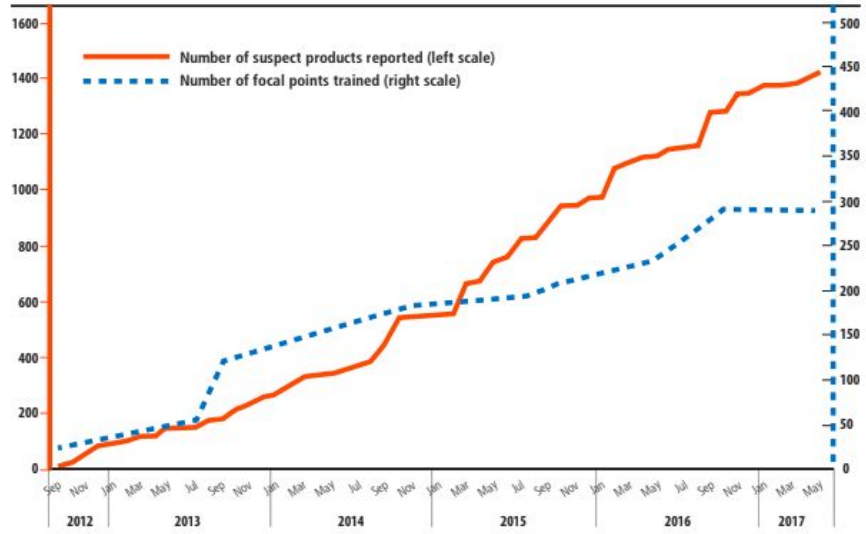


The figure above graphs all the available data on the discovery on falsified medical goods in the world

The common myth with falsified medical goods is that developed nations are less prone to it, which is incorrect as there have been many reports on them from Western Europe and the North America.
The goods can be produced on a large scale, or on a smaller scale. These industries have been found on all continents. The import and export of these medicines cause this issue to be more widespread, as it a falsified drug could be discovered in a different location to the origin.

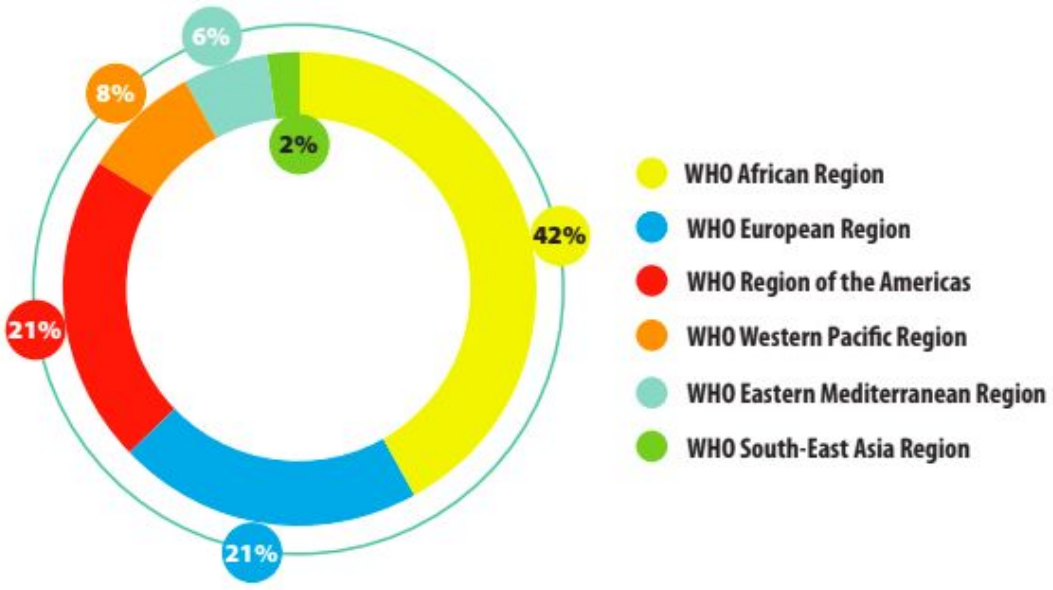
The same can be said about the nations that have not been reported in, because the more the goods are searched for, the more is found, although it is very difficult.

