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**A** counterfeit medicine is a compound that is not made by an authorised manufacturer and is presented to the consumer as if it were. Counterfeit or spurious drugs may not contain or may not even have the required amount of active ingredients to be effective, or may contain an improper ingredient and sometimes even toxic substances. A person taking a counterfeit "antibiotic" with little or no active ingredient, for example, can die of an infectious disease and /or exacerbate public health problems, if the disease spreads.

World Health Organisation (WHO) analysts have estimated that 30-70 per cent of the drugs in many developing countries are counterfeit. No country is immune from the threat of counterfeit drugs and those with weak or ineffective regulatory bodies suffer the most. Demand for cheap drugs and fat profit margins reaped out of counterfeit drugs push greedy criminals into this business. The counterfeit drug criminals are spreading their operations taking advantage of interstate loopholes in regulations, shipping, distribution and ineffective application of law. The sad part is that the present laws often hinder those who play by the rules as opposed to smugglers who get away by bribing corrupt officials.

Clearly, there is an urgent need for action to stop the unnecessary human suffering caused by counterfeit drugs. India, a country with probably more laws than any other, has sufficient legal infrastructure. But seldom do the authorities concerned implement these regulations effectively. If you seek the help of police by reporting counterfeit incidence, the police most of sweep aside this commercial complaint and pay attention to most urgent cases like murder, riot and other similar incidents. The counterfeit complaint doesn't get the attention it deserves, even though it may possibly cause more harm than other matters.

The effects of fake drugs include:

- physical or mental disability, and or death
- loss of confidence in medical practice
- loss of revenue to government - counterfeiters do not pay taxes
- loss of profits and growth for the company

We must change the mindset and regard counterfeit drug manufacturers and dealers as criminals and treat them as such. It is the duty of the government to protect the lives of its citizens by enforcing laws of the nation, it is better to prevent counterfeiting than trying to cure it. To foster a culture of prevention, the government should introduce regulatory rules such as:

- Making it mandatory for manufacturers to incorporate anti-counterfeit marks and packaging and imposing stiff penalties for not complying
- Allowing the cost of the security device/method to be a certain per cent of the sales price (rather than a fixed dollar amount) to cover the cost of incorporating such devices or methods
- Ensure that the relevant regulatory authorities enforce the existing laws
- Impose stiff penalties for fake drug manufactures/dealers

Remember there is no single panacea or silver bullet that will stop counterfeiting. It must be realised that this is a multifaceted problem that needs to be fought on many fronts. The public must be made aware to follow safe practices to protect their health such as to buy all needed drugs from registered pharmacies in sealed complete packs.

## COUNTERFEITING

# Lines of defence



The pharma industry must ensure:

- safe manufacturing
- safe logistics and distribution
- monitoring of the retail network
- employment of cost effective and counterfeit packaging to ensure that only the genuine drugs are in the supply channel

The way forward is a highly proactive, interactive and collaborative effort by all stakeholders in the healthcare industry. It is amazing that companies will spend millions on protecting assets purchased from the proceeds of the brand through risk cover like insurance, security guards, but will go into "analysisitis" mode to justify expenditure to protect the brand from counterfeiting. The cost of protecting the physical assets is far bigger than the cost of protecting the brand. In fact, the cost of protecting physical assets only makes a return when there is a calamity. Whereas, the cost of employing any anti-counterfeit measures yields results in increased brand sales, value and consequent profits. Brands that employ some form of brand authentication/protection enjoy better sales than those that don't. It must be noted that counterfeiters copy only the successful brands and products. Therefore, if your brand is successful it will be copied, unless it is protected.

Counterfeiting is a "no cash loss" phenomena. Losses due to counterfeiting do not appear in the profit and loss or balance sheet statements. As a result, most actions to curb counterfeiting, are taken too late and often after some form of counterfeiting already done some damage to the brand.

Today, there is a wide range of security devices and systems available to address a range of issues relating to anticounterfeited protection.

