Falsified and Substandard Medical Products All Around the World

World Health Organization (WHO)

I. Introduction

The United Nations World Health Organization, also known as WHO, is an organization that focuses on helping people all over the world achieve a healthier future. This organization helps combats all health-related problems. It works with the 194 Member States and has approximately 7000 employees. WHO was founded on April 7, 1948, every year we celebrate that date as World Health Day. The organization is financed by annual benefaction made by member countries.
WHO focuses on bringing relief to countries that are having a health-related problem. The organization works with nongovernmental organizations, governments, agencies, foundations, etc... The organization mainly works on advising health ministries and provides treatment and care through the health field.

Since the beginning of time, the falsification of products has been a problem for human society. In 500 a. C., in Egypt Queen Hatshepsut, wanted to get the greatest medicine of the land. She confidently knew the market was full of imitations and false products. Hence, she decided to send her servants to seek the best and original plants/resources to produce the desired medicine. Nowadays, falsified and substandard medical products (FSMP) are a worldwide problem. At first, this problem resided mainly in underdeveloped countries and regions, like South Asia and South and Central America. However, falsified products are also a widespread issue in developed countries. Every member state should be worried about the topic because of the harmfulness of these falsified products. This type of product is commonly produced under miserable conditions and made by people without any professional or recognized expertise; there is an extremely high probability of impurities and bacteria existing inside the products. The main problem and principal concern of government is the great “invisibility” these medical utensils have. Most of the times the producers even make the packaging as similar as possible to the original one; they are sold as failed packaging products or medical samples. Consequently, people acquire these products at the lowest price in the market. However, many studies and reports have demonstrated the production becomes nugatory to alleviate the illness they were previewed as and result in other health problems or even death. In addition, globalization and cultural exchange have played a momentousness role regarding this issue. External and international commerce has expanded and modified the way people trade. At this moment, there are multiple selling/trading points where people may obtain this illegal commodity. As a consequence, millions of illegal and low-quality products cross borders all around the world being reported as medical samples or even as furniture, which made impossible for the UN, WHO, and governments to recognize the seller, the acquiring person, and the number of products sold on a daily basis. People diminish the problem

due to their necessities and a vicious circle is created within this situation. The producer is disposed to produce as many products as society demands and people are willing to acquire these products to heal and cure their patients at the lowest price.

II. History and Description of the Issue

Vocabulary

To achieve a full understanding of the problems generated by these drugs all around the world, some key concepts must be defined. According to the World Health Organization (WHO), they are three different and important definitions according to this topic. Those are substandard, falsified, and unregistered/unlicensed products. Substandard products are authorized medical products that fail to meet either their quality standards or specifications or both. Similarly, unregistered/unlicensed products are medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulations and legislation. Finally, falsified products are medical products that deliberately/fraudulently misrepresent their identity, composition or source.

Origins and Causes

As mentioned previously, the falsified and substandard products' problem has existed from the beginning of civilizations. Tons of examples of falsified medical products appear throughout history. Another important situation was the Paludism in Europe during the XVIII century. The merchants wanted to save money to improve their profit decreasing the purity and quality of their products. Now, the increased medical product demand has created the perfect ecosystem for the criminals and culprits to develop their business. Mainly speaking, there are three general factors that allow the existent falsified and substandard medical products: constrained access, low and non-ethical standards, and limited technological capacity.

The falsified and substandard medical products have a great facility to establish inside the market because they fulfill a greatly important empty space in humans' lives. Most of the time, the patients need some important medical product and then the public/private service does not have it or the patient does not have the required prescription, consuming unauthorized and illegal products. In addition, price and affordability is another great factor. Many families do not go to a public hospital or are not ensured, then they have to completely pay their medicine and sometimes there is not any product available or even stolen. Price and affordability cases are presented almost everywhere as an opportunity to introduce false products. Bevacizumab in the US, Ephedrine in Afghanistan, and Harvoni in Japan are some of the most recent and famous cases where criminals take advantage of the great medical demand and introduce low-quality products to dupe some consumers and earn some money. Patients and sometimes pharmacists know non-authorized merchants sell them the products, but their situation gets a higher importance level. Similarly, many times people can't access to medical products due to the medicine's acceptations. For medical providers, it is highly difficult to foresee specific demands. Some public workers have a low payment and complement their profit with other activities. These people influence people to buy imported or more expensive products, earning a percentage within each purchase. The greatest situation to exemplify this fact is the falsification of vaccines in Indonesia during 2016. Criminals

observed worker's opportunity to earn money and offered them falsified products with a considerable discount; making them believe they were the same products. Miscreants even falsify WHO seals, stamps, or brands to increase the credibility of their products.