FIG. 4: CUMULATIVE NUMBER OF FOCAL POINTS TRAINED, AND OF PRODUCTS REPORTED TO THE WHO SURVEILLANCE AND MONITORING SYSTEM DATABASE (FROM PILOT PHASE TO 2017)



The graph above underlines the value of mandating and training particular individuals to help provide information, sensitizing health care workers and others about the threat by products that are not standard. Regions with more training have seen more reports of products which are not up to the mark.

FIG. 5: PERCENTAGE OF REPORTS FROM EACH WHO REGION TO THE GSMS (2013–2017)



Taken together, these data strongly suggest that the greater the efforts made to look for substandard and falsified medical products, the more of them are found. That leads to a second conclusion: because the system is new, the appointment of focal points was only formalized in 2017, and training is ongoing, it is highly likely that the cases now reported represent only a fraction of the problem.

Substandard and falsified medical products:

The Causes

Before we go into how the number, types and distribution of these falsified and substandard drugs, we need to understand the motive and opportunities that come up. Since the beginning of commerce, products that are believed to cure illnesses have been falsified due to the appeal of making profits in such a high demand market when one lacks the ability to fairly compete with powerful individuals and firms. In the eighteenth century, when malaria was still endemic in Europe, the continent was inundated with fake and poor-quality cinchona bark, used to treat fevers. A British doctor, William Saunders, pinpointed both the reason for the falsification and its consequences stating that the greed of dealers to be the driving force behind the trade of such practices. This leads to the undermining of public confidence in medicines being a grave consequence, especially in areas that lack the proper resources to gain alternatives to the pharmaceutical.

Due to the fact that there are more of these products, in part because the aggregate demand for medicines, vaccines, and diagnostic kits has grown at an unprecedented rate, the growing market

has also been opened up to unscrupulous traders, businesses and criminals. This is true specifically in regions of high demand, yet shortage of supply, aligned with the fact that low-cost products are coveted if sales volumes are high enough. Substandard and falsified pharmaceuticals are most likely found in areas where: there is limited access to affordable yet reliable medical products; government standards, regulation and interference is low from poor infrastructure to corruption in both public and private sectors; and where there is limited capacity to meet the standards of quality for manufacturing and distributing.

Constrained Access to Affordable, Safe and Quality Medical Products

These falsified and poor-quality medications find easiest access to the market when there is a vacuum created from the lack of products available in a consumer's budget. The lure of *any* medications being able to be bought from untrusted, unreliable and unlicensed sources. Also owing to the shortage in manufacturing due to an outbreak of disease or exceeding national capacity, medical institutions must also now rely on these sources to administer critical care to those in immediate need of medication

A patient and/or their family will always need to keep in mind the price of medications needed by them, considering that health systems and insurance does not cover it as they will need to pay from their own income and wealth stores. When faced with the choice of obtaining good-quality medicine form a well-known supplier at a high price, or an unlicensed supplier selling a cheaper one. The individual will choose the latter due to the pressures of cost that he/she faces. A consequence that arises when firms aim towards profit maximization.

Avastin, a trademarked brand of the cancer medicine bevacizumab was widely used in the United States to treat many types of cancer, including advanced breast cancer, at a cost of around US$ 2400 per injection. In November 2011, following a review of new clinical trials that showed no real benefit for breast cancer patients, the United States medicine regulator (US FDA) decided that the manufacturer should no longer sell it for that use. Several health insurance companies changed their policies to match, saying they would not cover the cost of the medicine for new users. But some women and their doctors still wanted to use it.

Three months after the change in policy, the US FDA announced that at least 19 medical practitioners in the United States had bought falsified Avastin from a Montana-based distributor who (according to a court indictment filed in 2015), was linked with an Internet pharmacy purporting to be based in Canada. The distributor was reported to be offering the sophisticated injectable medicine under its Turkish brand name Altuzan for US$ 1900 per dose, US$ 500 less than its normal price in the US market at the time. When the US FDA tested suspect vials of the medicine, they found that it contained no bevacizumab. Unravelling the supply chain proved difficult. The US distributors had acquired the medicine via the Internet-based pharmacy from a subsidiary wholesaler based in the United Kingdom. The British dealer had bought it from a company in Denmark, according to regulators. The Danish company, in turn, had acquired it from a Swiss company, who were supplied by an Egyptian businessman. The Egyptian told the Reuters news agency that he had himself bought the medicines (thinking they were the genuine

article, made in Turkey) from a Syrian dealer, who signed a hand-written sourcing document with his thumb-print because he could not write.

