Confederation of Indian Industry

Anti-Counterfeit Packaging Technologies

A strategic need for the Indian industry

Anti-Counterfeit Packaging Technologies

A strategic need for the Indian industry

A Study Report by :
Rajiv Dhar
Director - Indian Institute of Packaging

Confederation of Indian Industry

249-F, Sector-18, Phase - IV, Udyog Vihar, Gurgaon - 122015, INDIA
Tel : +91-124-4101044 / 40144060-67 • Fax : +91-124-4014057
Email : ciico@cii.in • Wesbite : www.cii.in

ACKNOWLEDGEMENT

This study report was researched and compiled by Dr. Rajiv Dhar, Director, Indian Institute of Packaging for CII. The primary objective of this report is to provide the industry member organizations a robust reference document for selection and effective implementation of technology solutions to combat counterfeit menace.

Dr. Rajiv Dhar Director, Indian Institute of Packaging is also the Chairman, Education and Member on the board of World Packaging Organization and Chairman of Bureau of Indian Standards Technical Committee apart from being a member of various other national and international committees and organizations. Dr. Dhar with his rich experience of over 2 decades in the areas of operations, logistics and engineering has been able to provide a holistic perspective on combating counterfeit menace through this study report.

We are very grateful to Dr. Dhar for agreeing to research and compile this very important report for CII.

Dr. Dhar can be contacted on dharrajiv@gmail.com

Comments and requests for additional copies (including electronic versions) of this document may be sent to:

Anjan Das
Senior Director
Confederation of Indian Industry
249-F Udyog Vihar
Sector 18, Phase IV
Gurgaon 122 015, INDIA
Email: anjan.das@ciionline.org

TABLE OF CONTENTS

Tables

Figures

Pictures.

FOREWORD

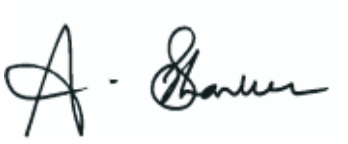
With the current threat of product counterfeiting taking endemic proportions, brand protection and security are crucial elements in global industry's fight against this pervasive threat. Analysis by OECD (Organization for Economic Co-operation and Development) indicates up to US$200 billion of International trade could have been in counterfeit or pirated products in 2005 where as Pira International reported an estimated loss to world trade due to counterfeiting and piracy to be almost $521.6 billion in 2006. Today, the menace of counterfeiting knows no borders, affecting corporations, governments, consumers and entire nations.

That is why we need both countrywide and industry-level cooperation, as well as public and private sector collaboration, to detect and decisively combat counterfeiting activity. A truly integrated approach, involving key stakeholders such as global, national and local law enforcement bodies, NGOs, technology solution providers and corporations, can pave the way for the development and implementation of strategies to stop counterfeiting in its tracks.

The strategic deployment of technology solutions can help secure a brand or product and also help build integrity within a supply chain. To explore this issue in depth, CII has issued a new report, "Anti-Counterfeit Packaging Technologies - A Strategic Need for the Indian Industry." This report provides insight into counterfeiting and the spectrum of solutions that could be effectively used by a wide range of organizations to combat its effects.

CII engaged the services of Dr Rajiv Dhar, Director, Indian Institute of Packaging, who is an expert in the field of counterfeiting research and linking its root causes with a variety of anti-counterfeiting technology measures, such as packaging innovations. I believe that that this report will be a valuable reference document and enable us to take meaningful steps in protecting our brands and products, and in turn help consumer's access genuine goods.

All of that is in line with the CII's ongoing endeavor to provide a sustained value proposition to Indian industry. I offer my appreciation to CII and Dr Rajiv Dhar for publishing this important report.



Shanker Annaswamy

Chairman, CII National Committee of IP Owners &

Managing Director - IBM India Private Limited

1. INTRODUCTION

Liberalization of economies across the globe has brought packaging technology to the forefront. Packaging being pervasive, in today's business plays an important role and each member in the supply chain looks forward ***'to use packaging as a strategic tool for business development and improved business performance under the present and future needs'***[1] ***.***

The scope of packaged products has broadened from luxury watches and designer clothing to include items which impact directly on personal health and safety — including food, pharmaceutical products and automotive replacement parts in fact everything we consume. Packaging also helps in creating the successful brands that becomes company's greatest single assets. Counterfeit packaged products as commonly understood means producing products and packaging similar to the originals and selling the fake as authentic products.

Counterfeiting with reference to packaging is not a problem in isolation; it is the part along with: ***Duplication -*** i.e. copying labels, packaging, products, instructions and usage information, ***Substitution -*** placing inferior products in authentic or reused packaging, ***Tampering -*** by altering packages/labels and using spiked, pilfered, or stolen goods in place as real. Together with Diversion and the ***Returns and Warranty frauds*** they are addressed as ***Brand Theft***.

Counterfeit is a problem of product security. Other type of improper products can be considered threats to product security even if not thought of as a traditional counterfeit. Product that is for example, diverted from its proper distribution channel, or sold after it is out of date, or tampered with by being laced with poison or by alteration of the package is related to the problem of counterfeiting. Trademark-infringing products may include correct ingredients in incorrect quantities or may be composed according to a wrong formula. Products can furthermore contain non-active or even toxic- ingredients. Ailments which could be remedied by genuine products may go untreated or worsen; in some cases this may lead to death. Most purchasers of counterfeit products are likely to be completely unaware that they have been victimized.

[1]Carl Olsmats, "The business mission of Packaging", Abo Akademi University Press 2002.

