



REVIEW ARTICLE

Counterfeiting Medical Devices: A Global Threat

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The safety of patients is constantly and seriously threatened by counterfeit medical devices. Counterfeit medical supplies violates patients' rights, diminishes the value of the brand, and costs original equipment manufacturers revenue. The objective and purpose of medical treatment can be completely defeated by fake or inferior equipment. When a counterfeit product is used in the life sciences sector, particularly medical devices, it puts the patient at risk and has an impact on the manufacturer through potential brand damage, the expense of removing these counterfeit products from the supply chain, and additional work to prevent future problems. Therefore, it is imperative that producers of medical devices make sure their supply chain, packing, and labeling are tight and carefully traced until the point of use. Both the manufacturer and the consumer are safeguarded by anti-counterfeiting techniques. Manufacturers can include deterrents to each of components of packaging to prevent counterfeiting like hologram, UV identifying code, a 2D barcode with special numbering or serialization, or concealed text written with magnetic or security ink. To make sure the functional quality and effectiveness of these medical devices, proper adaptive and regulatory measures are needed to be in place.

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Introduction

An Extremely broad category, medical devices include everything from tweezers to ventilators. The market for medical supplies and equipment is currently evolving substantially. Through 2028, there will be a 5 % predicted compound annual growth rate for the global market of medical devices. With the collection, curation, and analysis of patient data, the medical device business is likewise undergoing a technological revolution. Wearable technologies and machine learning are becoming standard business tools. There are difficulties associated with these scientific advancements. The inability of the industry to create enough of certain medical supplies to meet demand, as well as high distribution and procurement costs, are significant obstacles. Inflation causes a flood of inferior or

counterfeit goods onto the market (U-Nica, 2022). A product that is counterfeit has not undergone the regulatory requirements that must be fulfilled by any medical device or drug. This means that the intensity of the effects of counterfeiting might vary substantially. With a counterfeit T-shirt, somebody loses a little bit of profit, but at the end of the day nobody's life is at risk but counterfeit medical devices may be dangerous. The key difference between counterfeit and substandard goods is that the former are purposefully mislabeled, whereas the latter do not adhere to specifications or have labelling faults. In addition to posing a serious risk to public health, counterfeit medical devices also cost businesses money since they reduce sales and necessitate further spending to remove the bogus products from the supply chain (Millar A., 2021).



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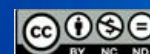
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Counterfeiting of Medical devices

Every new device must meet our three main requirements in order to be taken into consideration for our practice

- It must be secure
- It must be efficient
- Beneficial financially for both the patient and the doctor (Stevens et al., 2014)

Medical supplies that is counterfeit fails to meet all three criteria. Medical devices typically need to go deep extensive investigation to prove their safety before they can be offered to the general public. Substandard and falsified (SF) medical product incidents increased by nearly 47 % between 2020 and 2021 during the COVID-19 pandemic (Perapadan P.S., 2022). Only 20 % of countries have established regulations to prevent the spread of counterfeit medical devices, which make up about 8 % of all devices sold globally. The most frequently imitated medical equipment is surgical equipment, such as clip cartridges, mesh, plates, and screws (The world's biggest medical device recalls, 2019).

Medical equipment that are counterfeited may be damaged, flawed, or contaminated and are not FDA-approved. For example, a false respirator won't let individuals breathe properly so they can survive until their lungs can function on their own. Insulin pens that are fake may injure, irritate the skin, and infect people. Inaccurate readings from fake thermometers can prevent illnesses from being correctly diagnosed and treated (Wang et al., 2020). Alibaba, a Chinese online store similar to a combination of Amazon and eBay, is a significant hub for these kinds of products. Alibaba sells almost 200 000 fake Cryolipolysis systems as well as hundreds of thousands of fake VelaShape™, UltraShape, and Zerona systems.

Reviewing data from clinical studies about the technology are always the first steps we take when considering the purchase of a new medical equipment or system. Clinical trial findings that have been published and show safety, effectiveness, tolerability, and economic viability will be available for genuine medical devices. Counterfeit medical devices do not have peer-reviewed, rigorous clinical study data to support even basic claims of safety and efficacy (The world's biggest medical device recalls, 2019).

Medical equipment fraud not only compromises public health, but also erodes confidence in the healthcare system. The original device registration holder, who spent a lot of money demonstrating the preparation's safety and efficacy and registering it with the Ministry of Health, is harmed by the use of the counterfeit medical device, which compromises their quality and safety and

gives the user a false diagnosis of the patient's condition. The goal and objective of medical treatment can be defeated by fake and inferior equipment (WHO, 2013).

