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COUNTERFEIT (FAKE) DRUGS & NEW TECHNOLOGIES TO IDENTIFY IT IN INDIA

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ABSTRACT

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A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting apply to both branded and generic product which include products with the wrong ingredients, without active ingredients, with insufficient active ingredients. According to WHO, 25% of medicines consumed in poor countries could be counterfeit or below standard. An estimate suggests that these drugs are a \$200 billion industry worldwide. India could be an easy target for counterfeits, as the manufacturing costs is 40% cheaper here as compared to other countries. Deputy drug controller general of India says, counterfeit medicines often resemble the originals in chemical composition, but he thinks the biggest problem is in the packaging. A committee set up by the Indian Ministry of Health has approved a proposal to put 2D bar codes and scratch-off labels on medicines. The user scratches off the cover and tests what is underneath to a free phone number, to find out if a pill is real. Quick Response (QR) codes are also being tested. These printed squares are an advanced version of the 2D bar codes. Anyone with a camera-enabled phone and web access can scan the code and be taken instantly to the pharmacy company website to authenticate the drug. The uses of holograms, tracers, traggants and inks, plastic tags, radio frequency identification, mass encryption technology are some other techniques to limit the counterfeiting of drugs.

INTRODUCTION: Counterfeit drug is a pharmaceutical product which is produced and sold with the intent to deceptively represent its origin, authenticity or effectiveness. It may contain inappropriate quantities of active ingredients, may be improperly processed within the body or may contain ingredients that are not on the label, and is often sold with inaccurate, incorrect, or fake packaging and labeling.

The phenomenon of drug counterfeiting is relatively recent, having first been identified as an emerging problem by the WHO in 1985. Since then the scale of the problem has substantially increased to the point that, today, it is estimated that more than 10% of drugs

worldwide are counterfeit, and in some countries more than 50% of the drug supply is counterfeit ¹. Until recently, the most frequently counterfeited medicines in wealthy countries were new, expensive lifestyle medicines, such as hormones, steroids and antihistamines.

In developing countries the most counterfeited medicines have been those used to treat life-threatening conditions such as malaria, tuberculosis and HIV/AIDS. As the phenomenon spreads, more and more medicines are counterfeited, including expensive ones, such as anticancer drugs, and those highly in demand, such as antivirals.

In 2006, lack of sufficient active ingredient has detected in the legal supply of Lipitor, a drug use for lowering cholesterol, at United Kingdom. Xenical, a drug for obesity has sold in United States via internet sites operated outside USA with no active ingredients in 2007. In 2008, Viagra and Cialis for erectile dysfunction has smuggled into Thailand from an unknown source from an unknown country. One of the most severe one was in 2009, in China an antidiabetic traditional medicine used for lowering the blood sugar, with six times the normal dose of glibenclamide leads to the death of 2 people and the hospitalization of 9. Many more cases are appearing, not only in the developing world but, increasingly, in developed countries²⁻⁴.

The purpose of this article is to review extant information on this problem, discuss a number of critical issues, and explore the implications for the Indian pharmaceutical sector. However, a mere listing of a set of problems is unsatisfying without discussion of potential solutions. The second part of this article will review the options available to the pharmaceutical industry to combat this problem.

Types of Counterfeit Drugs and their consequences:

Illegal drugs are often produced and sold with the intent to deceptively represent their origin, authenticity or effectiveness. The nature of these fraudulent drugs ranges from those containing no active ingredient (eg. when a bag of powdered lactose claimed to be cocaine), with insufficient active ingredient or with some diluents (e.g., Baking soda or lactose) or sometimes with a wrong active ingredient (e.g., when methamphetamine is sold as cocaine) or with a fake packaging⁵⁻⁶. The various types of counterfeit drugs are:

1. Counterfeit drugs containing same dose of the active ingredient,
2. Mislabeled medications,
3. Counterfeit drugs containing an incorrect dose of the active ingredient,
4. Counterfeit drugs which do not contain the active ingredient,

5. Counterfeit drugs containing a potentially harmful substance,
6. Counterfeit drugs containing an unlisted active ingredient.

Counterfeit drugs containing same dose of the Active Ingredient:

They are close replicas of the genuine drug with the same dose of the active ingredient. They constitute only 5% of the fraudulent medicines. Even though they contain the same active ingredient as the originals they are of poor quality as it is not manufactured according to the rules of good manufacturing practice approved worldwide.