2. STRATEGIC VIEWPOINT- WITHIN PACKAGING PARADIGM

During 90's in India, the loose marketing of edible oils allowed considerable scope for mixing, adulteration, misbranding, short weight etc. The outbreak of dropsy in Delhi due to the adulterated mustard oil led to an unfortunate loss of over 200 precious lives created a shock wave amongst the consumers and became a matter of grave concern for the Government to restore confidence of consumer and all concerned. There was a general consensus that suitable packaging is an essential need. Packaging was accepted as a medium for avoiding contamination and maintenance of hygienic condition, preventing /minimizing quality deterioration besides conveying the product in convenient unit packs. Delhi High Court order banning the sale of mustard oil in loose form and the subsequent Edible oil Packaging (Regulation) order were conscious decision taken, having regard to distinct as well as accepted advantages of packaging. Have such action really been able to overcome the menace? Certainly not. But what is achieved is making the task of adulterator/ counterfeiter difficult, making consumer aware and giving him/her certain tell tale indicators to identify a counterfeit, help in creating brands that assure the quality of a product with the burden on the reputed manufacturer to protect them. However, today it is amply clear that manufacturers alone can not handle the menace of counterfeits. There is a need for well established strategies at the national and international levels across product segments and supply chains to fight this menace.

Not to be confused with values, mission, purpose, vision and goals, strategy is something with ***"long term"*** with a ***"broad scope"*** at a ***"higher level"***, but becomes complete only if it is combined with the basic issue which is to maintain a competitive advantage.

Paradigm proposed by John Wiley and Sons in the year 1997 states ***"Packaging is a socio scientific discipline which operates in a society to ensure delivery of goods to the ultimate customer in the best condition intended for their use"***. With this paradigm and among large number of models available to understand, analyze and prepare strategies, for the Packaging Industry, the ***"value chain"*** concept given by Michael Porter[2] appears to be the best model. Interpreting Porters concept, it is opined that a company can identify its ability to compete and accordingly should look at creating anti-counterfeit protections at each of the five primary links (inbound logistics, operations, outbound logistics, marketing and sales, services) and four supporting structures (infrastructure, human resource management, technology development and procurement). Paradigm also suggests considerations from social set up and consumer habits, infrastructure available including product based are part of the overall strategies.

[2]Michael Porter, Competitive Advantage (New York: The free press, 1985).

3. ANTI COUNTERFEITING STRATEGY - A CASE FOR INTERDISCIPLINARY APPROACH

During an interesting conference[3] held on Dec 2002 at Mumbai," Counterfeit Products: Consumer Beware" some views presented were:

a) **By the Industry.** Deputy M.D., Tata Tea informed that 65% of total tea sold, is sold as loose tea, which has some form or other of tampering done to it, Food grade color is added to husk and this mixed with loose tea. Some tea bags are even re-bagged. A G.M, Legal Affairs HUL, explained how *"Fair and Lovely"* became *"Flair and Lovely"* and spawned another 123 copies of this popular product. He opined that destruction of spurious stocks has not solved the menace; only vigilant consumer could tackle this problem. PepsiCo expert while sharing his concern informed that lakhs of bottles of Pepsi are counterfeited. Either spurious drinks are rebottled in authentic Pepsi bottles or the drinks are sold under the similar sounding names. "In a case study in Rajasthan he announced there were 65 factories selling over 40 spurious brands. VP Legal of Nutrine Confectionary brought out that look alike names, identical copies, old bottles with new labels and spurious refills make him realize that caution while buying is critical.

b) **Views on Judiciary and Law enforcement.** A Bombay High Court Judge brought out that the courts have laid principles which are sufficient to deal with this problem, but fines imposed are small and cases take too long, so the counterfeiter is free to go back to his old life. He also felt that the business community had to do more on this count and that special people had to be appointed to follow through wherever needed. A Joint Commissioner of Mumbai Police brought out *"All illegal acts are not the realm of the police"* Counterfeiting is a non cognizable act and so the policemen's role ends even as it is being reported.

c) **Consumer's views.** And finally the grand old man of Consumerism from Ahmedabad, Mr. Manubhai Shah had a view to share *"If counterfeiting is non cognizable, you are still not helpless. Contact the local consumer organization; they will fight on your behalf"*. Fight for your rights was his plea.

Even after our realization of the magnitude of the menace and possibly better IPR provision, it is quite relevant to note that the views that were shared almost 7 years ago remains the same even today. Quoting the recent views of a leading manufacturer[4] of packaged drinking water *"Anti counterfeiting is really a serious issue and needs a lot of attention. We have used hologram but consumers are not completely with the hologram and it is too complicated for them or they don't have the patience to look carefully the messages on the hologram. We all use what is called the pilfer proof cap however this pilfer proof cap are not too difficult to make in small units and the unscrupulous manufacturers buy the caps to make counterfeit product. We had developed a break away seal but we ourselves had great deal of difficulty in ensuring the consistency in quality and the convenience to the consumer. 3 years ago we started working on the two color cap for our 20 Liter container which required very sophisticated mould and an expensive molding machine from Larsen & Toubro. We spent more than Rs. 3 Crores and 1½ years time to get the pilot project for our Delhi plant alone. This did work for 2 months but in 2 months time the local engineer's people developed a two color very deceptively similar cap which consumers could not differentiate"*

Interdisciplinary Approach. Globalization has further compounded the problem. Taking an example where one

[2]Conference: Counterfeit Products Consumer Beware" 02 Dec 2002 by FICCI, FLO at Mumbai. Views as reported by Kiran Gera, Chairperson, FLO, Bombay (Packaging India Journal Vol. 35 No 6 Feb Mar 2003.)

[4]Mr. Ramesh Chauhan, Chairman, Bisleri. As shared with the author.

may know about the intellectual property rights law as it applies to a bottle design in the United States, but might not have any experience prosecuting similar cases in Cambodia. Or may have experience reducing product tampering, but not in deterring container theft in international free trade zones. To deal with the complex nature of counterfeiting, the interdisciplinary approach should reach out to a number of areas to develop insights and make choice for suitable technologies that can be incorporated through Packaging. It is proposed that the Interdisciplinary approach should have following components to understand the type of counterfeiters and the type of counterfeiting and arrive at the means of handling them.

Corporate and Brand owner's commitment. Many time with the inadequate market intelligence and the belief that counterfeiting is a criminal act and therefore dealing with it should be in the public domain, makes brand managers complacent, particularly, when counterfeiting is an insidious industry practice. Recently enacted Indian law that imposes harsh measures on counterfeiting activities that result in public harm is said to be adding to this view point. *"Adoption of innovative technologies are simply too expensive and will require company to elevate the price of its drugs which in turn will repel the cost conscious Indian consumer and the prescribing Doctor'* is another mindset shared by a few decision makers. However, by and large companies are looking forward to adopting means and remaining one step ahead of the counterfeiters by modifying their packaging from time to time.