Since the packaging and labelling, as well as the product, are identical to those of the genuine article, it has become more difficult to identify counterfeit devices. Furthermore, both the medical community and purchase departments are not very aware of the existence of counterfeits. The existence of externalities makes it difficult to mitigate healthcare fraud (Mori et al., 2011).

However, sometimes it is difficult to tell whether poor performance is brought on by a fake device or by other problems like subpar clinical facilities or environmental factors (for instance, some devices perform worse in tropical climates (Glass B.D., 2014).

According to the INTERPOL report, law enforcement organisations involved in Operation Pangea discovered 2,000 web links promoting products connected to COVID-19. The medical item that was most frequently purchased online was a fake surgical mask. The identification of more than 34,000 fake and inferior masks, "corona spray," "coronavirus packages," or "coronavirus medicine" reveals only the tip of the iceberg regarding this new trend in counterfeiting (Interpol, 2020; Reactions Weekly, 2020).

Scenario in India

India is already accused of being a major supplier of fake pharmaceuticals on the pharmaceutical front. As per the April 2019 report of the Office of the United States Trade Representative, China and India are reportedly the top producers of fake medications that are sold around the world. Even though it may not be possible to pinpoint an exact number, the study suggested that up to 20 % of the drugs sold on the Indian market may be fake, which could pose a serious risk to the health and safety of patients. The market for surgical and medical devices shares a similar sentiment. There are numerous reasons underlying it, such as:

It is simple to produce counterfeit devices due to the low cost of labour and the low cost of production.

Unregulated internet sales of pharmaceuticals and medical equipment help these counterfeits spread.

Access to reasonably priced and efficient data makes it simple to construct and use websites and conduct online transactions.

Lack of education, poverty, and public awareness - People who are poor tend to spend less even on life-saving medical equipment.

In India, the market for medical devices has long been dominated by imports. Additionally, because the majority

of products lack UDIs, it is incredibly challenging to keep track of the tools and equipment ([Kambli R., 2019](#)).

But after the Introduction of Medical Device Rules 2017, all companies interested in importing, producing, and selling medical devices in India must go by the regulatory framework established by the guidelines, which are in conformity with the framework established by the Global Harmonisation Task Force. The current law covers only a small percentage of the total spectrum, despite the fact that India now has a medical device regulation that includes 23 major categories of devices.

Additionally, the Ministry advised all manufacturers of implantable medical devices, CTs, etc. to register their products on the CDSCO's SUGAM portal for e-governance, which provides stakeholders with a single point of access to online services ([Medical Device and Diagnostics, 2023](#)).

Recalls of Devices

The term "recall" use by USFDA, When a manufacturer takes a corrective or removal step to address a problem with a medical device that violates FDA regulations. Recalls take place when a medical device poses a risk to the user's health or is both defective and unsafe. Based on the relative health concerns they pose, the USFDA has categorised the recalls.

Class I recalls (the most severe) take place when "there is a reasonable chance that a product will cause serious health problems or death"—for instance, when a pacemaker lead is defective and would prohibit normal operation.

Class II recalls (moderate severity) happen when "a product may cause a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death"—for instance, a surgical clamp that is not tight enough.

Class III recalls (low severity) take place when a product "is not likely to cause any health problem or injury" but when a problem still needs to be fixed, like a labelling error ([MAUDE, 2019](#); [What is a Medical Device Recall, 2018](#)).

India, the US, and the EU will publish medical device recalls and alerts on websites. India, EU, and US have the classifications of recall. In India, EU, and US medical device recalls are generally done by the device manufacturer (voluntary recall). In rare instances, the respective authority could issue a recall order to the manufacturer when the manufacturer fails to voluntarily recall a device that is posing a risk to health (statutory recall)

Shortfalls of Indian New Medical Devices Rules concerning the recall of medical devices: India is having

the process of recall of medical devices under the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945, but not in accordance with the 2017 New Medical Devices Rules. Comparatively, the laws governing the recall of equipment in the US and the EU are different.

Data on all types of product recalls are published in the FDA's medical device recall database. Researchers can connect a recall to at least one particular previously-regulated product by using the database, which ties recall information to specific clearance/approval decision identifiers ([FDA, 2018](#)).

Case studies associated with counterfeit Medical devices

The Zeltiq device has received international medical approvals as well as US FDA clearance. The actual Zeltiq device employs a trademarked technique known as "cryolipolysis" that is described to as a patented method to selectively harm adipocytes through a noninvasive, external procedure. With built-in thermal feedback safety measures, Zeltiq's technology uses controlled cooling to avoid overcooling tissue. In the field of cosmetic medical equipment, there has recently been a severe counterfeiting issue. These appear to be freeze injuries based on the clinical images, which may have happened as a result of a lack of a temperature monitoring and feedback mechanism or a failure to protect the skin in other ways. Over a million treatment cycles using Zeltiq's technology have not resulted in any reports of such injuries ([Biesman et al., 2014](#)).

