The Business of Counterfeit Drugs in India: 
A Critical Evaluation

Saurabh Verma, Rajender Kumar and P.J. Philip

Research Scholar, Department of Humanities & Social Sciences,
NIT, Kurukshetra–136119, Haryana

Abstract

Drug counterfeiting has become a problem of immense magnitude worldwide which has aroused a significant level of attention among researchers, managers and policy makers. The counterfeit drug industry is estimated to be worth $200 billion a year [1] and has been defined as the “The crime of the 21st century” (ACG Report 2003), present in almost every industry with Asia appearing to be the single largest producing region for counterfeit drugs. 75% of counterfeit drugs supplied world over have some origins in India, followed by 7% from Egypt and 6% from China responsible for 3000 deaths across worldwide per year. Drug Counterfeiting is a worldwide phenomenon having both social and economic impacts, and India is not an exception to it. According to BASCAP- “Pharmaceutical industry is the most counterfeited industry in India”. CDSCO conducted a nationwide survey in 2009, collected 24136 samples from 1995-2008, out of which 1693 found counterfeited. The Pharmaceutical Security Institute (PSI, 2013) discovered 2,193 incidents of pharmaceutical crime during 2013. The present study is based on the extensive review of the relevant conceptual and empirical literature derived from various agencies to evaluate the reach of counterfeiting in Indian pharmaceutical sector. Results indicate the role of IP rights in pharmaceutical industry and provides for various strategies and recommendations to deter the illegal business of drug counterfeiting in India.

Keywords: Counterfeiting, Drugs, Pharmaceutical industry, IP
1. Introduction
The business of counterfeit drugs is not a new one to the world although it persists throughout the ages. The issue of counterfeit drugs emerged in the 1980s when more and more member states of the World Health Organization (WHO) reported counterfeit medicines. According to the Black law dictionary ‘Counterfeit drug’ is a drug made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or right, with a view to deceive or defraud [2]. World Health Organization (WHO) has given a new name to counterfeit medicines i.e. the substandard, spurious, falsely labeled, falsified and counterfeit (SSFFC) medicines. A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity or source. The term ‘Spurious Drug’ has been defined under Section17-B of the Drugs and Cosmetics Act, 1940 as a drug which is an imitation of another drug or manufactured under a name which belongs to another drug, or if it has been substituted wholly or partly by another drug or if it wrongly claims to be the product of another manufacture [3]. A generic drug is a drug which is manufactured and delivered without patent protection or marketed under its chemical name without advertising. Generic drugs are marketed under a non-brand name. Generic drugs are frequently as effective as branded drugs, as but much cheaper than the brand-name drugs. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the wrong ingredients, without active ingredients, missing key ingredients, with insufficient active ingredients, improperly labeled, stored or handled with fake packaging.

2. Drug Counterfeiting–The Global Scenario
Counterfeit medicines are mostly present in industrialized and developing countries. The extent of the problem and several other factors concerning the counterfeited drugs however differ significantly between industrialized and developing countries. E.g., the market share of counterfeit drugs is below 1% of the total medicines market value for countries like the USA, Japan or the EU. In contrast, this number can reach over 30% for parts of Africa, Asia and Latin America [4]. The fake drug market is estimated at $200 billion by the World Customs Organization (WCO). 30% of drugs sold in developing nations are branded drugs which are counterfeited (WHO). Almost 15% medicines sold globally are false. The number of deaths and drug resistance levels continue to rise due to consumption of fake drugs, which is creating a healthcare nightmare, and more so in developing countries. According to cases reported, it is assessed that, in China, between 200000 and 300000 persons die every year because of fake medicines or bad quality of drugs [4]. A major concern for the whole Asian region is the high prevalence of counterfeit anti-malaria drugs. Counterfeits are however not limited to anti-malaria drugs at all. E.g. other anti-protozoal drugs like Miltefosine, for treatment of leishmaniasis, have been targeted as well as vaccines against influenza, rabies and tetanus [5]. Fake antibiotics, birth-control pills and pain-killers have been found among other counterfeited drugs. In 2013, incident data was analyzed with respect to seven regions of the world. Every
region experienced a pharmaceutical crime incident. In total, there were 124 countries found to have been impacted by pharmaceutical crime (PSI, 2013) as mentioned in Fig. 1.