This case reveals the complexity of managing legitimate drugs when exposed to the market. Seeing as how the increased trade of the goods led to an increase in national border movement, making it even harder to ensure that no falsified or substandard medical product enters into the market. As seen, the pressures of acquiring medicines at a cheaper market and the promises of low prices overwhelms the buyer and causes them to ignore the legitimacy of the supplier. This is made even more apparent when they compare the prices to the usual fixed rates applied for medicals goods in a country. For legitimate suppliers, they face the pressures of increasing profits and always looking for more cost-saving measures, which in turn, leads more substandard drugs entering the supply chain under the guise of cheaper-to-produce medications.

High prices are not the only reason as to why people have difficulty obtaining medical products which they need. They stretch to the fact that the necessary medicines are simply not available due to poor infrastructure, war, disasters, geographical isolation, all of which disrupt distribution. Bad planning, theft or mishaps also lead to stocks being depleted and the speed at which they manufacture new goods cannot keep up. When this shortage of quality medicinal products occurs, less reliable products often quickly flow in to fill the gap.

Conflicts, which already goes in relation with fragile administrative structures, disrupts healthcare systems that aim to help people. It also displaces people, creating an influx of patients suffering from various conflicts to receive medical attention, leading to an increased consumption and depletion of medicines, vaccines and diagnosing kits, reducing the likelihood of them being available.

Kandahar, in Afghanistan, has had to deal with such a constellation of fragility. In April 2014, the city was tense ahead of presidential elections that some feared could tip the country back into civil war (25). A large hospital in the city, operated with the support of an international agency, was running low on ephedrine, a stimulant of the central nervous system used to keep blood pressure constant in trauma surgery and during other operations. Killings and suicide bombings had recently resumed in the city, and surgeons knew they needed the medicine in stock in case violence spread more widely following the elections. Stock management was, however, complicated by restrictions on import and export of ephedrine, which is also used as a precursor chemical in the illegal manufacture of meta-amphetamines. In order to avoid bureaucracy, many local suppliers import the medicine without all the proper clearances. From one of these wholesalers, the hospital bought ephedrine advertised as having been manufactured by Bayer in the United States. After using it for a month, doctors began to worry; unusual numbers of their patients were suffering from hypertension. They stopped using the ephedrine, and, with the help of WHO, sent photos of the product to Bayer. They also kept samples, but there is no laboratory qualified to perform quality testing of ephedrine in Afghanistan, and the hospital was unable to send the samples to a foreign laboratory because of the strict export controls on the substance. On the strength of the photos alone, Bayer confirmed that the packaging did not match that of their genuine product.

The international agency quickly sourced an emergency supply of genuine ephedrine overseas to fill the gap before regular supply chains could be re-established. Afghan customs authorities held up the shipment, saying it could not be released until the previous (falsified) stock had been used up. Although the situation was eventually resolved, the hospital was without a quality-controlled supply of this important medicine for a full four months.

Theft is also a serious concern among both suppliers and manufactures. This relates to not only theft in the store from which purchases take place but also in the transport of these medical products. Cracking down on drug store thefts have already been implemented and strict measures on the storage of these drugs has been undertaken. This is a serious harm as it greatly reduces the availability of these goods and causes further shortages. Yet it isn't restricted to the lower end of supply but extend to even the high areas where such measures such as in-person monitoring and managing proves ineffective. By no means are these problems confined to low-income or middle-income countries, seeing as how even countries such as Italy, face theft of medicines (high value types like those that help treat cancer).

The mark of an effective health care system is the ability to predict which drugs will be in demand at what period of time. This is extremely beneficial to help manage the quantities and types of medication that need to be obtained. Developed countries implement this to high standard and are efficient at providing at any instance in time. Lesser developed countries find this difficult as they lack the means to do so and suffer from this as well. However, what needs to be addressed is the way in which a state deals with a sudden outbreak of a known or unknown disease. This is crucial in rapid relief and response to these situations as it relies heavily on the judgements made by the healthcare systems in place in a country. Predictions of the need for pharmaceuticals is made based on the history of diseases, outbreaks and incidents within a particular state. Yet this is challenged when a country is exposed to a disease rarely or never seen before in *that* state. This means that the medications for in response to the particular disease will not be kept in stock and will likely be in low quantities. Dealing with this is an important measure that needs to be implemented.