A thorough brand protection has three elements - the three lines of defence. They are:

- **Deter** It is a visible device to deter the counterfeiter, authenticate the brand and is known as overt security
- **Detect** This would be something not easily visible, usually a hidden feature not known to the consumer, but to the manufacturer - this is the covert security feature
- **Forensic** This would be a feature that is known only to a few in the company and would be a forensic device that would require a special test and would be conclusive proof suitable for court of law To have an optimal brand authentication /protection device, one does not necessarily require all these three lines of defence. In many cases, it would not be practical and possibly uneconomical.

In practice, just the application of a deterrent is sufficient to stop most counterfeiting activity. It is very much like protecting your house just by locking the doors and windows with adequate locks. But if you have valuables and other high value items in your house, then one adds grills, bars, a security guard, CCTV, electronic surveillance etc.

Similarly, if your brand is likely to be at great risk, then one must employ a range of overt, covert and forensic features.

What is important and the key to success is to take effective action and have:

- Clear objective as to why you want authentication/ protection for your brand
- Budget based on possible risk and losses incurred
- Select devices that address 80 per cent of requirement

• Monitor incidents of counterfeiting and progressively improve the deterrence So far holograms have proven to be the most successful device to deter counterfeiters. Today, holograms are no longer holograms but have evolved into optically variable image devices (OVID) with very intricate optical technology. OVIDs are overt devices that can also incorporate covert information. It is designed to meet specific budgets and security requirements. OVIDs are very secure and used on currency notes such as British Pound, Euro, Swiss Frank, Japanese Yen etc. Similar OVIDs are now available for use on pharma products packaging.

The advantage of OVIDs is that they cannot be scanned, simulated by any

known printing technique or electronically transmitted, impossible to photocopy, involves the viewer image, which is kinetic, colour changes, different image at different angles and it is economical - unit value of an OVID is low compared to its effectiveness.

Combining OVID/hologram with other techniques, for example holograms incorporated into Labels, aluminium foil, PVC, induction wads etc also offers a greater security advantage to the packaging. Incorporating holograms with a watchful

eye of the brand owner ensures highly secure packaging that would be very difficult to copy.

Just as security printers are required for the production of cheques, bank drafts etc, a good security conscious manufacturer of OVIDS must also be sought.

A company looking to address a counterfeiting situation should establish a multi disciplinary team, preferably headed by a director to work on the issue. Successful implementation is typically preceded by a thorough review of key areas like:

- Agree target objectives
- Effect on brand image and the consumer
- Cost benefit analysis
- Security device specification
- Select vendors and cooperate them on to the team Companies that value their brands protect them and enjoy consumer's loyalty and superior profits.

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### Who is stealing your Profits ?

A brand can make or break the reputation of a company. Your successful brand is a sitting target for many counterfeiters who are out to steal your thunder.

Don't take a chance!  
Protect your brands with :



HOLOTECHS : 109, Blue Rose Ind. Estate,  
W.E.Highway, Borivali (E), Mumbai-400 066.  
Tel : +91-22-6570 4590-3, Fax : +91-22-2854 0872  
e-mail : holographic@vsnl.com,  
www.holotechonline.com

DEVICE	FEATURE	BENEFIT	Remarks	TYPE
Substrates	Watermarked paper, polymer paper, special boards, phosphorescent particles	Uniqueness - limited supply, exclusivity	Needs excellent stock control and auditing systems, long supply times	Detect & forensic depending on specifications
Inks	UV, IR, colour changing, coin reactive, thermo-chromic	Wide range, easy to use and incorporate, very cost effective	Other than colour changing inks, other inks often needs an expert to verify	Deter, detect & forensic depending on specifications
Chemical markers	DNA & chemical markers can be specifically designed	Ideal for forensic testing	Specialist or laboratory required to verify, offers definite evidence	Detect & forensic
Optical variable image devices (OVID)	Generally mistaken as holograms, the latest technology optical images today are very secure and bright.	Cost effective, easy to incorporate into packaging, labels, etc. Wide range of applications, well proven	Most successful device to deter counterfeiters, available with wide range of security features & budgets, now even used on currency notes	Deter & detect
RFID	Mass remote data collection, sensing, ID	Excellent automatic data collection, no human intervention required	Expensive & lack of infrastructure, read rates 95% or less	Deter & detect
Track & Trace	Mass serialization	Versatile, easily adaptable, can be used with bar codes, cost effective	Needs good data collection and management systems	Detect