

Counterfeit drugs: an organized crime

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Abstract: Counterfeiting is selling or marketing of non-genuine products as genuine under the name of famous manufacturer without the awareness of both real manufacturer of the product and the consumer. Drugs are consumed for prevention or treatment of disease and hence they provide optimal wellbeing for patients. If the drugs are counterfeited it leads to decreased prevention and treatment of the disease and leads to increased morbidity and mortality. At the same time counterfeit drugs may make loss to the real manufacturer and the government. Counterfeit drugs are one of the global major problems. It's seen in both the developing and developed countries. Drugs can be counterfeited by many ways from changing the concentration of the active ingredient to packing and labeling. The present article provides a brief overview of the present scenario of the counterfeit drugs in India and worldwide, problems caused by the counterfeit drugs and the preventive measures taken to reduce the counterfeit drugs.

Keywords: Counterfeit, Drugs, Morbidity, Mortality.

I. Introduction:

The word Drugis derived from French 'Drogue' means 'a dry herb', is a single active chemical entity present in a medicine that is used for diagnosis, prevention, treatment or cure of a disease. The WHO defines drug as "any substance or product that is used or is intended to be used to modify or explore physiological systems or pathological states for the benefit of the recipient."¹ Counterfeit drugs are defined by WHO as "A product that is deliberately and fraudulently mislabeled with respect to identity or source. Counterfeit products may include products with correct ingredients, wrong ingredients, without active ingredients, with the incorrect quantity of active ingredient or with fake packaging"³ No active ingredient ,low levels of active ingredient, poor quality drugs, wrong ingredients ,wrong packaging or source are the mechanism by which the counterfeit drugs are manufactured and marketed without proper regulatory approval and there by not meeting the determined standards of safety, quality and efficacy.⁴

Drug counterfeiting is relatively recent, being first identified as an emerging problem by the WHO in 1985. Since then the scale of the problem has increased substantially .At present more than 10% of the medicine in the global market is said to counterfeit drugs. The 60% of the counterfeit drugs comes from the developing countries were as 40% comes from the industrialized countries.⁵ According to a report by the Organization for Economic Cooperation and Development, 75% of fake drugs supplied world over have origins in India, followed by 7% from Egypt and 6% from China⁶. The largest numbers of reports are related to antibiotics, antiprotozoal, hormones and steroids. WHO in 2006 established the "International Medical Products Anti-Counterfeiting Taskforce (IMPACT)". European Commission is an active member of IMPACT and has specifically co-funded and supported WHO in the development of the recommendation "Principles and Elements for National Legislation against Counterfeit Medical Products.

There are many examples of dangerous drug counterfeits in past. Other than drugs there are also examples where vaccines have been counterfeited. In 1995 during the meningitis outbreak in Niger, the government received a donation of vaccines from Nigeria which turned out to be counterfeits, with no active ingredients. At least 50,000 fake vaccinations are estimated to have been given, resulting in 2,500 deaths.⁸ Ninety five people in Haiti in 1995, died on usage of paracetamol cough syrup contaminated with diethylene glycol. Similarly in India about forty infants died of paracetamol cough syrup contamination with diethylene glycol in 1998. In 2001 in India about 700kg of counterfeited drugs and 1000kg of raw material and boxes containing labels of another company were seized. In Myanmar in December 2003 approximately 4.5 million capsules of amoxicillin, ampicillin were seized.⁹ In United Kingdom , Lipitor drug used for cholesterol lowering in 2006 detected in the legal supply lacked sufficient active ingredient. Similarly Zypexa used for the treatment of the bipolar disorder detected in the legal supply chain lacked sufficient active ingredient in 2007

and lead to the Recall of counterfeit Zyprex batches.¹⁰ In United States Of America Xenical used for the treatment of obesity in 2007 contained no active ingredients which was sold through internet site operated from outside the USA. Later in 2009 federal agencies come across contaminated, counterfeit, and sub potent influenza products. FDA with U. S. Customs and Border Protection intercepted product claimed to be generic versions of the influenza drug Tamiflu which actually contained vitamin C and other substances not shown to be effective in treating or preventing influenza.¹¹ In China in 2009 anti diabetic traditional medicine which was used for the lowering blood glucose levels contained six times more the normal dose of gilbeneclamide leading to two deaths and several being hospitalized.¹²

The consequences of counterfeit drugs can be drastic for individual health, global health and for the global pharmaceutical industry. At the level of the individual patient, the counterfeit drugs may fail to treat or prevent the targeted disease, may even worsen condition or may lead to death of the person. At the larger scale of community, national or international public health, counterfeit drugs can have devastating effects by contributing to the development of antimicrobial resistance. Incorrect dosing of medication can lead to development of resistance which is a great concern for widespread infectious diseases like tuberculosis and malaria. Counterfeit drugs also have a significant impact on the pharmaceutical industry's business. This is due not only to the violation of patents and the subsequent loss of income, but also to loss of reputation as counterfeiting can destroy public trust in the safety and efficacy of pharmaceutical products.¹³