Government Actions. The socio economic fabric of an emerging economy such as ours is more prone to exploitation and distressing situation for customers, illiteracy and low quality acceptance adds on to the woes of the poor customers. Significant revenue loss on account of counterfeits should arouse the interest of the Government in enforcing anti counterfeiting solutions. However, the pressure from the Government for more aggressive implementation of anti-counterfeiting measures emanates from the fundamental issues around consumer safety, economic progress, and even the National image[5] .A national policy paper on the subject is an urgent need.

International laws, Regulatory framework and compliance. International treaties, bilateral agreements, covenants, rules and regulations, advisory notes, directives etc. by various National governments may impose restrictive conditions if the products are not adequately secure. Like European Commission has initiated a proposal for protecting the products throughout the supply chain -Anti Counterfeiting Trade Agreement (ACTA) for discussions with their trade partners[6] . In US, FDA has recommended implementation of supply chain tracking for pharmaceutical products in 2004[7]. State of California (SB 1476) imposes stringent requirements for imports and sales of the drugs where it is mandatory to use the anti-counterfeit measures to single item level[8]. The US Prescription Drug Marketing Act 1987 included key provisions –

a) A requirement that wholesale distributors of prescription drugs who are not authorized distributors provide a statement of origin, also known as drug "pedigree" to each wholesale distributor. The pedigree traces each prior sale, trade or purchase of the prescription drug.

b) Section 203 (u) defines 'ongoing relationships' to include a written agreement between manufacturer and wholesaler.

[5] Special address by Shri Navin Chawla, Secretary, Ministry of Consumer Affairs,2004 (ficci.com/media-room/speeches-preentations/2004/apr/apr 21-piracy-navin.htm)

[6] IP fact sheet: anti counterfeiting trade agreement. Report from EU

[7] Combating Counterfeit drugs: a report of FDA,2004

[8] Background and summary of the California e-Pedigree Law.

c) Section203.50 specifies the fields of information that must be included in the drug pedigree and states that the information in the pedigree should be traceable back to the first sale by the manufacturer.

FDA Amendment Act 2007 (H.R. 3580-131) – Section 505D Pharmaceutical Security:

2) Standardized Numeral Identifier – implement by March 2010 for prescription drugs from point of manufacturing and repackaging;

3) Promising Technologies – The standards developed shall address promising technologies, which may include –

(A) Radio frequency identification technology
(B) Nanotechnology
(C) Encryption Technologies
(D) Other track and trace or authentication technologies

A bill, also known as H.R. 4829, states that the Secretary of Health and Human Services, who overseas a number of U.S. agencies including the U.S. Food and Drug Administration (FDA), "shall require that the packaging of any prescription drug incorporate (1) radio frequency identification (RFID) tagging technology, or similar track and trace technologies that have an equivalent function; (2) tamper-indicating technologies; and (3) blister security packaging when possible."

Washington, D.C., March 16, 2006 - The Electronic Industries Alliance (EIA) applauded President Bush for his signing of H.R. 32, the Stop Counterfeiting in Manufactured Goods Act, today. The Stop Counterfeiting in Manufactured Goods Act prohibits the trafficking in counterfeit labels, patches, stickers, hang tags, or medallions that are unattached to goods. In addition, the bill makes mandatory the forfeiture and destruction of counterfeit goods, as well as the assets used to produce, package, and distribute them. It also requires the forfeiture of property and assets derived from counterfeiting

SB 1476 bill. The State of California vide this bill envisages that all packaged medicines pass through a secure supply chain system and the movement recorded electronically, known as e-pedigree. The law was to take effect at the beginning of 2009 but under industry's pressure the date for implementation is postponed by two years.

Anti-Counterfeiting Trade Agreement (ACTA) by the European Commission has initiated a proposal for protecting the products throughout the supply chain.

Directive 2004/48/EC of the European Parliament on the enforcement of Intellectual Property Rights specifying in Article 29 – Industry should take an active part in the fight against piracy and counterfeit and preparing a model code of conduct for all EU nations.

Summary report of EU[9] while singling out India as the major source of fake drugs confiscated by its customs has issue special directives raising an alarm at the magnitude of pharmaceutical counterfeiting. With all this and more happening, need for a continuous effort backed by strategic actions is required by the exporting companies to not only to maintain their competitive advantage but to remain in business.

Consumer behavior and rights. It is important to note that the counterfeiter either attempt to deceive the consumer into thinking that they are purchasing the legitimate item, or convince the consumer that they could deceive others with the imitation. Most of the look alike products get sold because of the ignorance of the consumers. Many times to grab the best offers, like through internet sales, consumer fail to check the

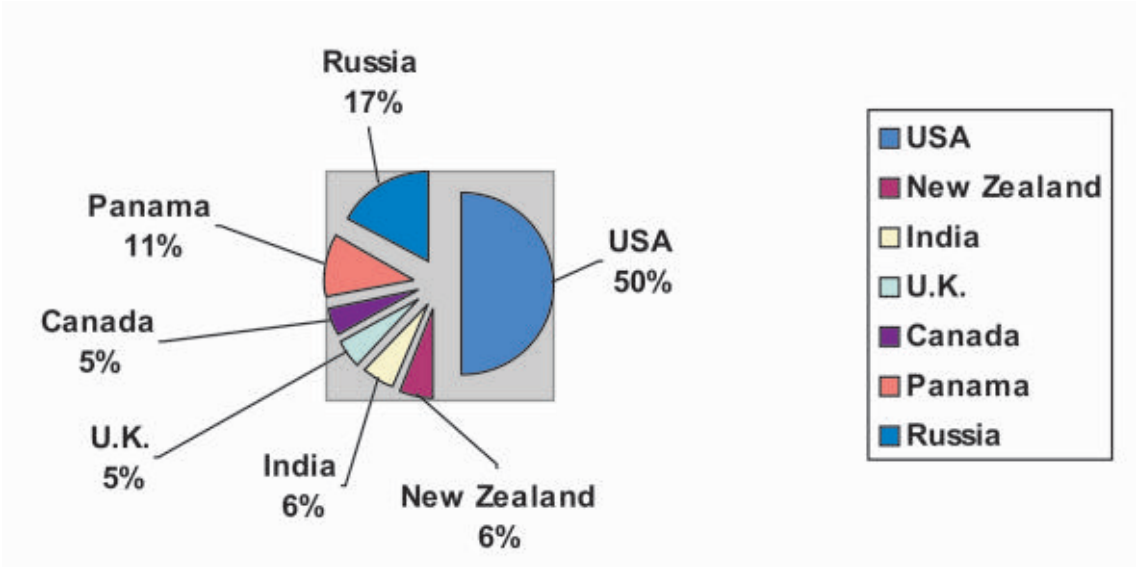
[9] Summary of Community Customs Activities on Counterfeit and Piracy. Report of EU Taxation and Customs Union.

