

**Global Threat of Counterfeit Drugs –
A Study Covering Extent of Problem and Anti-counterfeit
Measures in Europe & India**

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EXECUTIVE SUMMARY

Counterfeit Drugs – A global phenomena

Counterfeiting is generally perceived by society as a victimless crime, with 'fakes' simply constituting a cheap alternative option, and seen by criminals as having a low risk of prosecution with light penalties relative to the large profits to be made. The reality is that the international trade in counterfeit products is estimated to exceed six percent of global trade. The range of counterfeit products is extremely broad and the trends indicate that counterfeiters no longer confine their activities to luxury goods but increasingly are exploiting consumer goods, including everyday items such as baby food, medicines, cosmetics, aircrafts and vehicle parts.

But the counterfeiting of medicines is a particularly insidious practice. This is not only illegal but constitutes a serious threat to public health and safety since counterfeit drugs are not subject to safety checks. For example, a total of 1,92,000 patients are reported to have died in 2001 only in China from fake drugs.

The World Health Organization (WHO) estimates that counterfeit drugs account for more than 10 percent of the global medicines market. They are present in all regions but developing countries bear the brunt of the problem. An estimated 25 percent of the medicines consumed in developing countries are believed to be counterfeit. In some countries the figure is thought to be as high as 50 percent. Trade in these products is more prevalent in countries with weak drug regulation control and enforcement, scarcity and/ or erratic supply of basic medicines, unregulated markets and unaffordable prices. However, as counterfeiting techniques become more sophisticated, counterfeits are increasingly present in better-controlled markets.

Counterfeiting of drugs as a 'problem' was first mentioned at the WHO conference of experts on the 'Rational use of the drugs' held in Nairobi in 1985. Today, the production of substandard and fake drugs is a vast and underreported problem. Information on the scale of the problem is inadequate.

WHO says that previous attempts to combat the problem were poorly coordinated. There is an urgent need for national and international level cooperation, data exchange and political awareness to safeguard public health.

Purpose & Methodology

The aim of this dissertation is to provide a compiled reference for the problem of counterfeit drugs and anti-counterfeit measures exists / planned in Europe and India. The problem will be addressed as a global phenomena and the role played by the WHO will be documented in detail.

Today Europe with as many as 25 Member States is an example economy with very different living standards and varying social security systems. Free movement of goods has not only positive impacts but it is largely seen as an 'easy way' for drugs counterfeiters. Western European countries have become vulnerable to drug trafficking with alarming incidences of fake drugs in past several years particularly after EU expansion though effective drug regulation exist in almost all the Member States.

Problem of counterfeit drugs is much more serious in developing and under developed countries of Africa and Asia. Here too, extreme differences exist in legal and economical situations of almost all countries making it nearly impossible to properly compile, study and interpret the problem altogether. Hence, in this dissertation India is selected as an example country, not as an extreme counterpart of the Europe but as a comparable counterpart. Study of similarities and differences in drug regulatory system, extent of fake drugs on the market etc. between two extremities is not worth because the outcome is obvious.

India is a classical example of developing country with a strong pharmaceutical industry and which also has effective drug regulatory system. Indian pharmaceutical industry is growing at the rate of over 10 percent for the last decade and it is the fourth largest in the world in terms of volume. But consumers have good reasons to be concerned about the quality of drugs produced and distributed from India considering weak legal enforcement.

In this dissertation the problem of counterfeit drugs will be addressed globally however specific concerns will be directed and considered with reference to Europe and India.

The aim of present work is to analyze related facts and to derive conclusions as given hereinafter:

- The scope and extent of the fake drug penetration will be documented.
- The problem will be studied from a perspective of overall legal system and drug regulatory environment.
- Influence of various socioeconomic factors, health and social security factors will be considered.
- The extent of damage to the public health, overall economy and directly to the pharmaceutical industry will be discussed.
- The reasons for proliferation of fake drugs will be studied. How poverty, availability of essential and desired medicines (considering cost factors and intellectual property rights protections¹), supply chain, parallel imports, difference in price structure in different markets, internet sale of drugs, legal, political, constitutional, socioeconomical and technological reasons contributing to the problem will be analyzed.
- Recent changes in drug regulatory system to incorporate anti-counterfeit measures will be studied critically and based on this it will also be possible to suggest further amendments to strengthen the system.
- The WHO is a driving and coordinating partner in anti-counterfeit measures; it is also a vital source of information. The role played by WHO will be discussed in-depth.
- How is the involvement of all the stakeholders like end users, pharmaceutical industries, governmental and non-governmental institutions etc. to combat counterfeits will be considered and ways to better coordinate such efforts will be suggested.
- Anti-counterfeit measures taken around the world and reasons for their success/ failure will be discussed and also the ways to make such efforts more fruitful will be suggested.