According to WHO, falsified medical products reach consumer's hands due to inadequate governance. The globalization and new technological era have allowed different countries to start producing more medical products and commercialize them. The new commercialization system is international and nowadays the number of medical products traded daily in countless. As a consequence, countries have signed different regulations and rules to regulate the quality of their productions. However, the governments are ultimately responsible for protecting the health and welfare of their inhabitants and for assuring the quality of medical products. Governments do not have any systematic process to detect and be aware of the imported products' quality. Therefore, governments trust the international regulations agreed by the remitter country. However, lawbreakers use those flaws in the system and trade illegal products. Customs random revisions sometimes detect false medication laws. Then, illegal businessmen trade in the least regulated market zones; like South Africa and South Asia. In addition to government deficiencies, it is difficult for hospitals to detect substandard medications because they have the main components with a considerable decrease and the original medications can sometimes suffer these imperfections due to external factors. Then, different results are hardly detected. The government is inefficient during investigations. International organizations like WHO want to investigate any report about falsified products and obligatory have to work along with the health departments, which completely hinders the process and methods. Finally, faulty governance allows the falsification of medical products throughout their judicial system. All around the world, illegal medical products are reported and prosecuted. However, most of the times the judicial system gives ridiculous penalizations to these people. Compared to drug-trafficking, falsifying drugs seems a way better option due to profit and low risk.

Standard manufacturing procedures wrongly followed is the third reason why substandard products exist. Inner and laboratory procedures are greatly important for medical products to achieve the required quality. In a perfect world with a perfect system, medical products would be produced and immediately stored at hospitals and required places. However, the transporting process is the most dangerous part of the cycle. After the medicine is produced, it must be stored at a required temperature. At extremely high or low temperatures the active ingredients become unstable and lose their properties. Most of the carriers do not follow the requirements and the medical products are stored in the wrong conditions most part of the transport process. Nevertheless, carriers are not always the blameworthy subjects of the situation. Many times, the inefficient costumes process makes the medical products to be detained averagely 2 weeks under radical and rough conditions, causing some important and vital modifications to the products. If falsified products are placed into this situation, it is important to denote that these products are mainly hidden from authorities, which means discreet means. Consequently, falsified merchandise does not have any prevention regulation nor even temperature control. Lastly, the missing technical equipment is indispensable for detecting falsified products. Nowadays, even at this moment, a falsified and substandard commodity is used and prescribed everywhere. However, this is not detected because many of these places where the medicine is used have neither the necessary equipment nor personnel to analyze a product. If any conjecture about a product is made, this same

product can be analyzed to find something wrong about it. Notwithstanding, the equipment would give an inaccurate analysis and the people in charge of it would not notice anything amiss about it due to their great inexpertise or insufficient knowledge about it, reducing the chances of detecting any falsified product. The existent falsified and substandard medical products are an important subject that must be solved as fast as possible.

III. International Response and Bloc Analysis

The World Health Organization (WHO) has been a pioneer in finding solutions for the problematic. The most recognized action taken is the creation of the Global Surveillance Monitoring System (GSMS), an excellent development to obliterate the previously explained situation. The GSMS was launched in 2013, and according to the WHO, its main objective is to work with the Member States in improving the quantity, quality, and analysis of accurate data concerning SF medical products, and to use that data in the better prevention, detection, and response to those products to protect public health. This organization mainly receives reports about any suspicion of a medical product and provides adequate equipment and personnel to help any country deleting the product from its market. The most useful activity GSMS does is its "WHO Global Surveillance and Monitoring System for substandard and falsified medical products: Reports and Executive summary". This report is the first done by this organization. However, it was the first document 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. This report is available in 7 languages including English, Chinese, and Arabic. The document is characterized by its quality, including in its more than 50 pages examples of falsified medical products reported to the WHO and how the proper organization reacted to bowl out the situation.