authenticity. It is essential that consumer gets what he/she is paying for. The economic compulsions of consumers especially in rural areas along with their illiteracy and low quality acceptance make them highly vulnerable. The issue of counterfeit products is a very deep rooted malaise today. It is true that the impact of spurious products and negative aftermath from their usage, cuts across all segments of the consumers, gender included. According to a study[10] increased public awareness is a key tool in combating counterfeiting in pharmaceutical sector at the patient level.

Distribution and Retailing Both the distributors and the retailers can not afford to loose their reputation by sale of duplicate products. In case of any mishaps they will be primarily blamed for selling spurious products and this can end their business or cause heavy losses. Further the dealer or the retailer can also be entangled into legal hassles in case of any tragedy that may occur due to consumption of spurious products and all the hassles they have to face for the act they are not responsible for. In general it is imperative that anti-counterfeit measures adopted consider all the aspects of the LSCM for the product-Company business plans. For an example, pharmaceutical products may or may not follow a supply path as followed by other retail products. But drugs typically follow a more disjointed supply chain than other manufactured items, often being sold from one distributor to other to balance stock levels (as many as 10 distributors or wholesalers may handle a drug before it finally gets to a retailer or end user). A given distributor may carry upto 40,000 SKU's. And drugs are often repackaged within the supply chain. It will not be wrong to state that subsequent to manufacture, packaged product safety depends on critical supply chain controls.

Internet sales provide the ability to purchase products on line. A study[11] conducted by ***OpSec*** reports that medicine is counterfeit in over 50% of cases when the drug is purchased from internet sites that conceal their actual physical address. Such operators work from the unsecured locations as shown at Fig 1. Such retailing in other consumer products is expected to have its own share of concern.

Fig: 1 Y 2009 Online Pharmacy host locations[12]



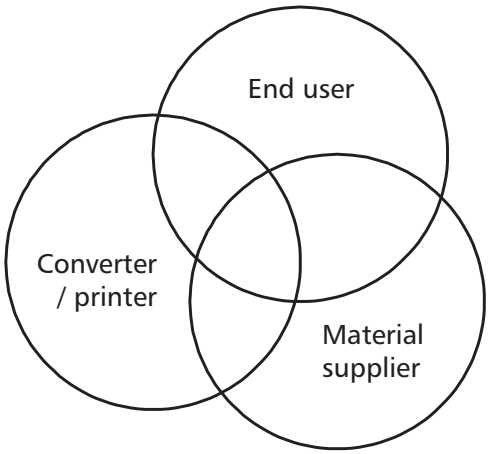
[10] NAFDAC,2006,http://mednet3.who.int

[11] Assessing the risk of counterfeit pharmaceuticals in the online marketplace. www.opsecutity.com

[12] Assessing the risk of counterfeit pharmaceuticals in online market place, A white paper by OpSec Security Inc. (www.opsecurity.com)

Partnership of industry players. With the views as expressed in this section , it becomes clear that for effectiveness of using anti-counterfeiting options there is a need to adopt a tightly controlled and monitored procurement, manufacturing and disposal protocols. A partnership with mutual trust generates security features where customized substrate in substantial volumes can become very cost effective.

Fig: 2. Partnership Trust Trio



4. PROBLEM STATEMENT AND ASSESMENT

4.1 Harmonized definition for Counterfeit product.

Counterfeit packaged products as commonly understood means producing products and packaging similar to the originals and selling the fake as authentic products. As per Wikipedia, a counterfeit product is an imitation which infringes upon a production monopoly held by either a state or corporation. Goods are produced with the intent to bypass this monopoly and thus take advantage of the established worth of the precious product. The word counterfeit, frequently describes both the forgeries of currency and documents, as well as imitation of clothing, software, pharmaceuticals, watches, electronics, and company logos and brands. In case of goods it results in patent infringement or trademark infringement.

However, under the WTO regime a unified definition is necessary for assessment and declaring the packaged goods. As such one of the efforts for the sake of international trade the Federal Food, Drug and Cosmetic Act[13] defines a counterfeit drug as 'a drug which, or the container or labeling of which, without authorization, bears the trade mark, trade name. or other identifying marks, in print, or device, or any likeness thereof, of a drug manufacturer, processor, packer and, or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drugs and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by such other drug manufacturer, processor, packer, or distributor. U.S. law[14] defines counterfeit drugs as those sold under a product name without proper authorization. Counterfeiting can apply to both brand name and generic products, where the identity of the source is mislabeled in a way that suggests that it is the authentic approved product. The World Health Organization provides an elaborate insight on Counterfeit medicines and its menace in its Fact sheet N°275, Revised 14 November 2006. It reports that Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals – medicines manufactured below established standards of quality and therefore dangerous to patients' health and ineffective for the treatment of diseases. The difference is that counterfeits are deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients. The main issue arising from the World Health Assembly discussions at the Third General Meeting at Tunisia on 3 - 5 December 2008, highlighted the delegations were not ready to support the draft resolution on definition of counterfeit medicinal product included in legislative principals and risks to imply that many generics could be regarded as counterfeits. The Assembly proposed a revised definition in legislative document is still under finalization.