The pharmaceutical industry in India is among the five largest in world. 64% of the companies operating in India servicing the domestic and global market. The Indian pharma industry has a domestic turnover of more than Rs.20,000 crore and exports over Rs.10,000 crore. The industry is growing at the rate of over 10 percent for the past one decade.¹⁴ According to the WHO, India accounts for nearly 35% of world's spurious drugs market and has been estimated that 40% of the pharma market at the value of Rs 8000 crore is under the grip of spurious and black marketed drugs.¹⁵ A report by Rama Lakshmi suggests that an estimated 12 to 25 % of all drugs sold within India are thought to be counterfeit. The health ministry estimates that 5% of drugs in India are counterfeit, while 0.3% is spurious. In India Bhagirath palace, Chandnichowk in New Delhi is said to be the hub for counterfeit and spurious drugs. Most cases of fake and spurious drugs in the local market were found in Bihar, West Bengal, Uttar Pradesh and Gujarat.¹⁶ Drug counterfeiting business is booming in India because of various reasons such as growing pharmaceutical industry, poor pharmaceutical regulation, high drug prices, value added tax, prescription of drugs without registration, lack of public awareness, weak enforcement of legislations and flexibility in the current legal framework. India's status as a low cost manufacturing base has opened up the gates for counterfeiters. Counterfeiters share none of the heavy research and development costs incurred by genuine manufacturers and hence earn high profits. In prevailing situations where demand for drugs exceeds supply there increases the opportunity for the drug counterfeiting business.¹⁷

According to the World Health Organization (WHO), the fundamental first step towards fighting counterfeit drug production is the establishment of a drug regulatory body. Other recommendations by WHO for reducing the counterfeit drugs are increased random inspection of drugs, consumer awareness campaigns, use of more sophisticated technology for inspection, increased regulation of the pharmaceutical supply chain, and increased punishments for counterfeiters.¹⁸ These initiatives should be led by the government through the drug regulatory body of a country. Inspection of drugs is an easier task for net medicine importers relative to exporting nations like India. Countries importing the drug should conduct inspection at the port of entry and thereby reduce the entry of counterfeit drugs.¹⁹

India took its first steps towards tackling this issue with the establishment of drug regulatory in 2008, the CDSCO. It has a number of goals that are aligned with the solutions discussed above like increased capacity of CDSCO to perform its duties, large scale surveys of counterfeit medicines, greater checks on imports, and consumer awareness campaigns initiatives. Many of these initiatives are ongoing, and some implementation timelines extend to 2020. India in 2008 has increased its penalties for counterfeiters. Convicted counterfeiters are now fined a minimum of USD \$22, 550 or three times the value of drugs confiscated, and the minimum jail sentence for counterfeiting is now ten years.²⁰

The pharmaceutical industries should also take appropriate measure to reduce the counterfeiting of drugs by upgrading the distribution channels by latest technologies so as to decrease entry of the counterfeit drugs into the supply chain and helping in the identification of the counterfeit drugs. The many such technologies used by the pharmaceutical industries are

i) Holograms:

Holographic technologies provide a simplified means for consumers to identify the authenticity of a drug. The advantage of hologram is that they can be applied at the item level, such as a blister pack or vials. The major problem, however, is that they are generally costly and not effective over the long term. Holograms themselves can also be eventually duplicated by counterfeiters, making the initial investment by the brand

owner ineffective. Holograms also do not provide the brand owner with an implementable protocol for supply chain management, track-and-trace ability (e-pedigree), or with the intelligence that is required in the event that counterfeiting occurs. Other more technologically sophisticated measures include nanotagging or chemical/physical forensic measures. These are far more expensive and have not yet been used by the pharmaceutical industry in an appreciable extent.²¹

ii) Barcodes:

These are high-density linear or 2 dimensional bar codes incorporating product identity down to unit pack level, which are scanned and referenced to the central database. One popular implementation is the 2D data matrix code. A 2D code can typically be 1cm square or smaller and yet contains up to 1 Kb of data with some "redundancy" or error correction. Where space is not a limitation, linear bar codes may also be used. The codes are printable by on-line methods including inkjet or digital printing, allowing direct computer control and transfer of records to the central database. Hierarchical systems are developed whereby the label on a shipping case is inextricably linked to the identities of all its contents, and this can further extend up the chain to pallet labels, thereby overcoming the necessity for line of site scanning through the supply chain.¹³

iii) Radio-frequency identification (RFID):

RFID is a wireless data collection technology that uses radio signals for identifying objects, delivering dynamic asset supply chain contents and visualizing the entire asset lifecycle. The basic principle behind RFID systems is that you mark items with tags. These tags contain transponders that emit messages readable by specialized RFID readers. Most RFID tags store some sort of identification number; for example a customer number or product SKU (stock-keeping unit) code. A reader retrieves information about the ID number from a database, and acts upon it accordingly. RFID tags can also contain writable memory, which can store information for transfer to various RFID readers in different locations. This information can track the movement of the tagged item, making that information available to each reader. RFID tags fall into two general categories, active and passive, depending on their source of electrical power. Active RFID tags contain their own power source, usually an on-board battery. Passive tags obtain power from the signal of an external reader. RFID readers also come in active and passive varieties, depending on the type of tag they read¹⁸. A passive tag reader can constantly broadcast its signal or broadcast it on demand. When a tag comes within the reader's range, it receives an electromagnetic signal from the reader through the tag's antenna. The tag then stores the energy from the signal in an on-board capacitor, a process called inductive coupling.⁴

v) Mobile Verification:

Unique code for each product which can be verified by sending texts to the number given. Manufacturers print these codes on packaging, and monitoring begins the minute the product leaves the factory. This way consignment is protected while in transit until they reach their destination.¹³

II. Conclusion:

As counterfeit drugs are one of the global problems having impact on the health of the mankind. Government should take appropriate measure to avoid and make more stringent laws against the counterfeiting of drugs. The pharmaceutical industries should come with the advanced technologies by which their products cannot be counterfeited. Last but not least the consumers should be educated in differentiating the counterfeit drugs from the original drugs.

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