¹ There are no concerns to deal with patent infringements or legal generic versions of patented medicines. Local laws dictate this, consistent within international rules.

- The latest technological advancements to protect genuine and to detect counterfeits will be considered and what is still need to be done in this segment will be discussed.
- The major hurdles those make anti-counterfeit tasks difficult to realize will be identified and discussed.
- How the Governments can give better chances to the pharmaceutical industry to earn legal money by facilitating and promoting the use of sophisticated technologies to stop counterfeit versions and by providing incentives in various form will be discussed.
- What ways can Governments promote pharmaceutical industries to be more involve in the overall vigilance network by transparent information exchange and rapid alert systems, use of latest tracking technologies, control over the distribution networks and consumer awareness will also be analyzed.

The data and information used in the dissertation will be acquired through primary and secondary sources. Primary sources include official gazettes, press release or information from the official web site of the concern Agencies for example WHO, WIPO, European Court of Justice (ECJ), Government of India, etc. Information about drug regulatory system, legal system, Intellectual Property Rights protection, export-import regulations, social security system etc. will be taken from the primary sources. Secondary sources consist of reviews of peer reviewed and other published literature including but not limited to articles from the journals, periodicals, newspapers and related web based sources and the author's review and opinion.

BACKGROUND INFORMATION

Counterfeit Drugs – Definition, extent of the problem & encouraging factors

Counterfeit drugs are part of the broader phenomena of substandard pharmaceuticals. The difference is that they are deliberately and fraudulently mislabeled with respect to identity and/or source.

There is no universal definition of counterfeit drugs, and the legal definitions vary from country to country.

WHO defines a counterfeit pharmaceuticals product as a product that is deliberately and fraudulently mislabeled with respect to identity and / or source. The definition applies to both branded and generic products. According to WHO definition, counterfeit products may include products with correct ingredients, wrong ingredients, without active ingredients, with the incorrect quantity of active ingredient or with fake packaging (1).

The problem of counterfeit drugs is global in nature. Although it is difficult to obtain precise figures, estimates put counterfeits at more than 10 percent of the global medicines market. It is known to affect both developed and developing countries. A WHO survey of counterfeit medicines reports from 20 countries between January 1999 and October 2000 found that 60 percent of counterfeit medicines cases occurred in poor countries and 40 percent in industrialized countries. The largest numbers of reports are related to antibiotics, antiprotozoals, hormones and steroids (2).

The problem is more pronounced in countries where the manufacture, importation, distribution, supply and sale of drugs are less regulated and enforcement is weak (3). The number of counterfeit drug cases being investigated by the U.S. FDA has quadrupled from an average of five per year in 1990s to about 20 per year recently (4).

It is estimated that as many as 20 percent of the annual deaths from malaria worldwide may be the result of taking ineffective drugs. A recent study in the Lancet concluded that up to 40 percent of artesunate (the best medicine to combat resistant malaria today) products contained no active ingredients (5, 6).

5 percent of total world output (US \$ 250 billion) is estimated to be counterfeit considering all industrial sectors. Pharmaceutical is a huge market of US \$ 225 billion and global counterfeit drugs market is estimated to be \$ 20 to over a \$ 40 billion. Innovative medicines are valuable to mankind. They are life saving and improving overall health, resulting in decrease hospitalization and health related expenses. For example, the use of beta-blockers following heart attacks resulted in an annual cost saving of up to US \$ 3 billion in preventing second heart attacks (7) and within 10 years (1977-1987), ulcer operations dropped from 97,000 to 19,000 after the introduction of H₂ antagonists (8). Fake drugs not only cause economical damages but they are also to some extent responsible for drug resistance and outbreaks of epidemics in poor parts of world, where unfortunately, the initial steps to subside the epidemics are taken with the help of counterfeit drugs.