The dissolution profile of the drug may vary, so the amount of drug available for absorption by the body may vary and finally the efficiency of the drug is less. The inactive ingredients in this type of drugs are not documented and they can be detected only by laboratory analysis. Sometimes these inactive ingredients can cause health risks.

Mislabeled medications:

Mislabeled medicines are those which are sold in the package of another brand medicine. The label of counterfeit medicine also contains batch number, manufacturing number and other details which are fraudulent. For example in 2006 the US government issued a public warning against buying brand name medicines off the internet. This was after the case of prescription weight loss medication Xenical (orlistat). The packaging appeared authentic but the batch number; (a genuine one) did not matched with the expiry date for the batch by the manufacturer⁷.

Counterfeit drugs containing an incorrect dose of the active ingredient:

This can lead to much health related problems. In case of antibiotics low dose therapy may not kill the bacteria but may lead to the emergence of resistant strains. In 2000 in Cambodia counterfeit malaria tablets caused death of 30 people⁸.

Counterfeit drugs which do not contain the active ingredient:

1. **Counterfeit drugs containing a potentially harmful substance:** Over hundred children died in Nigeria in 1993 due to the harmful substance in the counterfeit cough syrup. Similar cases were

reported in China and India in 1990-2007 and in panama due to ethylene glycol in cough syrup instead of glycerol. In 2002 more than 190,000 deaths occurred due to poly ethylene glycol contamination in paracetamol syrup ⁹.

2. **Counterfeit drugs containing an unlisted active ingredient:** This type of counterfeiting is commonly found in recreational drugs which may contain some herbal ingredients. Even though they are natural they may exhibit some pharmacological actions in the body. So it should be taken into consideration and use of such type of drugs should be discussed with the health care provider.

Certain Statistical Data's:

1. Between 1984 and 1999, there were 771 reports of counterfeit drugs with 78% of these coming from developing countries ¹⁰.
2. The consumption of paracetamol cough syrup prepared with diethylene glycol (a toxic chemical used in antifreeze) led to 89 deaths in Haiti in 1995 and 30 infant deaths in India in 1998.¹¹
3. From January 1999 to October 2000, 46 reports of counterfeit drugs were received from 20 countries; 60% from developing countries and 40% from developed nations ¹².
4. A study conducted in WHO's South-East Asia Region in 2001 revealed that 38% of 104 antimalarial drugs on sale in pharmacies did not contain any active ingredients ¹¹.
5. The number of cases of counterfeit drugs being investigated by the US Food and Drug Administration (FDA) has quadrupled from an average of five per year in the 1990's to about 20 per year in 2001 and 2002 ¹³.
6. The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) has estimated that 7% of all drugs sold around the world are counterfeits ⁸. Furthermore; they have suggested that the value of this trade is more than USD 30 billion. In Russia, the figure has been put at 12% while in the Ukraine it may be as high as 40% ¹².

7. In 2003, the WHO estimates that the annual earnings of counterfeit drugs were over US\$32 billion ¹⁴.
8. The Centre for Medicines in the Public Interest, in the United States, predicts that counterfeit drug sales will reach US\$ 75 billion globally in 2010, an increase of more than 90% from 2005 ¹⁵.
9. In late January 2006, the United States Food and Drug Administration (FDA) issued an alert about fraudulent flu remedies, including counterfeit prescription oseltamivir (Tamiflu) medication ¹¹.
10. Peru's Ministry of Health estimates that illegal sales of medicines account for 15-20% of the local market ¹¹.

India- Capital of Counterfeit Drugs: Making pills that could save lives both in India and abroad, Indian pharmaceutical companies are growing faster than ever before. Worth over \$12bn, the industry is expected to grow more than four-fold in the coming decade. But even as global attention is focused on the healthy growth in India, it is threatened by a serious malaise - counterfeiting. Fake drugs in the system risk not just lives of patients, but also the reputation of drug makers.

India is fast becoming capital of counterfeit drugs, accounting for one third of the counterfeit drugs produced worldwide. It is estimated that 40 per cent of the pharma market in our country, i.e. Rs 8000 crore is under the grip of spurious and black marketed drugs. Not only is the people's health at stake but also there is a serious loss to the exchequer of both central and state governments as they are deprived of huge amounts on account of sales tax and excise duty.