![Graph showing Pharmaceutical Crime Incidents worldwide, 2013.](image)


**Fig. 1:** Pharmaceutical Crime Incidents worldwide, 2013.

The Pharmaceutical Security Institute also documented 2,193 incidents of pharmaceutical crime during CY 2013. Fig. 2 clearly represented an 8.7% increase of counterfeiting incidents over CY 2012.

![Graph showing Total Number of Incidents CY 2009-CY 2013.](image)


**Fig. 2:** Total Number of Incidents CY 2009-CY 2013.
2.1. Drug Counterfeiting in India
The Indian Pharma industry is a highly knowledge based industry which is growing steadily and playing a major role in the Indian economy. India's Pharma industry is 4th in the world in terms of production volumes and over 55% exports are to highly regulated markets. India's drug exports totaled $14.6 billion (around Rs.82, 730 crore) in the financial year up to March 31, 2012. India is a classical example of a developing country with a strong pharmaceutical industry and which also has effective drug regulatory system. A report by Rama Lakshmi suggests that an estimated 12 to 25 percent of all drugs sold within India are thought to be counterfeit. India is not only one of the biggest producers of counterfeits drugs but it has also a huge market for spurious and counterfeit drugs (IMPACT). The health ministry estimates that 5% of drugs in India are counterfeit, while 0.3% is spurious. In India ‘Bhagirath palace’ Chandni Chowk, New Delhi is said to be the hub for counterfeit and spurious drugs in India. Fake drugs form 20% of the 40,000 crore Pharma market in India. What was once confined to exotic and costly pills like Viagra has now proliferated to cough syrups, vitamin supplements and painkillers [6]. India, being the world’s largest supplier of generic drugs, has become an epicenter for counterfeit and fake drugs. In India, Most cases of fake and spurious drugs in the local market were found in Bihar, West Bengal, Uttar Pradesh and Gujarat [6]. The major source countries of counterfeits seized by European customs organizations include China, the United Arabian Emirates and India [7] as shown in Fig. 5 below.

![Source: [7]

Fig. 3: Source Countries for Counterfeits seized in the EU in 2006.](image)

3. Reasons for Growth
The business of Drug counterfeiting 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
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awareness, Weak enforcement of legislations and flexibility in the current legal framework. Drug Counterfeiting in India is a very lucrative business. 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, yet are able to earn high profits. Identifying counterfeit drugs is quite complex and costly. Consumers, and sometimes prescribing physicians themselves, cannot tell the difference between the legitimate product and a counterfeit one. For example, if a patient consumes the fake, but recovers naturally, there is no reason to suspect a counterfeit product. Drug counterfeiters are growing more and more sophisticated by using latest technology systems in their illegal business. In a recent study examining the prevalence of inactive ingredients in counterfeit artesunate (an anti-malarial), investigators discovered that the ability of counterfeit producers to employ advanced printing technology, such as holograms, had improved dramatically between 2001 and 2005. In situations where demand for drugs in pharmaceutical industry exceeds supply, criminally minded people tend to derive profit out of crime by manufacturing and distributing counterfeit or spurious drugs as a substitute for genuine medicines. Also, many a time’s consumers who use medicines inappropriately generate demand for such medicines, the sources of which may be counterfeit. For example, weight supplement drugs have generated market for counterfeit steroid containing medicines. Often these medicines are distributed through unauthorized channels or illicit markets at very high prices. Drugs made for export by the home country are not regulated by many exporting countries to the same standard as those produced for domestic use. In addition, Drugs are sometimes exported through free trade zones (FTZ) where drug control is awkward because of which repackaging and re-labeling take place. This type of careless trade system provides better opportunities for counterfeiters to introduce illicit drugs into the distribution chain even when the system is extremely regulated. Legislation and regulations form the basis for drug regulation. A competent national drug regulatory authority with the necessary resources is required to control the manufacturing, import, distribution and sale of medicines in the country. WHO report states that out of 191 member states, about 20% have well developed drug regulation and legislations. 50% are implementing drug regulation at different levels and the remaining 30% either have no drug regulation in place or a very limited capacity that hardly functions. Inadequate, ineffective or weak drug regulatory control is responsible for encouraging unregulated importation, manufacture and distribution of drugs, leading to the proliferation of counterfeit drugs in the genuine distribution channels [8].