A total of 1,92,000 Chinese patients are reported to have died in 2001 from fake drugs and in the same year Chinese authorities closed 1,300 factories while investigating 4,80,000 cases of counterfeit drugs worth US \$ 57 million. In 2004 Chinese authorities arrested 22 manufacturers of grossly substandard infant milk powder and closed three factories after the death of over 50 infants (5). Counterfeit Viagra is a worldwide problem. The University of London reported in September 2004 that half the men buying Viagra are getting counterfeit drug (5, 9).

The Interpol categorized drug counterfeiting as a form of organized crime and links some terrorist groups using this type of trade to finance their activities worldwide (10).

The factors facilitating the occurrence of counterfeit drugs vary from country to country. However, the most common factors are considered to be: lack of legislation prohibiting counterfeiting of drugs, weak penal sanctions, weak or absent national drug regulatory authorities, weak enforcement of drug laws, shortage or erratic supply of drugs, lack of control of drugs for export, trade involving several intermediaries and free trade zones, sale of drugs over internet, corruption and conflict of interest (1, 2, 3, 4, 11).

The production of counterfeit drugs need not occur in large infrastructures or facilities. Counterfeiting of medicines is a lucrative business due to high demand and low production costs. When prices of medicines are high and

price differentials between identical products exist there is a greater incentive for the consumer to seek medicines outside the normal supply system.

Reports have shown that the prevalence of substandard and counterfeit drugs is higher in countries where drug regulation is ineffective for example in Asian and African countries (12). National drug expenditure as a proportion of total health expenditure currently ranges from 7 percent to 66 percent worldwide. The proportion is higher in developing countries (24-66 percent) than in developed countries (7-30 percent). In the former, at the individual and household level, drugs represent a major out-of-pocket health care cost. Most of the developing countries have poor state of the economy and low income per capita and poverty has been directly linked to the problem (1, 2, 13).

Also there is a lack of proper information exchange from pharmaceutical companies and Governments in certain cases. Many pharmaceutical companies and governments are reluctant to publicize the problem to health staff and the public, apparently motivated by the belief that the publicity will harm the sales of brand-name products in a fiercely competitive business besides other political reasons. Such attitude does not only obstructs the require action but indirectly helps flourishing the dirty game. The WHO has received no reports of counterfeit drugs from member countries after 2002, and it received only 84 reports between 1999 and 2002 (5, 14).

In a multi-country study covering 10 countries (viz. Australia, Cuba, Cyprus, Estonia, Malaysia, Netherlands, Tunisia, Uganda, Venezuela and Zimbabwe) it is reported that data regarding the quality of drug products, drug information and distribution channel, especially in the illegal sector, are often unavailable or in short supply. It is further written that – ‘If the purpose of drug regulation is to promote public health and protect the public from harmful and dubious drugs, it should cover all products for which medicinal claims are made and all activities associated with the manufacture, importation, distribution, dispensing and promotion of drugs. This study has found that drug regulation does not meet these requirements in all the countries studied’ (15).

The lack of integrity in the supply chain is mainly responsible for cross-border drug trafficking. The Haiti contaminated paracetamol incident which

caused many innocent lives, illustrates the extent and dramatic consequences of improper handling of excipients by supply chain brokers. Several distributors were involved in this incidence; the product was shipped all around the world – from Asia via Europe to Haiti, with no traceability, insufficient controls and documentation lacking (16).

Counterfeit Drugs – European & India perspectives

There are many different reasons for penetration of fake drugs in the European and Indian markets. There are discrete distinctions between legal, regulatory, health and social system in both, even such differences exist to smaller or greater extent between European Member States.

The problem is compounded in Europe, where free trade in pharmaceutical products exists. Governments can and do set different pricing, leading to highly divergent price structures among the Member States. This encourages parallel imports, which in turn allows counterfeit products to be introduced.

The Indian pharmaceutical industry is the fourth largest in the world in terms of volume with domestic turnover of more than US \$ 450 million and exports over US \$ 225 million. But a consumer has good reasons to be concerned about the lack of availability of safe and genuine medicines originated from India. Weak and inefficient legal enforcement, poverty and corruption are main causes of the entry of counterfeit drugs in to the Indian trade zone.