Furthermore, the other prevalent issue that arrives from this is the mislabelling and misidentification of certain medicines. In May 2017, a pharmacist in the Niger capital Niamey received an unexpected consignment of vaccines from their regular wholesaler in neighbouring Burkina Faso. Remembering the falsified vaccine scandal two years previously, the pharmacist contacted the Brazilian manufacturer listed on the packaging. Although the manufacturer exists, they do not make this specific version of meningitis vaccine; the manufacturer therefore alerted regulators in Brazil, who in turn requested that the manufacturer contact the WHO surveillance team. WHO coordinated with the health authorities in Niger, who had asked for help investigating the case. Early indications suggest that this new case involved far more than just extending the expiry dates on the labels of formerly genuine vials. Expertly produced labels and newly printed cartons bearing seemingly plausible but fictitious product information suggest that the falsification of meningitis C vaccine has shifted from being a cottage industry to a more industrial scale. Proving how the dangers of misinformation could lead to adverse effects of the usage of these medicines.

Acceptability is another challenge to be combated seeing as how the preferences of consumer to their provider affects the marketing practices and the influence to be held over a consumer. Policy-makers find it already difficult to respond to the demand, dosing regime, or brand marketing in some way or the other. This is made next to impossible with the manipulation of the way public citizens perceive a certain brand to vary their strategies at marketing and maximize profits. However, this is also abused by various underground actors as well. Illegal suppliers gain access to disposed vaccine bottles and storage units for medical products and then repurpose them by filling them with cheap and low-quality vaccines, saline solutions and sometimes even antibiotics and then relabel and repackage them for redistribution as expensive brand companies. This mislead the consumer to make an illegitimate choice on the purchase of these goods.

While press coverage often focuses on the falsification of high-priced medicines, the cases reported to the WHO substandard and falsified medical products surveillance database make it abundantly clear that those involved in the production and supply of falsified medical products are attracted by profit margins, rather than just price differentials. Even low-priced medicines can make money for criminals, as long as the sales volume is high enough. As Table 1 in section 3.3 showed, antibiotics (many of which sell relatively cheaply, but in huge quantities) account for 17% of the falsified products reported so far. The trick for criminals is to make their low-priced falsified products acceptable to large numbers of consumers. They do this by hijacking marks of quality.

Lack of Good Governance

Falsified and substandard medical products often reach patients because of a failure of governance. In this context, governance is a very broad term: it covers the rules that control the manufacture and trade of medical products and the systems that monitor them. Governance also refers to the laws that underpin existing rules and regulations, and the institutions that enforce those laws. The term includes poor ethical practice through to corruption in both the public and private sectors.

Sometimes, governance fails because there are not enough well-trained people, functioning laboratories or temperature-controlled warehouses to ensure that the rules are followed adequately: those cases are discussed in section 4.3 on technical capacity. Other cases, some of which have already been described, are more egregious: greed leads to deliberately unethical and criminal behaviour, and current governance structures are often not strong enough to hold perpetrators to account.

The pharmaceutical trade has become a web of international exchange. As middle-income countries improve their technical capacities and industrial bases and more countries start participating in pharmaceutical production, the multinational provenance and global journey of a single bottle of tablets is likely to grow even more complex. This global interconnectedness must be mirrored by regulatory structures that allow national authorities to exchange information and

skills quickly and efficiently. The WHO GSMS aims to provide regulators with just such an information hub.

No country has the capacity to inspect tens of thousands of different medical product formulations coming from hundreds of different manufacturers. Often, the best they can do is to assume that if the product is manufactured in a well-regulated country, it will be of acceptable quality. That is generally a safe assumption, especially where cooperative agreements allow the importing regulator to carry out due diligence checks with regulators in producer countries. However, even in some of the most regulated markets such as the European Union (where the work of the pan-European regulator is reinforced by agencies in each nation state), falsified medicines sometimes slip through the net. As in any market, they are especially likely to escape detection if the falsified product is sold exclusively to less regulated markets.

The cases of falsification reported to WHO represent a small fraction of the true total. The very fact that they have been discovered and reported internationally means they are also among those most likely to be followed up. The investigation and prosecution of those involved is the responsibility of the competent authorities in the countries in which they are being manufactured, distributed and supplied. Yet, even among the cases in the WHO database, only a minority have led to successful prosecutions.