The pharma industry, including those manufacturing spurious drugs, is growing at the rate of 20 percent annually, which means that every year the chances of buying a medicine that can do more harm than good is also rising proportionately. Despite the use of a hologram by large pharmacy companies to protect their products, spurious drugs business continues to flourish in Punjab, Haryana, Himanchal Pradesh, Delhi, Utttar Pradesh, Gujarat, Maharashtra, and Karnataka.

Many pharma industries are adopting highly pressurized marketing practices like unrecorded discounts, dumping goods, and raising fake invoices in the name of hospitals and institutions. These goods never reach the hospitals and are sold in the open market without proper bills. Manufactures of spurious drugs are taking advantage of this situation and selling their spurious drugs in major drug mandis like Patna, Agra, Kanpur, Satna, Coimbatore, Bangalore, Mumbai, Kolkata and Delhi. Nearly 60 per cent of the total spurious drugs and black marketing in the country are sold under the very nose of the Central Government – at Bhagirath Place in Delhi. “Everyone knows where counterfeit drugs are sold in Delhi,” says a scientist from the Delhi Science Forum, a non-governmental organization. “Anyone can go to Bhagirath Place and buy any medicine one wants including empty capsules at a fraction of their actual price and no action has ever been taken,” he points out¹⁶.

At December 2010, the Madras High Court upheld the detention of 13 people allegedly involved in selling spurious drugs, some fake and some expired, under the Goondas Act. The Goondas Act allows suspected spurious drug sellers to be detained while being prosecuted, rather than released on bail, to deter them for continued selling until their trial date. The detainees are accused of collecting expired medicine and returning them to the pharmaceutical retail market as valid drugs by altering the batch numbers and expiration dates.¹⁷

1. 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 China.
2. The WHO has indicated that India is responsible for about 35% of the world’s counterfeit medicines with the business being worth USD 200 million¹².
3. A recent EC report claimed that India was the largest source of the 2.7 million counterfeit drugs seized by its custom department in 2006¹⁸.

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 and is said to be

the fourth in the world in terms of volume. However, a consumer has good reasons to be concerned about the lack of availability of safe and genuine medicines. The problem of spurious and substandard drugs in the country is quite rampant, as is evident from periodic reports in the media on seizures and confiscation of fake drugs from large consignments or godowns. These, however, would constitute only a small fraction of the real extent of the illegal activity, which perhaps is no different from the extent of counterfeit trade in other commercial products.

Technological Ideas to Curb Counterfeiting:

Technologies are increasingly employed to protect and authenticate products. In the past, this field was somewhat neglected partly because of the limited availability of suitable technologies as well as the perception that the implementation of the technologies would not be cost-effective. However, this trend has changed with more victims of counterfeiting becoming aware of the potential that technological solutions hold out and the falling costs of implementing these. The various technologies available today vary considerably in the degree of sophistication and in the principles on which the protection against counterfeiting is based. They range from simple cost effective printing technologies through optical technology, biotechnology, chemical and electronic fields. The nature of the product and the type of counterfeit risks will determine the most appropriate technology.

The various technologies are as follows:

Holograms: Several Indian pharmaceutical companies have implemented changes in their packaging formats as a way of reducing the impact of counterfeit activity. Among the more proactive options that have been employed are those based on holographic technologies, which provide a simplified means for consumers to deduce the authenticity of a drug.

Holograms are now widely available in a variety of formats such as:¹⁹

- (i) Holographic shrink sleeves to protect branded bottled products against counterfeiting and refilling,
- (ii) Blister packaging aluminum foil,

(iii) Pharmaceutical PVC, where the hologram is applied as a thin stripe to PVC sheets used to make blister packs, (iv) holographic induction cap seals, (v) polyester-based tamper evident labels used to seal packages and (vi) holographic hot stamping foil where the hologram is fused to the host surface by heat and pressure.

Advantages to the use of security holograms include the following²⁰:

- (i) They are difficult to counterfeit,
- (ii) They are recognizable to the consumer,
- (iii) They can feature covert tools such as nanoimagery, micro-imagery, digital watermarks and hidden images,
- (iv) They are relatively cheap and;
- (v) They allow the tracing/tracking of products through the distribution chain.



TWO BLISTER PACKAGES OF THESE ANTIMALARIAL DRUGS, ARTESUNATE, ONE GENUINE (RIGHT), AND ONE COUNTERFEIT (LEFT). A WELL-CRAFTED HOLOGRAM IS THE ONLY DISTINGUISHING FEATURE OF GENUINE PRODUCT.