The past May 22nd of this year, in Vienna, the UNODC held the 28th Commission on Crime Prevention and Criminal Justice. During this commission, the UNODC launched the "Guide to Good Legislative Practices on Combating Falsified Medical Product-Related Crime" supported economically by France and several international institutions like the Council of Europe, the Economic Community of West African States, the European Union, the International Council of Nurses, the International Criminal Police Organization (INTERPOL), the New Partnership for Africa's Development, the World Customs Organization and the World Health Organization. The first action taken to counteract this illegal business by the UN committee was made in 2011. Resolution 20/6 was created during the United Nations Congress on Crime Prevention and Criminal Justice in 2011. This resolution is the only one of its kind. Even though it is a current extremely important problem, resolution 20/6 has been the only one referring to the falsified medical products' topic. Due to its early creation, the resolution can be ineffective and too nonspecific. The resolution denotes the importance of the problem and generally suggests the increase of the governments about the situation and invites to create a global committing to achieve its eradication.

Other countries and international response

Other countries have been concerned about the topic and upgraded their trading systems to find any flaws and attack them. The greatest example is Europe. Europe has been characterized by

having a regulated trading system. However, there have been some famous cases where European nations have been involved in falsified medical product situations. The European Union was the first international organization to make an international agreement to counterfeit illegal medicine, In 2010, the Council of Europe signed Treaty No. 211 titled "Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health". Drafted as the final version and completely signed in Moscow, in October 20111, has as main objective to prevent and counterfeit public health threats. Due to the early creation date, the document does not focus at all on falsified and substandard medical products. In addition, the documents protect people from every type of falsification crime, like falsified documents or even process certifications. Another benefit from this signed document is the great aperture the European council has had. The document has been mainly directed or written to European countries. However, the council and its members had decided to invite any other country that wants to internationally collaborate and knock out this threatening problem. Countries like Guinea, Morocco, and Israel had signed and declared their great willingness to achieve their common goal.

Additionally, Spain has been the only and unique country that ratified this agreement, which demonstrates without any doubt the great commitment this European Union member has with the public health services of its residents. Spain has ratified the agreement and other European countries like Ukraine, Moldavia, and Guinea followed the steps of the Iberian country.

Even though the European Council's agreement has been the strongest international signed document, other countries have been inspired and want to follow the culture of responsibility and health care., The most recent case is in Africa, specifically promoted by a Rwandan doctor named Clet Niyikiza. The agreement has already been presented at all the members' parliaments and governments and has been approved unanimously by all of them. Hence, the WHO has approved the idea and currently, the African countries are in a preparation period. Hopefully, this preparation process will finish during this year and the African countries will start a new regime that imposes new and better regulations for their markets.

IV. Committee Mission

Throughout the ongoing debate on possible ways of condemning and reducing the creation of falsified and substandard quality products, all delegates must keep in mind the committee's main purpose is to promote healthy lifestyles and ensure healthcare access to the world's population with the help of governments and NGOs. Delegates must have in mind there are different types of falsified medical products and different situations where the medicine was exposed to brutal conditions. Delegates would analyze with expertise the impact of substandard medical products and in governments, business, and society in general. In addition, delegates would think of solutions that envision a safe environment for both society and the pharmaceutical industry.

The mission of this committee in this simulation is to combat the health aspects of falsified medical products, and perhaps provide guidelines for other UN bodies to carry out the criminal prosecution aspect of the issue. Furthermore, this committee should address potential issues relating to people who have been taking falsified medical problems for extended periods of time and who now face negative health repercussions.

Questions for Further Consideration

- How can the production of falsified and substandard medical products be withdrawn?
- Which zone/country/state/ or city needs immediate help?
- Are current regulations appropriate to last more years?
    - Do they need any modification?
        - Which?
- Could nations in Latin America and in other continents work together to figure out a way of reducing and condemning the falsification of medical products?
- How can the civil society contribute to the eradication of illegal false medicine sales?

V. Annotated links for further research

The following links are meant to guide delegates and help them in their research:

- Country Links

  UN Member States
  This link provides an overview of each country in the context of the United Nations.

  The World Factbook
  It provides information on all nations of the world.

- Committee Links

  WHO
  This is the first official website for the World Health Organization, where it includes its mission and current events happening.

  UNODC Statistics and Data
  This is taken from the official website for UNODC, which provides useful statistics about falsified medical products and drugs.

- Topic Links

  Substandard and falsified medical products
  This article by the WHO analyzes and gives data and a general understanding of FSMP.

  Resolution 20/6
  This is the previously mentioned resolution 20/6, which enhances the elimination of FSMP and calls for international collaboration.

GSMS
This is a description text by the WHO, which explains the main goals and composition of the GSMS.

Executive Summary for Substandard and Falsified Medical Products
This is a summary by the WHO>GSMS which summarizes most of the reports made by the countries and other important data.

SF Medical Products – Background
This is another WHO page which gives a background about FSMP and the bottom links other important sites about the topic.

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