This is in part because successful prosecution of pharmaceutical crime is very difficult. Most often, falsified medicines only come to light when they reach the retailer or the patient – it is very hard to trace them back through complex supply chains, or to prove where the criminal activity occurred. Successful investigation requires an extraordinary level of collaboration, which is sometimes hampered by governance structures. In some countries, medicine regulators are a unit of the ministry of health; in others they are separate entities. In either case, coordination between the agency or unit charged with oversight of the quality of medical products on the one hand, and the group reviewing pharmacovigilance data and treatment guidelines on the other, is not always smooth. This is usually the result of the siloed structures common to most large institutions; it is sometimes aggravated when the decisions made by these different units affect budgets, for example because they have implications for procurement or generate licensing fees. Whatever the reason, siloed structures mean important information is not always quickly shared.

The long journey between tablet formulation and administration to the patient involves many entities: producers of raw ingredients, manufacturers of finished products, transport companies, stock managers, brokers, distributors, and retailers or health facilities, at a minimum. Accountability is thus very hard to establish: it is not always clear where one actor's responsibility ends and another's begins. And yet transparent accountability mechanisms are critical to effective oversight of the production and supply of medical products.

Front-line health workers, who handle medical products daily and observe their effects, are often first to become suspicious about the quality of vaccines or medicines. Yet they are often reluctant to report their suspicions to the national regulator for fear of reprisals from the criminal networks that produce and distribute falsified medical products, or from health service managers who may have procured the product in ways that were not fully transparent. Legitimate manufacturers and traders who provide information to investigators have sometimes been told by powerful forces in

the market that their businesses will suffer if they do not stop cooperating with the investigators. Where there are no transparent accountability mechanisms that encourage reporting and protect those who voice their suspicions, distributors can continue to trade substandard and falsified medical products with impunity at the lower levels of the supply chain. They know they are unlikely to be reported. If a falsified product is made or sold by a company licensed to handle medicines, vaccines or diagnostic kits, the company can be sanctioned by regulatory authorities. However, in many cases, sanctions are imposed by the courts. While most judiciaries are now very familiar with cases involving illicit drugs, they do not always understand the potential gravity of pharmaceutical crime. While illicit drugs can certainly be harmful, they are at least taken knowingly. Those who consume falsified medicines are often as gravely threatened, but their exposure to risk is entirely involuntary. Since falsified medicines also threaten family and national budgets and confidence in health services, as well as cultivating drug-resistant infections, one might expect penalties for the falsification of medical products to exceed those for the traffic in illicit drugs. And yet, in most countries, sentences for falsification of medical products are much less severe.

Weak Technical Capacity and Tools

The cases discussed so far illustrate the role that imbalances in supply and demand and shortcomings of governance play in undermining the quality of medical products all over the world. They show that falsified medicines are produced largely out of greed, while poor governance, coupled with limited capacity for oversight, allows them to reach consumers. Substandard medical products, on the other hand, are usually the result of a technical deficit coupled with poor oversight. Both are often the result of limited capacity. Good manufacturing practices – well equipped laboratories; field detection technologies; transport and storage systems that keep products at the right temperature while accurately tracking their whereabouts; competent oversight of production and supply chains – all depend on having the right equipment and well-trained staff. In many countries, some or all of those things are already in short supply, and the rapid expansion of both globalized supply chains and demand in lower income settings is stretching capacity still further.

Good manufacturing practice (GMP) depends on having standard operating procedures, clearly laid out and easily available, together with trained staff who follow them diligently. In late 2011, hundreds of patients began arriving at hospitals in Lahore, Pakistan. They were suffering from a darkening of the skin, bleeding and nausea. At first an outbreak of dengue fever was suspected but was later ruled out. Experts were baffled: however, suspicion began to focus on a suspected adverse drug reaction. All of the hospitalized patients had attended the same cardiac hospital and were taking a range of medicines. Dispensing of those medicines was suspended and samples sent to a number of laboratories. Analysis showed one of the cardiac medicines was contaminated with lethal levels of an antimalarial. More than 200 patients died and 1000 were hospitalized during this crisis. Once the cause of the contamination was identified, treatment was quickly administered. The Government of Punjab established a judicial enquiry tribunal which

determined that the contamination was a result of poor manufacturing standards that had led to an active pharmaceutical ingredient being confused with an inert excipient.