The major problem, however, is that they are generally costly and not effective over the long term. For example, holograms can cost as much as 10–25 paisa, depending upon their level of sophistication.²¹ This can add significantly to the MRP of low-end medicines that are the staple of the indigenous pharmaceutical market. Another problem is that the holograms themselves can also be eventually duplicated by counterfeiters, making the initial investment by the brand owner ineffective when such knock-offs enter the marketplace.

Finally, passive technologies such as holograms 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. For example, an expertly produced counterfeit medicine with a hologram cannot be distinguished from the genuine product, nor can the brand owner trace the origin of the fake products. Given that pharmaceutical companies themselves can face such problems with these technologies, the ability of the consumer to distinguish authentic products becomes even more tenuous.

Tracers, taggants and inks: Additions of chemical and biological tracers to the packaging and/or product have been relatively commonplace as an anticounterfeiting measure. According to Prebble²², “verification ranges from simple to complex, with certain paper systems authenticated using specially developed color change pens.” With respect to inks, many types are available and these include UV fluorescent, phosphorescent, thermochromic and those at specific light frequencies. These are typically applied on product labels and packaging. When exposed to either heat or light they change color, and when exposed again the color reverts to the original.

Generally the effect is reversible as often as required. Inks have also been developed that are invisible to the human eye but which can be read by bar-code scanners. These have been used in the fragrance and pharmaceutical industries to authenticate products. Other reactive inks change color when brought into contact with specific substances, for example ink from a felt-tipped pen. To assist in the identification of counterfeits, the inks may contain security taggants of which there are four major types²³:

- a. Spectroscopic taggants which comprise inks that may be UV absorbers and may be incorporated into particles, fibres or security threads embedded into paper or packaging;
- b. Biological taggants which may include strands of specific DNA. This DNA-embedded ink technology is cost-effective; the ink is difficult to replicate²⁴ and allows for real-time product authentication²⁵;

- c. Chemical taggants which include pH-sensitive and other materials which can only be detected by IR spectroscopy or X-ray fluorescence and;
- d. Physical taggants such as the use of microscopic plastic particles which are only visible with the use of microscopy. Upon magnification, colored layers or sections are detected which allows rapid authentication.

Use of Plastic Tags: Another type of anti-counterfeiting device in this field involves the use of plastic “tags”. These were originally developed as a means of marking and tracing explosives. By incorporating microscopic plastic tags into bulk explosives, the origin of the explosive can be determined both before and after use. A microscopic tag is a virtually indestructible, microscopically small plastic particle of random irregular shape, constructed from up to ten different colored layers. The sequence of colors denotes the unique code of the tag and the total number of possible codes ranges up to 4.5 billion. The tags can be applied to both product and packaging in a number of ways, including incorporation in clear varnish.

Radio- Frequency Identification: The technology is based on an electronic chip that emits radio frequency waves encoding a specific ID or code. This information is then captured by a specialized chip reader as the products proceed through the supply chain. The major advantage of RFID technology is that no line of sight is required. The chip can be embedded in cartons or pallets in a hidden manner that resists tampering.



RFID CHIP

The major problems with RFID technology are cost, readability, and lack of item-level protection. The cost of RFID chips remains very high and actually is prohibitive for many uses.

Cost estimates vary in India but each chip is typically in the range of 5 to 15 rupees. Although this is a manageable cost if the chips are only applied to product batches (e.g., cartons or pallets), the price becomes simply unacceptable at the item level. The readability problem has a technical origin and constrains the use of this technology due to high error rates. Although estimates vary from study to study, error rates of 2.5% and above have been reported²⁶.

The final impediment to use of RFID is that it is not yet possible to implement it at the item level, for two reasons. The first is the cost of each electronic tag which, as discussed above, would make the MRP of most medicines prohibitively expensive and place them outside the boundaries of established price ceilings, both government and market imposed. But perhaps the greatest impediment to item-level tagging is that the consumer does not carry RFID readers, which are electronic devices that decode the radio signal. As such, RFID simply cannot be implemented at the item level and thereby fails to include the consumer in the authentication process.

Pfizer uses radio frequency identification (RFID) tags on certain highly counterfeited products in order to further ensure patient safety in the United States. RFID technology enables pharmacies and wholesalers to track medicines from manufacturer to pharmacy by verifying the unique electronic product code, or EPC, on the product packaging. Pfizer is the first pharmaceutical company to put in place a comprehensive program of this type focused on EPC authentication as a means of deterring counterfeiting.