Tamper evidence. There is no official recognized definition followed internationally of what constitutes a tamper evident closure. The FDA published 21 CFR 211.132, Tamper-resistant Packaging requirements for over the counter human drug Products. The FDA definition reads:

"Having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred."

Harmonization of the definition of counterfeit product is of utmost importance for international trade for protecting the image of the industry. For an example it is essential to avoid genuine generic medicines being considered counterfeit-a term normally associated with illegally produced or supplied medicines that may or may

[13] 21USC Sec 32(g)

[14] Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update May 18, 2005 (http://www.fda.gov/oc/initiatives/counterfeit/update2005.html).

not conform to quality specifications. India has stressed that a generic or branded medicine not registered in a particular country, but available in that country is not a counterfeit, but simply an unregistered product[15].

4.2 Magnitude and Market structure for counterfeit products

The infringing products are being produced and consumed in virtually all economies,

Indian market. Delhi's leading Newspaper[16] carried a story on the scale of fake goods in India. According to ASSOCHAM (the Associated Chamber of Commerce), fake goods worth Rs. 20,000.00 Crores are being sold in the Indian market. According to A C Nielsen, 10 to 30 percent toiletries, cosmetics and packaged food are counterfeit! In another research the International Anti-Counterfeiting Alliance has found that 35% of all the automotive parts worth about Rs 2000/- Crores, sold in India are fakes. The problem is huge and becoming bigger and worse. It is difficult to believe that out of the 3.5 Crore watches sold in India, only 1.2 Crore are produced by the organized sector. That means 65% of the market is either fake or smuggled goods. With the 4th global ranking in terms of volume and 13th in terms of value Indian pharmaceutical industry is poised to grow at average rate of 9% per annum[17]. A highly organized sector with a due importance as India's first ranker science based industry. Currently, Indian Pharmaceutical companies produce about 20-22% of the World's generic drugs (in value terms) and therefore counterfeiting is a subject that has a great relevance for the industry..

International Markets. Counterfeiting as an inevitable result of Globalization has become a global nuisance in the recent years and the range of goods subject to infringement has increased significantly. According to the study of CIB (Counterfeiting intelligence bureau of the ICC, International Chamber of Commerce) counterfeit goods probably make up to 5-7% of World Trade. A recent report by the OECD indicates that upto 200 bn USD of international trade could have been in counterfeit and illegally-copied goods in 2005 (2% of World Trade in 2005)

Quantitative analysis carried out by the OECD indicates that the volume of tangible counterfeit and pirated products in international trade could be up to USD 200 billion out of which the counterfeit drug sales will reach US $ 75 billion globally in 2010, an increase of more than 90% from 2005 as indicated by The US based Centre for Medicines in the Public Interest and WHO. This figure does not, however, include counterfeit and pirated products that are produced and consumed domestically, nor does it include the significant volume of pirated digital products that are being distributed via the Internet. If these items were added, the total magnitude of counterfeiting and piracy worldwide could well be several hundred billion dollars more.

Reports from developing countries, especially in sub-Saharan Africa, are extremely rare and do not permit to draw a realistic picture of a situation that is generally considered to be highly unsatisfactory because of the weakness of regulatory and enforcement systems and the widespread presence of unregulated distribution and retail facilities. Apart from the huge differences between regions, variations can also be dramatic within countries, i.e. city versus rural areas, city versus city. Counterfeiting is greatest in those regions where the regulatory and legal oversight is weakest. This situation puts rural and the poorer segments of the population at a particular disadvantage.

Asia is emerging as the single largest producing region for counterfeit products. Enforcement authorities have

[15] Generic drug industry in India; the counterfeit spin. Nitin Shukla and Tanushree Sangal Journal of IPR Vol 14, May 2009, pp 136-240

[16] The Hindustan Times dated 17th of July, 2006.

[17] IIP 2008 study report "packaging material items used by pharma industry for formulation in the country"

stepped up efforts to intercept counterfeit items in international commerce, but counterfeiters and pirates have the upper hand in light of the enormous volume of goods being legitimately traded and the ease with which counterfeit and pirated items can be concealed. The difficulty in breaking into established supply chains has helped to limit counterfeiting and piracy, but there are signs that counterfeiters and pirates are successfully expanding operations. The Internet has provided an important new platform for increasing sales. Criminal networks and organized crime are playing a major role in counterfeiting and piracy operations; they are attracted to the relatively high profits to be made and the relatively light penalties that could be applied if their operations were detected.

The extent of counterfeiting is impossible to quantify. Currently, the sources of information available include reports from nongovernmental organizations, pharmaceutical companies, national medicine regulatory and enforcement authorities, ad hoc studies on specific geographical areas or therapeutic groups, and occasional surveys. These sources of information emphasize the complexity of making estimations.

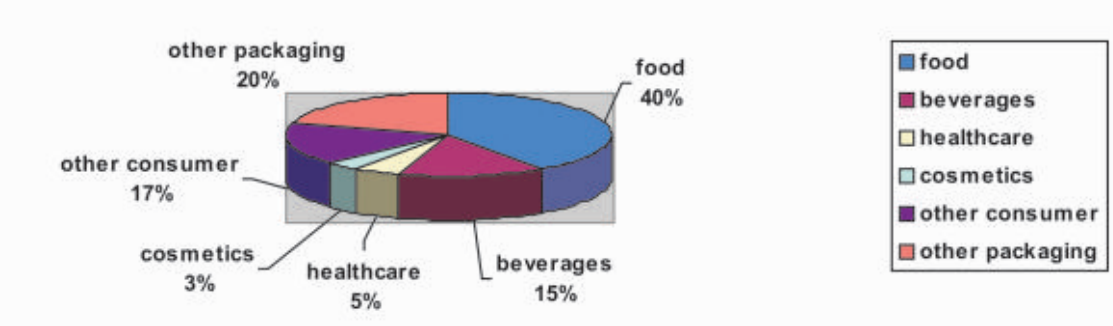
4.3 Anti-counterfeit Packaging- End use market share & investment decision

Globally as shown at Table-1, out of overall forecast packaging sales of $ 564 billion in 2009, consumer packaging markets is expected to account $ 450 billion with remaining $ 114 billion accounted for industrial/bulk packaging markets. Within consumer packaging, food packaging is the single largest element, valued at $ 227 billion. This drives the need for technology solutions for the consumer consumption and safety. Fig 3 indicates a general comparison between end use sectors. With food sector contribution of 40%, cosmetics 3% and pharmaceutical 5 % it is expected that Packaging converters will like to make the investment decisions in anti-counterfeiting technologies which are of a common nature as far as their use is concerned, unless converters see a good value realization from a particular sector. Such a scenario is likely to make certain specific sectoral technologies very costly.