4. Role of IPR
India’s acceptance to WTO (World Trade Organization) and agreement to implement TRIPS (Trade Related Aspects of Intellectual Property Rights) has observed the changes in Indian pharmaceutical industry. The Intellectual property laws applicable to Indian pharmaceutical industry have faced major changes globally. The patents act 1970 provides an impulsive growth to the generic pharmaceutical industry in India.
During the period of 1970 to 2005, India became the global player in the production, distribution and marketing of pharmaceuticals including patented drugs because of the era of process patent [9]. India thus became world’s major supplier of generic drugs, API’s (Active pharmaceutical ingredients [10]. This liberal process patent scenario made tremendous changes in Indian pharmaceutical industry by making the drugs easily accessible at a very cheaper rate. Local Indian firms by developing their own drugs manufacturing processes started making copies by getting it patented too. Indian companies were also free at that time to export their copied products to patent recognizing countries abroad. India’s obligation to implement a TRIPS obedient patent system from 1 January 2005 brought in a product patent era for the pharmaceutical industry in which Indian pharmaceutical companies can no longer manufacture or market patented drugs without license from the patent holder. The generic pharmaceutical industry in India that flourished on process patent was no longer allowed to do so in this new product patent era. This act put on restrictions on Indian pharmaceutical industry to manufacture generic drugs and on the other hand it opened up the gates for investment in research and development of new drugs. This era results in increasing trend in awareness, public participation, patenting and patent enforcement in Indian pharmaceutical sector. In India, there is about 30% share for Pharma in filing and grant of trademarks and patents [11].

5. Suggestions and Recommendations

Drug counterfeiting has become a worldwide problem. There is no country, which can deter the existence of counterfeit drugs in its pharmaceutical market. Counterfeiting or falsified medicines requires collaboration at national, regional and international levels between the law providers, enforcement agencies, manufacturers and suppliers. Health professionals and medical practitioners in particular have a crucial role to play in notifying patients to counterfeit medicines and educating them to detect their presence. In pursuance to this, many Pharma companies are using holograms so that consumers can determine the authenticity of the drug by checking the hologram, but these days, fake drug manufacturers have been able to copy the holograms as well. Therefore there is a need to upgrade the technology from the manufacturer’s end as well. Companies have also started using barcodes on medicines that can be photographed using smart phones like blackberry and I-phone and the image messaged to a number. This also depends on the quality of the camera. This method again is accessible only to the few consumers who have smart phones and not the majority. In all, there is little that a consumer can do at his/her end to determine the authenticity of the drug. Government, Law enforcement agencies and Pharmaceutical industries should take necessary steps to provide generic and branded medicines easily available to consumers at reasonable rates so as to meet their demand effectively. In order to combat counterfeitters, it is necessary to develop and enforce appropriate mechanisms of effective collaboration between health authorities, police, customs, the judiciary, manufacturers, wholesalers, retailers, health professionals and consumers. The distribution channel of Indian pharmaceutical industry should be regulated effectively so as to avoid counterfeitters to
penetrate into the supply chain with their inferior drugs. The distribution channel should be upgraded with the latest technological instruments like Barcode, Holograms, hidden identification marks, Radio Frequency Identification (RFID) chips and tags so that individual serial numbers on each product can be tracked and traced through the supply chain.

References