In another area we see that medicines, that met the correct specifications when they left the factory, can be substandard by the time they reach patients, because they may have degraded during transport or storage. Medicines can lose their potency because they were not packaged properly, because they were not protected from the elements during transport, or – commonly – because they are transported or stored at temperatures or levels of humidity at which their active ingredients become unstable. It is particularly hard to ensure good distribution practices for medical products because of the weak regulatory structures. While national regulatory authorities are tasked with overseeing storage and distribution of products destined for their own citizens through the public sector, they often have less influence over the private sector, or over products supplied by international donors. And, perhaps more importantly, often there are no clear oversight structures for medicines in transit. That means that there is minimal regulatory oversight of conditions either during shipment or in the many transit points through which a single medicine might pass on its journey from maker to market.

Standard operating procedures and protocols are of little use without the tools, personnel and associated budgets needed to operationalize them. Those tools are very often in short supply, especially in the areas where the other factors that facilitate trade in substandard and falsified medical products are most commonly found. And the tools that do exist are not always in the hands of the people who need them most. Drug quality testing technologies are a case in point. In several of the cases cited so far, including that of cough syrup in Pakistan and Paraguay, ephedrine in Afghanistan and paracetamol in the Democratic Republic of the Congo, national authorities could not perform the sophisticated tests that would allow them to ascertain the composition of a medicine that was apparently harming patients. Some of those who might have had the technical capacity to do laboratory analyses could not obtain the expensive or restricted reference standards against which to test the medicines. And while front-line customs staff are most likely to encounter potentially low-quality medicines before they enter the national supply chain, and front-line health care workers are most likely to spot them once they do, it is very rare indeed for either of these groups to have access to simple field tests that would help them to triage suspect products. Where field testing equipment is available, staff do not always have the training or the time to use it correctly or consistently.

Even with the best equipment, regulators cannot function properly if there are simply not enough appropriately trained people to do the job. In an assessment of regulatory capacity in 26 countries in Africa published in 2010, WHO concluded: “On the whole, countries did not have the capacity to control the quality, safety and efficacy of the medicines circulating on their markets or passing through their territories.”

Substandard and falsified medical products: Introduction to Solutions

Throughout the guide, the various issues both outcomes and premise have been thoroughly analysed. Driven by the growing market of trade and increasing complexity of supply chains, it is a given that these issues will become increasingly prevalent, unless serious, well-resourced and structured efforts are made to tackle the situation.

The Basis of the Solutions should revolve around: **PREVENT, DETECT** and **RESPOND.**

Most of these actions require the coordinated participation of a number of different actors, including national and regional governments; global organizations; the private and non-profit sectors; and civil society. Effective action also requires close collaboration between disciplines: health authorities must work with customs and law enforcement agencies; pharmacovigilance systems must link to those that track antimicrobial resistance and falsified products; pharmaceutical and logistics companies must exchange information with regulators; patient and consumer groups must interact fluently with authorities. While many of these relationships already exist, all must be strengthened and expanded to maximize the chance of success.

WHO itself contributes to these actions in many different ways. Technical efforts are led by the Safety and Vigilance Unit of WHO's Essential Medicines and Health Products Department, which aims to strengthen national and global responses, improving affordable access to quality, safe and effective medical products; strengthening governance and regulatory capacities; and improving technical capability. However, many other programmes and divisions within WHO are also involved, including disease-specific programmes which are themselves challenged when medicines, vaccines or diagnostic kits do not work the way they should. Regional and country offices also play a role in dealing with the measures and policies to be undertaken by the member states.

The solutions drafted up must play out on a global scale not limited to the scope of developed nations where it is relatively easier to tackle, but must also be addressed on the area of underdeveloped states where the situation is fundamentally different and needs to be drafted as more challenging and comprehensive.

An example of usage of resources to tackle the issue, would be the better implementation of the global network of trained national focal points. At the core of WHO's medicine quality surveillance system stand individuals mandated by national medicine regulators or health ministries to exchange information about medicine quality with colleagues globally. Trained by the Geneva-based Substandard and Falsified Medical Products Group, they are able to quickly to alert the global body, as well as a range of partners nationally or regionally, if substandard or falsified medicines are suspected in the national supply chain.