Table: 1. World Packaging consumption by end use markets 2003-2009 (US $ million)

	2003	2004	2005	2009	CAGR (%) 2004-09
Food	168,219	182,291	190,055	227,156	4.5
Beverage	64,586	68,922	71,166	83,689	4.0
Healthcare	16,944	18,872	19,914	25,468	6.2
Cosmetics	12,464	13,719	14,565	18,491	6.2
Other consumer	69,918	76,063	79,371	94,512	4.4
Other packaging	95,077	99,397	102,022	114,531	2.9
Total	427,210	459,263	477,094	563,847	4.2

Fig: 3. End user market share (value terms) in Packaging business -World (Y 2009)



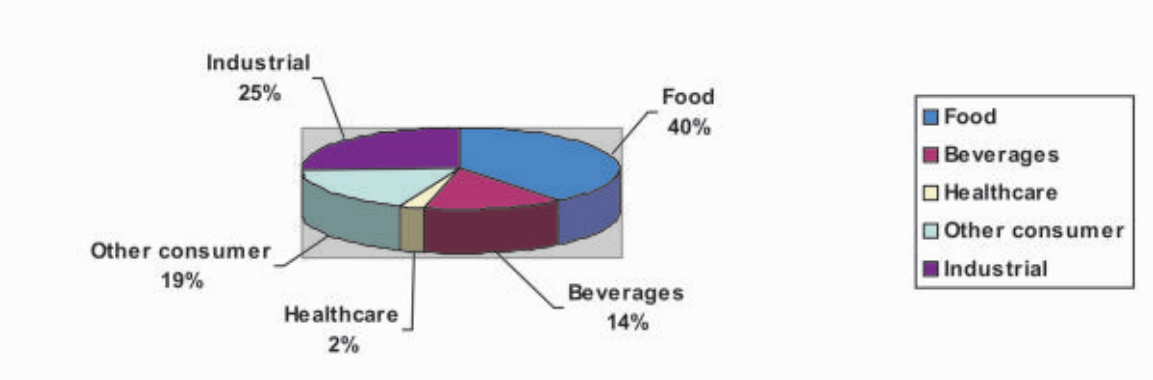
In Indian packaging market (Table:2) with an overall forecast packaging sales of $ 13.4 billion in 2009, consumer

packaging markets is expected to account $ 10 billion with remaining $ 3.4 billion accounted for industrial packaging markets. Within consumer packaging, food packaging is the single largest element, valued at $ 5.3 billion. This drives the need for technology solutions for the consumer consumption and safety as in the case of global industry. Fig 4 indicates a general comparison between end use sectors. With food sector contribution of 40% pharmaceutical just 2 %, it is once again evident that technology solutions that have a common application in various end sectors will have a greater acceptance in the industry. Any specific sector depending technology is going to be prohibitive for Indian manufacturers.

Table: 2. Indian Packaging by end-user sectors 2003-2009 (US $ million)

Sectors	2003	2004	2005	2009	CAGR (%) 2004-09
Food	2336	2609	3028	5302	15.2
Beverages	844	940	1087	1885	14.9
Healthcare	130	148	175	326	17.1
Other consumer	1079	1210	1411	2498	15.6
Industrial	1857	2006	2234	3401	11.1
Total	6245	6913	7935	13412	14.2

Fig: 4. End user market share (value terms) in Packaging business- India (Y 2009)



India has still not reach a stage where packaging converters can be expected to make huge investments in R&D activities to handle the counterfeiting menace only for a specific sector like the pharmaceutical sector unless compensated adequately. By and large companies are dependent on the technologies developed globally. However, many pockets of indigenization and LCA through applied research by SME' is visible.

4.4 The scope of products being counterfeited

Infringing products are being produced and consumed in virtually all economies. Counterfeiters and pirates target products where profit margins are high, taking into account the risks of detection, the potential penalties, the size of the markets that could be exploited and the technological and logistical challenges in producing and distributing products. On the demand side, consumers either: (i) unwittingly buy counterfeit or pirated products thinking that they have purchased genuine items, or (ii) knowingly buy lower-priced counterfeit or pirated items. The degree to which consumers knowingly buy counterfeit or pirated products depends on the characteristics of the products concerned. For example, consumers who would knowingly purchase counterfeit garments without any hesitation may have no interest in purchasing counterfeit pharmaceutical products.

Pharma duplication remains the biggest area of concern as it is facing the highest level of threat and the

consumer of pharmaceuticals products are the worst sufferers. Liquor is another area, greatly affected by duplicates. Senior level management teams in FMCG companies are dwelling more and more on security options available to fight this menace

The products having the monopoly in the form of protection are targeted the most. For example a new drug developed over 10 years research work with a cost of $ 1.5 bn /years[18] and priced suitably to recover not only the cost but make profits before its marketing rights expire. This makes pharma sector the most vulnerable. Consumer goods especially if they are very expensive or the desirable brands or those which are easy to produce cheaply have become frequent and common targets

4.5 Government/Business initiatives to combat Counterfeiting & Piracy

Both governments and industry have been actively engaged in expanding efforts to combat counterfeiting and piracy in international and national contexts. While the efforts have had positive results, counterfeiting and piracy levels remain high. Governments have strengthened legal frameworks, enforcement efforts and have launched awareness-raising initiatives. Improved enforcement appears essential to reduce illegal activities further and well-publicized enforcement actions have a role in reversing the trend. Improving the situation may also require governments to strengthen their legal regimes yet further, possibly increasing the civil and criminal sanctions that apply to IP crime. Actions may also be needed to keep the Internet from becoming a more prominent distribution channel for infringing items. Multilaterally, ways to strengthen the existing framework and practices to combat counterfeiting and piracy could be explored. Industry has come together at the sector, cross-sector, national and global levels to develop common and unified responses to counterfeiting and piracy. Initiatives have been aimed at improving policy, providing technical assistance and enhancing awareness. It has also begun to devote effort to developing technological solutions to undermine infringing activities.