Mass Encryption Technology: In this technology, every product is given a unique digital identity that is generated by a computer based encryption engine. The same software is able to decrypt the digital code. The encrypted code itself is usually a 16-digit alphanumeric code that can be displayed in:

A linear format—



Scripted format-- **HJ21WFOHU20KB8N7**

2-D Data Matrix barcode--



2-D barcodes, which are now becoming the industry standard, are printed on packaging during manufacture and therefore provide each medicine with the identity before it enters the supply chain. In addition to the encryption and decryption of the codes, the software that supports this technology allows brand owners to fully manage their supply chain, i.e., track-and-trace. Pharmaceutical companies are empowered to track their shipments from the factory through all intermediate nodes right down to the retail level, in much the same way that courier companies track their shipments as they wind through the shipping chain.

An additional advantage of such a powerful supply chain management tool is that pharmaceutical companies are better able to manage any recalls, should they be necessary. A major advantage that mass encryption enjoys over all other currently available technologies is that it empowers the consumer to authenticate a drug. Given that the codes can be printed on blister packs and vials in script form, the consumer can simply verify the authenticity of the drug by entering the code into an internet site or via SMS.



AUTHENTICATION PROCESS BY CONSUMER INVOLVING EITHER SMS OR INTERNET

Counterfeit drugs will either contain no code or have an invalid code, which will not pass the authentication process. It is simply impossible for a counterfeiter to make up arbitrary codes because the combinatorial possibilities are astronomically large for a 16-digit alphanumeric format.

The Drug Consultative Committee (DCC) in its last meeting in February 2011 has approved the proposal that for every strip of medicine available in India ought to have a 2D bar code a unique randomly generated numeric code (UID). A phone number will be mentioned above the bar code, where the consumer can SMS the UID. A message will tell the consumer whether the drug is original or not. Once approved, India will join Italy, Malaysia and the European Union to make 2D bar code and UID mandatory in an effort to curb spurious and counterfeit drugs.

Quick Response Codes: Quick response (QR) codes are also being tested. These printed squares are an advanced version of the 2D barcodes. Anyone with a camera-enabled phone and web access can scan the code and be taken instantly to the pharma company website to authenticate the drug.



QR CODE

Unique Identification Mobile Verification: A pharmaceutical company, PharmaSecure, has come up with a technology called UIMV - unique identification mobile verification. It is a 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.

E- Pedigree: Work is on for developing an electronic pedigree (E- Pedigree) system to track drugs from factory to pharmacy, thereby preventing the diversion of drugs or counterfeiting by allowing wholesalers and pharmacists to determine the identity and dosage of individual products.

CONCLUSION: Counterfeit medicines represent an enormous public health challenge. It poses a public health risk because their content can be dangerous or they can lack active ingredients. Their use can result in treatment failure and contribute to increased resistance or even death as in case of anti-malarials that contain insufficient active ingredient. Unlike substandard medicines where there are problems with the manufacturing process by a known manufacturer, counterfeit medicines are made by people with the intent to mislead. The extreme difficulty in tracing the manufacturing and distribution channels of counterfeit medicines makes their circulation on markets difficult to stop. To fight counterfeit medicines effectively, a range of stakeholders is needed, not just health professionals.

Fostering international awareness of the problem and obtaining a concerted resolution to fight it are perhaps the crucial first tasks. It is imperative that two steps be pursued at the international level: firstly, a database of all known sources of counterfeit drugs, whether substantiated or not, needs to be developed by the key players. This database would become a reference for all countries, whether they are importing from or exporting drugs to a country specified as a source of counterfeit drugs.

Secondly, the pharmaceutical companies need to open the lines of communication with their sources of information to keep track of underground counterfeiting operation and should divulge all information to agencies Interpol or to the National police force of any country in which companies suspect counterfeit version of their products are being sold. Without the pharma companies' cooperation, it will be very difficult to confront offenders.

India now has a booming economy and an extremely bright future as a global player in many industries such as IT and pharmaceuticals. To propel the impression and global perception of India as a highly reputable supplier of medicines, the Indian pharmaceutical industry must take measures to combat the scourge of counterfeit medicines and take the lead in ensuring the safety of its supply chain.

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