One example of this is the recent fabrication of the medical device SURGICEL, a topical absorbable hemostat. A sterile, oxidised, regenerable cellulose product called SURGICEL is used in surgical procedures to control bleeding. Ethicon, a Johnson & Johnson company, has been selling SURGICEL products for more than 60 years. SURGICEL is well-known among surgeons and has a strong brand equity and accompanying goodwill. These favourable qualities, however, also make it a prime target for counterfeiters. When a neurosurgeon doing a craniotomy was about to insert what he believed to be SURGICEL into a patient's brain, he recognised an issue with it. Particularly, the product kept "rolling up" after being cut into shape since it was not folded properly in the pouch. After receiving notification from the concerned surgical team, Ethicon filed the problematic product as a complaint to the quality department for immediate escalation. Through our quality team, a sample of the questionable SURGICEL was obtained from the hospital and examined by our scientists. In addition to being counterfeit, the product was also shown to be bacterially contaminated and non-sterile ([Albiani R., 2021](#)).

Medical goods distributor RAM Medical Inc. admitted to importing and reselling supplies for surgical hernia mesh that were counterfeit and contaminated. Owner and president Richard Mazon, 61, admitted during the Department of Justice inquiry that the fakes were sold to seven RAM customers. The sale of numerous boxes between December 2008 and June 2009 was tainted by microbial contamination (USAO Archives, 2011; Hubbard D., 2011).

The 33-year-old lady was arrested, according to the Singapore Police Force (SPF), on suspected of taking part in the online sale of counterfeit thermometers. No matter what someone's actual temperature was, the fake thermometers only displayed 37 degrees Celsius. In the midst of the Covid-19 outbreak, it was revealed in April 2020 that counterfeit thermometer guns were being sold online. When the thermometers were opened, the interior was entirely empty and just the LCD chip was present. Infringements of intellectual property rights are taken seriously by the police, especially when they include counterfeit goods that could be dangerous to consumers' health (Hana O., 2021).

A gang that manufactured unbranded oximeters that are counterfeits and then sold them off as branded goods at exorbitant costs ranging between Rs 2500 and Rs 4000 has been nabbed by the enforcement branch of Kolkata. Raids are being conducted to catch the gang members, and many raw materials have also been recovered (Ghosh D., 2021).

Anti-counterfeit approaches

The packaging for medical devices typically consists of three layers: the primary packing (often a pouch), the secondary packaging of a product box, and the final packaging into a shipper where several goods will be placed in one container. Manufacturers can add deterrents like holograms, UV identifying codes, and 2-D barcodes with unique numbers to each of these package pieces to prevent counterfeiting. It is possible to use secret text printed with security or magnetic ink or ring/serialization.

A Unique Device Identification (UDI) is required for manufacturers in order to guarantee the traceability of their goods. The identification and clinical evaluations of medicinal products should be checked by healthcare providers before purchasing them. The fight against counterfeiting requires this kind of item-level serialisation. To protect the goods and the customer, you can supply secure printing for mass serialisation with the use of web-based "labelling and data management" solutions. In addition to enabling the ability to track a product's movement across the supply chain, serialisation also makes it possible to increase efficiency and, most crucially, protect end users (Bansal et al., 2013).

A skilled individual may determine the authenticity of a product fast, and they can go further by consulting the distinctive numbers used in the security marking on an authentication website.

Technology aids counterfeiters in creating exact replicas, but it can also help solve the issue. The answer is Phygital, which combines physical security with digitally enabled authentication systems. When used, Phygital will be able to guarantee a product's legitimacy (Combat Counterfeiters, 2019).

The entire ecosystem would undergo a beneficial shift if the government mandated the use of authentication technologies and the development of an extensive track and trace system (de Bruijn et al., 2009; Pasricha N., 2022).

Conclusion

When these life-saving equipment start behaving in a life-threatening manner, a real dilemma arises. Particularly when the manufacturers make safety compromises with their products, the threat is increased. According to the law, the product company is required to remove its device from the market and consumers in the event of any known hazardous effects caused by these medical devices in order to uphold its safety requirements. One of the main causes for such items to evade laws and destabilise the economy is a lack of understanding about them among healthcare professionals. The complexity and inventiveness of these medical devices have greatly increased throughout time. Manufacturing firms are advancing daily to create more sophisticated, life-saving medical equipment. However, to make sure the functional quality and effectiveness of these medical devices, proper adaptive and regulatory measures are needed to be in place.

Conflict of Interest

Authors declare no conflict of interest.

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