BASCAP. The Business Alliance to Stop Counterfeiting and Piracy, which was launched in early 2005 under the auspices of the International Chamber of Commerce, is one of the more recent and comprehensive global initiatives launched by industry. It seeks to bring firms together to pursue a more unified approach to combating counterfeiting and piracy. Its efforts include the creation of platforms for exchanging information on the counterfeiting and piracy situation in different economies and sectors, and for sharing information on effective brand protection techniques. It also seeks to provide stakeholders with improved information on the efforts being taken to address issues, with a view towards enhancing co-ordination. At the same time, research projects are being carried out to provide more effective methods for evaluating the counterfeiting and piracy situation in different economies. On the public policy front, efforts are being made to more effectively communicate the economic and social costs of counterfeiting and piracy to governments and the general public. A 2007 BASCAP Global survey on Counterfeiting and Piracy revealed that industry efforts have mainly focused on initiatives to develop technologies to combat infringement. Resources have also been directed to aiding enforcement and improvising awareness, but to a lesser extent.

WHO – IMPACT. In order to mobilize awareness and action in the fight against fake medicines, in February 2006, WHO created the first global initiative, known as the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). IMPACT (International Medical Products Anti-Counterfeiting Taskforce) is comprised of all 193 WHO Member States on a voluntary basis and includes international organizations, enforcement agencies, national medicine regulatory authorities, customs and police organizations, nongovernmental organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients' groups. These groups have joined to improve coordination and harmonization across and between countries so

[18] Generic drug industry in India; the counterfeit spin.Nitin Shukla and Tanushree Sangal Journal of IPR Vol 14,May 2009,pp 136-240

that eventually the production, trading and selling of fake medicines will cease. The World Health Organization spearheaded the creation of the WHO IMPACT coalition, which is supported by national medicines regulatory authorities and Ministries of Health of WHO Member States and a number of other stakeholders. These include: Interpol, Organisation for Economic Cooperation and Development, World Customs Organization, World Intellectual Property Organization, World Trade Organization, European Commission, Council of Europe, International Federation of Pharmaceutical Manufacturers and Associations, European Generic Medicines Association, World Self-Medication Industry, Asociación Latinoamericana de Industrias Farmacéuticas, Commonwealth Secretariat, ASEAN Secretariat, International Federation of Pharmaceutical Wholesalers, European Association of Pharmaceutical Full-line Wholesalers, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, International Alliance of Patients' Organizations, ReMed, Pharmaciens Sans Frontières, the United States Pharmacopeia, German Pharma Health Fund. IMPACT is helping to disseminate information useful for assessing technologies aimed to prevent, deter or detect counterfeit medicinal products. This assessment takes into account: a) cost; b) scalability; c) specific country needs and situations; d) feasibility; and e) regulatory implications. This work has lead to the following conclusions:

a) There is no "worldwide" applicable technology, different approaches are needed.

b) In developing countries the priority is to strengthen the capacity to tackle the informal trade of medicines such as street markets, smuggling and other unregulated or illegal activities.

c) Countries should implement technologies appropriate to their situation and prefer those that are compatible across borders.

d) Although it has been proposed as a promising solution, there are multiple weaknesses in radio-frequency identification (RFID) (including cost, privacy concerns, logistics throughout the distribution system, etc.). IMPACT consensus is that full implementation of RFID can only be envisaged in a distant future; as a consequence, the most realistic alternative to enable tracking and tracing medical products along the supply chain is the use of two dimensional barcode labels.

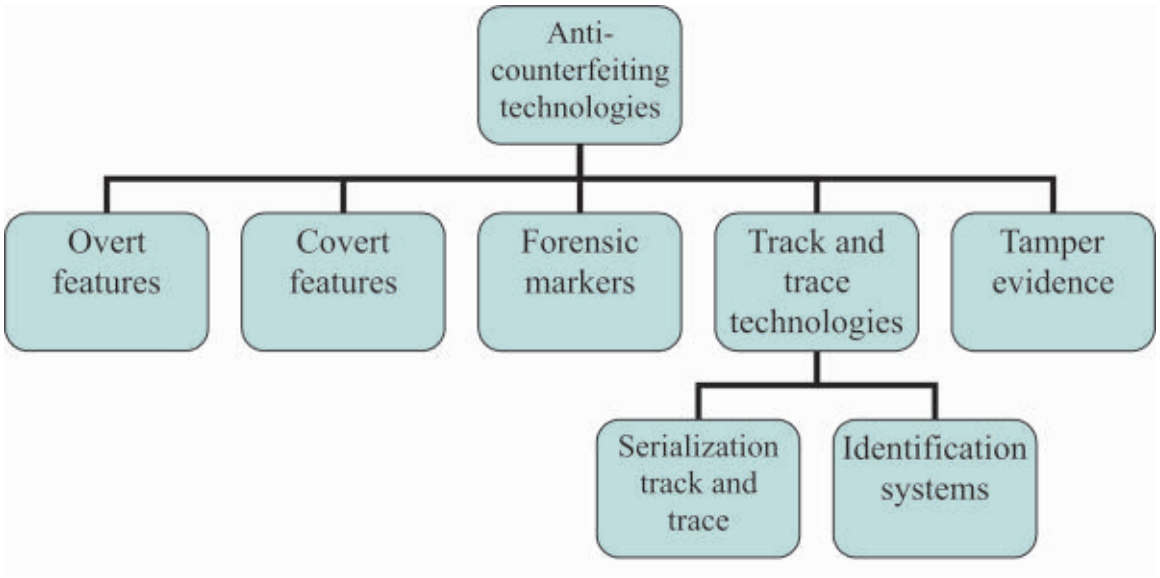
e) The working group's view is that authentication of medicines should only go as far as the pharmacist and that the burden of verifying that a product is authentic must not fall on patients.