Case Study

South and SouthEast Asia

In 2017, 10.5 percent of pharmaceutical drugs in low- and middle-income countries were found to be fake or substandard, as analysed by the WHO. This was true for countries such as China and India. Asia accounts for the largest proportion of counterfeit drugs in the world, due to India and China being the two biggest drug manufacturers, the repercussions affect a greater populace and have greater damage to the people of these regions.

In 2009, the International Criminal Police Organisation seized around 20 million pills, bottles and sachets of counterfeit pharmaceuticals, while a total of 33 people were arrested and over 100 retail outlets closed. The volume of these types of drugs is indicates the rampant spread of these drugs to patients in Asia. If there is insufficient product on the market, within days, the vacuum is filled with falsified version.

Falsified drugs enter due to the increase in self-diagnosing culture arising int these nations coupled with the internet being a key route to promote substandard pharmaceuticals and misleading patients to the 'Get Results Quick!' sham.

In 2016, the WHO issued a warning after two falsified hepatitis C pharmaceuticals and a falsified yellow fever vaccination were discovered being sold on the market in south-east Asian countries. Majorly countries in proximity to trade routes via sea, as a World Customs Organization (WCO) report stated that 50-60 percent of illicit traffic is channelled by the sea. The positions of countries such as Myanmar, Vietnam and Thailand make them ideal locations for the transport of counterfeit drugs.

The implications of falsified drugs being produced by China and India poses grave dangers to the world seeing as how these two nations are the biggest producers in the world. Half of the deaths from the opioid crisis in the U.S were from the synthetic heroin fentanyl, manufactured from a pharmaceutical company in China.

This can also be seen in the incident with Pfizer, whose sales in their successful drug Viagra plummeted, due to the sale of fakes from a Hong Kong based company. Causing not only patients to receive the ill-effects of the drug but to also lose trust in the legitimacy of Pfizer. Through these outcomes, Pfizer started a system that made use of serialisation technology, enabling their products to be tracked, to ensure that their drugs were not mistaken for counterfeits. This has proven successful and an example as to one way to challenge counterfeit pharmaceuticals.

Rural Africa

Countries like Niger and Cameroon have been vulnerable and susceptible to the threat of falsified pharmaceuticals for years, posing dangers to the already suffering populace in these nation

The circulation of drugs in Cameroon were to have found being comprised of different chemical substances that were easier and cheaper to manufacture but were harmful to patients. The WHO had given strict warning of this for the spread of awareness and caution in the future. Several African states have had a long string of incidents where an unfortunate confluence of struggling economies, weak regulation and poorly-educated consumption leaves the people vulnerable to those wishing to exploit them to make easy money. Again it becomes easier to smuggle in fake drugs from India and China seeing as how most legitimate drugs also originate from the same sources. Africa as a whole becomes more attractive for pharmaceutical players seeing how the value of Africa's pharmaceutical industry will rapidly increase to anywhere between $40 billion and $65 billion by 2020. However, this also greatly opens up the risk of being targeted by negative actors.

A WHO report shows Africa alone accounts for 42% of globally detected cases of substandard and fake medical products. The UN Office on Drugs and Crime suggests the penetration of counterfeit pharmaceuticals is much higher in the developing world, reaching 30%, as opposed to less than 1% in the developed world. It is widely accepted that perpetrators of the phenomenon see Africa as a soft target because the continent has weak technical capacity and tools when compared with more developed nations.

The way in which these fake drugs proliferate boils down to the profit-to-loss analysis for several dealers who want to gain money. The exploitation of these countries is relatively easier than most of the world, and is why majority of the problem lies in not finding these pharmaceuticals, but stopping the spread of them. Something which is increasingly difficult due to the patients being ill-advised or uneducated to know they are consuming a harmful substance.

Many initiates and measures need to take place and should be implemented in these African countries that possess a greater area of prescription of falsified drugs. However, any policy must have to keep in mind the lack of resources that these countries inherently have and are weighed down by. Seeing as how they do not have the means to combat this issue, it comes to how one would deal with substandard pharmaceuticals in an environment such as this.

Another major weakness of the regulatory agencies is their inability to close what Olike Chinwendu, in her thesis, "The Fight Against Fake Drugs by NAFDAC in Nigeria," calls the "chaotic drug market." This includes unlicensed drug vendors—most of them street, kiosk or open-market vendors.