European Federation of Pharmaceutical Industries & Associations has reported in a recent position paper that European markets have potential risk at penetration of fake drugs mainly from outside Europe (17).

In recent years number of counterfeit drugs have been reported in the Europe, some with the wholesalers, at retails pharmacies and some over the Internet. In mid 2005, in a police raid in the northern region of Catalonia, Spain, six laboratories were found to producing counterfeit anabolic steroids and hormone-boosting substances as well as cancer drugs. Total of seventy individuals were arrested in 56 raids conducted over 13 Spanish provinces. Authorities disclosed that the ingredients were obtained to make the counterfeit products from Mexico, Brazil and Thailand and the products

seized were destined for distribution in various EU countries. Also it was confirmed that the products have been exported to Italy, France and Portugal (18).

In Germany an investigation started when, during summer of 2002 referring to complaint of a patient about potential tampering of a medicine. In early 2003, German authorities raided a major wholesaler in this regards and counterfeit AIDS drugs valued almost one million Euros were found. The authorities suspected the products were sold outside the EU. The trace evidence led to a post office box company in Switzerland and to Israel (19).

The European Commission's Green Paper on 'Combating Counterfeit and Piracy in the Single Market' (1998) acknowledged that counterfeiting and piracy are detrimental to the proper functioning of the EU single market and result in a loss of confidence and investment. For these reasons, industry welcomes the recent legislative steps taken at European level. It is hoped that the adoption of Regulation (EC) N° 1383/2003 on customs action will facilitate customs seizures; and of EC Directive on enforcement of Intellectual Property Rights (IPR) will contribute to unifying legislation specifically targeted at effective enforcement of IPR. Through these set of regulations, customs authorities will now have a legal basis that gives them the ability to seize patent infringement products, so that suspicious pharmaceuticals can be seized and tested at customs (17).

But the complex nature of the supply chain across Europe, results in some medicines exchanging hands many times before reaching the patient. This creates more opportunities for counterfeit products to enter the supply chain than if the products were sourced nationally. Combined with the accession of ten member states that are significantly poorer than the rest of the EU and that have both current and historic trading tie with the former Soviet Union (where the WHO already estimate the medicines supply chain to contain up to 10 percent counterfeit products) it is almost inevitable that counterfeit medicines will enter the EU supply chain (20).

On the other hand, review of drug quality in Asia by the United States Pharmacopoeia, writes that 'Counterfeit drugs could be the single biggest problem in India in the next ten years due to the growth of garage-based drug manufacturing outfits, rampant corruption and weak drug control'. India

has been identified as one of the producer and distributor of counterfeit drugs worldwide along with other African and Asian countries (21, 22).

In November 2003 report of the expert committee on "A comprehensive examination of drug regulatory issues, including the problem of spurious drugs" was published in India. The committee was constituted by the Central Government of India under the chairmanship of R.A. Mashelkar, the Director General of the Council for Scientific and Industrial Research to examine all aspects of the regulatory infrastructure and to recommend a new structure for the country's drug regulatory system. The Mashelkar committee report was an alarming signal to total health system in India.

According to the report, some of the prominent factors contributing to proliferation of spurious drugs in India are lack of enforcement of existing laws, weak penal action, very remunerative trade, large scale sickness in small scale pharmaceutical industry, availability of improved printing technology that helps in counterfeiting, lack of coordination between various agencies, too many retail & whole sale chemist outlets, inadequate cooperation between stakeholders, lack of control by importing/ exporting countries, wide spread corruption and conflict of interest. The committee admits a need for changing the Drug & Cosmetic Act of 1940 and the judicial procedures related to offences committed under the act (23, 24).

Stiffer penalties (death, 10 years minimum prison sentence and higher fines) are recommended for those violating the drug laws. The committee suggested establishing a Central Drug Administrative that will control the licensing of all drugs in lieu of the current licensing system whereby state drug regulatory agencies allow the manufacture of drugs, which are not approved by the central regulatory agency. Other recommendations included greater surveillance, more frequent testing and paying informers who can help track down producers of fake drugs (23, 24).

Currently the Drug & Cosmetics (Amendment) bill – 2005 is under discussion in the Indian parliament taking in to consideration Mashelkar committee report. Surprisingly recommendation of death penalty has not given approval and further decisions are expected during summer 2006 (25).

Counterfeit Drugs – Working towards the solution

Counterfeit drugs are a global and persistent problem. They can only be combat by international collaboration. Very recently during February 2006, in the WHO international conference on 'Combating counterfeit drugs: Building effective international collaboration' held in the Rome, it was declared that the WHO should lead the establishment of an International Medical Products Anti-counterfeiting Taskforce (IMPACT) of governments, non-governmental and international institutions aimed at encouraging and coordinating anti-counterfeiting initiatives (26).

WHO medicines strategy 2004-2007 has identified anti-counterfeit measures as one of the agenda in coming years (27). WHO set the world's first web-based system for tracking the activities of drug cheats in the Western Pacific region in 2005. The Rapid Alert System (RAS) communications network transmits reports on the distribution of counterfeit medicines to the relevant authorities for them to take repaid countermeasures (28).

On February 18, 2004, U.S. FDA issued a report entitled 'Combating Counterfeit Drugs: A Report of the Food and Drug Administration.' This report has identified six critical measures to combat fake drugs. This includes securing the actual drug product and its packaging, securing the movement of the product through drug distribution chain, enhancing regulatory oversight and enforcement, increasing penalties for counterfeiters, heightening vigilance and awareness of counterfeit drugs and increasing international collaboration (4). The U.S. FDA has also recommended the use of Radio Frequency Identification (RFID) tags by 2007; the drug supply chain in the U.S. would be RFID-secure by this time frame.

Legal framework is under revision to boost up anti-counterfeit measures in many countries including European Member States, India and the United States. In Britain, there are proposals for the introduction of a charge of 'corporate killing' for companies who have contributed to the deaths of customer and this could also apply to drug companies if they do not take reasonable steps to warn the public of a fake product (29). Some countries such as Vietnam, the United Arab Emirates, Oman, Bahrain, Kuwait and Qatar even have provisions of death sentence as punishment for counterfeit drugs related offences (24).

Many research-based companies are working through the Pharmaceutical Security Institute (PSI), a counterfeit intelligence forum that conducts worldwide investigations. Information on illegal activity obtained by PSI is provided to governments and international agencies, which are responsible for proceeding against counterfeits (30). International Pharmaceutical Federation (IPF) and International Federation of Pharmaceutical Manufacturer Association (IFPMA) are actively involved as observers in WHO activities aiming to establish guidelines and rules for policies against substandard medicines. The German Pharma Health Fund (GPHF) has developed basic training methods for about 35 commonly used essential medicines in their finished dosage forms. International agencies like Interpol, World Customs Organization (WCO), World Intellectual Property Organization (WIPO) and International Chamber of Commerce (ICC) have contributed significantly in addressing the problem (17,22).

More and more pharmaceutical companies have adopted sophisticated techniques like holograms, watermarks and temper proof packaging to safeguard their products. An international coalition is working for consumer awareness and to educate the end users to differentiate between genuine and fake versions. The overall goal of WHO support has been to promote the regular availability and accessibility of affordable essential medicines of good quality. WHO provides support to countries to strengthen pharmaceutical legislation, Good Manufacturing Practice (GMP), national drug regulatory capacity and performance, to promote information exchange among drug regulatory authorities and to strengthen drug procurement (15, 26).

April 2006, report of the commission on intellectual property rights, innovation and public health says that governments have an important responsibility to put in place mechanism to regulate the quality, safety and efficacy of medicines and other products. As a starting point, adherence to good manufacturing practices and effective supply chain management can ensure product quality and will also curb the circulation of counterfeit product (11).

With stakeholder accountability and uniform systems to coordinate anti-counterfeit measures, we can win. Combating counterfeit drugs is a fight against illegal and inhuman – Let us work together.

LIST OF ABBREVIATES:

CSIR - Council for Scientific and Industrial Research

EC - European Commission

EU - European Union

GPHF - German Pharma Health Fund

ICC - International Chamber of Commerce

IFPMA - International Federation of Pharmaceuticals Manufacturer Association

IPR - Intellectual Property Rights

IPF - International Pharmaceutical Federation

PSI - Pharmaceutical Security Institute

RFID - Radio Frequency Identification

U.S. FDA - The United States Food & Drug Administration

WCO - World Customs Organization

WHO - World Health Organization

WIPO - World Intellectual Property Organization

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