Dora Akunyili, former director of NAFDAC (National Agency for Food and Drug Administration and Control), spent eight years trying to cripple the counterfeit industry in Nigeria. Having lost her sister to fake insulin, she saw it as more than a job. She fired corrupt officials, blacklisted over 30 manufacturers and led raids against open-air drug markets. Between 2001 and 2005, the proportion of fake drugs for sale went from 40% to 16.7%. The counterfeit

industry viciously fought back, burning the agency's labs, attempting to kidnap her son and nearly killing her. Her convoy was shot at and a bullet grazed her temple.

But "seizing, destroying and penalizing violators" did not root out the fake drug trade, according to Chinwendu. She touts strategies used by Tanzania and Ghana to train, license and regulate illegal drug vendors rather than shut them out. The cost of medicines is a determining factor for African consumers, since most pay for their medications out of pocket. Products sold in licensed pharmacies remain out of reach for many. A joint study by the WHO and Health Action International found that "duties, taxes, mark-ups, distribution costs and dispensing fees are often high, regularly constituting between 30% to 40% of retail prices, but occasionally up to 80% or more of the total."

People will continue to patronize drug outlets like open drug markets for first-line treatments, observes Chinwendu, because they're cheaper.

A team from the London School of Hygiene and Tropical Medicine was commissioned by WHO to investigate the health and economic cost of substandard and falsified medical products for first-line treatment of uncomplicated Plasmodium falciparum malaria in sub-Saharan Africa.

The prevalence of substandard and falsified antimalarials was based on a literature review of studies of antimalarial quality in sub-Saharan Africa using random sampling and published between 2001 and 2016 (10 studies, 17 countries). The proportion of samples with API below 85% was estimated at 7.6% for artemisinin combination therapy (ACT) drugs and 10.4% for other (non-ACT) antimalarials. The analysis modelled the incremental impact of such a prevalence of substandard and falsified antimalarials on treatment effectiveness, by comparing current prevalence against a hypothetical ideal scenario where all antimalarials contained levels of API above 85%. Reductions in efficacy of antimalarial were calculated for the proportion of cases receiving a level of API below 85%. The level of API consumed was calculated as a product of medicine quality and the amount of dose taken (i.e. patient adherence to treatment). Health impact was measured in terms of deaths and disability-adjusted life years (DALYs) and economic impact in terms of patient and provider costs related to additional treatment and further care due to failure of initial treatment. Results were estimated for a hypothetical cohort of 1 million malaria cases seeking treatment, containing a mix of cases from low transmission (<10% parasitaemia in patients presenting with fever) and high transmission (>10% parasitaemia) settings. Total health and economic impact of substandard and falsified antimalarials in sub-Saharan Africa was also modelled, based on annual malaria case estimates. Model parameters, including the probability of disease progression for patients not receiving effective treatment and the probability of severe illness leading to death with or without further care, were taken from the available literature. The parameterized base case model gives an overall CFR of 0.79% for malaria cases seeking treatment, and 1.04% for all malaria cases. A "CFR adjusted case" was also calculated, where estimates for disease progression and mortality were adjusted to generate an overall CFR of 0.45% for all malaria cases – consistent with the CFR used by WHO for modelling malaria mortality.

The base case analysis estimated an additional 529 deaths (CFR adjusted case: 230 deaths) per 1 million malaria cases seeking treatment, as a result of the reduced effectiveness of substandard and falsified antimalarials. Drawing on two different sets of annual malaria case estimates (from the World Malaria Report and Clinton Health Access Initiative), the base case analysis estimated that substandard and falsified antimalarials contributed an additional 72 000–267 000 deaths (CFR adjusted case: 31 000–116 000 deaths) annually in sub-Saharan Africa. Total annual economic impact (base case) due to additional treatment-seeking and further care was estimated at between US$ 12.1 million and US$ 44.7 million (CFR adjusted case: US$ 10.4 million and US$ 38.5 million).

Questions to Ponder

These are some of the questions you will need to put up to help understand how to effectively and efficiently tackle the current issue. Such as:

- Who are the vulnerable actors here?
- What measures have been undertaken that have proved successful? Why have they been so? What measures have been undertaken that have proved to be a failure? Why have they been so and how to improve on it?
- How to prioritize action between different countries?
- In what manner are these medical products substandard and/or falsified?
- How to implement the global surveillance system effectively