5. ANTI-COUNTERFEITING TECHNOLOGY SOLUTIONS

Anti-counterfeiting technologies currently available can be classified and explained in different ways. Since mostly such options are used in combination and their usage varies with the level of packaging, in this study technologies are identified by the way they are intended to be used as well as currently available for any packaging design. This is purely with intent for convenient explanation.

5.1 TECHNOLOGIES: USAGE CRITERIA

Fig: 5 Technology classifications on the basis of usage features.



A. Overt (Visible) Features. Overt features are intended to enable end users to verify the authenticity of a pack. Such features will normally be prominently visible, and difficult or expensive to reproduce. They also require utmost security in supply, handling and disposal procedures to avoid unauthorized diversion. They are designed to be applied in such a way that they cannot be reused or removed without being defaced or causing damage to the pack for this reason an overt device might be incorporated within a Tamper Evident feature for added security.

Pic: 1. Checquered board feature as an overt feature

A.1 Tamper evident packaging systems. Some packages are inherently tamper proof, like a tin can hermetically sealed, an aseptically packed multilayer carton or a vacuum or the retort pack. Other than the tamper evident system stated elsewhere additional systems are:

a) **Film wrappers** A transparent film with a distinctive design is wrapped securely around a product or product container. The film must be cut or torn to open the container and remove the product. Substrates options include ultra destructible films, voidable films that provides image when removed. solvent sensitive papers.

b) **Shrink seals and bands.** Bands or wrappers with a distinctive design are shrunk by heat or drying to seal the cap and container union. The seal must be cut or torn to remove the product.

c) **Breakable caps.** Such caps break when an attempt to open it is made. These caps provide external tamper evidence and can also be combined with the internal seals thereby providing double security.

Pic: 2. External and internal tamper evident feature

d) **Sealed tubes.** The mouth of the tube is sealed, and the seal must be punctured to obtain the product.

B. Covert (Hidden) Features. The purpose of a covert feature is to enable the brand owner to identify counterfeited product. The general public will not be aware of its presence nor have the means to verify it. A covert feature should not be easy to detect or copy without specialist knowledge, and their details must be controlled on a "need to know" basis. If compromised or publicized, most covert features will lose some if not all of their security value. For this reason such techniques will not be disclosed in detail in this paper.

Pic: 3. Encrypted text visible under special light as a covert feature

C. Forensic Markers. There is a wide range of high-technology solutions which require laboratory testing or dedicated field test kits to scientifically prove authenticity. These are strictly a sub-set of covert technologies, but the difference lies in the scientific methodology required for authentication.

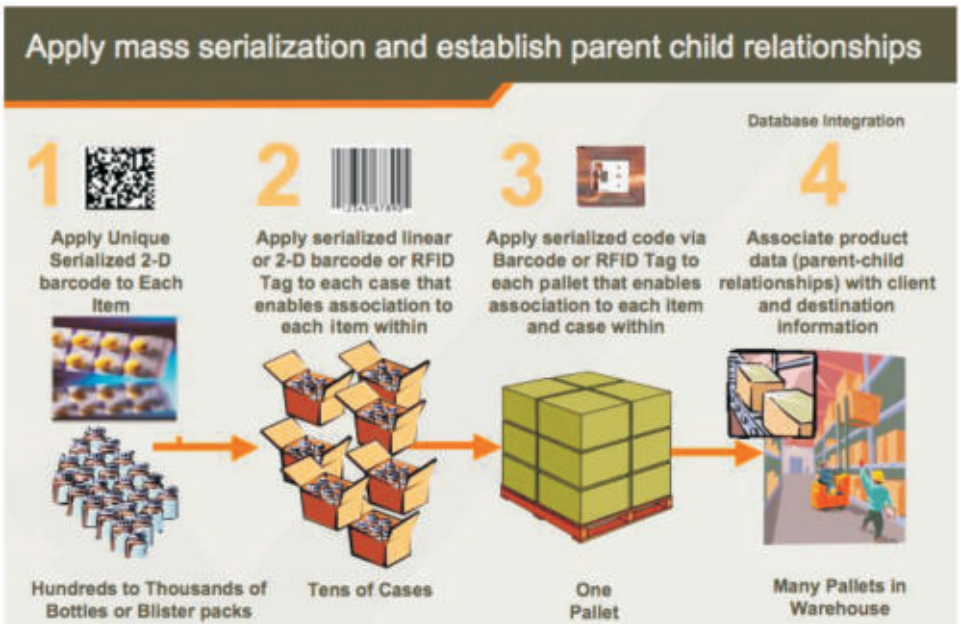
Pic: 4 Forensic markers

D. Track and Trace Technologies. These involve assigning a unique identity to each stock unit during manufacture, which then remains with it through the supply chain until its consumption. This identity will normally include details of the product name and strength, and the lot number and expiry date — although in principle it may simply take the form of a unique pack coding which enables access to the same information held on a secure database. (This latter solution overcomes some of the concerns about privacy where the encoded data can be read at a distance by radio equipment.)

D.1 Serialization

In itself te Track and Trace label may not be immune to copying or falsification, but its security is greatly enhanced by the inclusion of unique and apparently random serialization, or non-sequential numbering, ideally at individual item level. If the serialization was sequential, then the level of security would be very low as the sequence is predictable, whereas "random" serialization using a highly secure algorithm or method of encryption overcomes this. Individual packs may still be copied, but the database will identify duplicates or invalid serials, as well as those which have been cancelled or expired, or which appear in the wrong market, or with invalid product details. There are two main vehicles for the incorporation of unique pack data in order to facilitate automatic data capture:

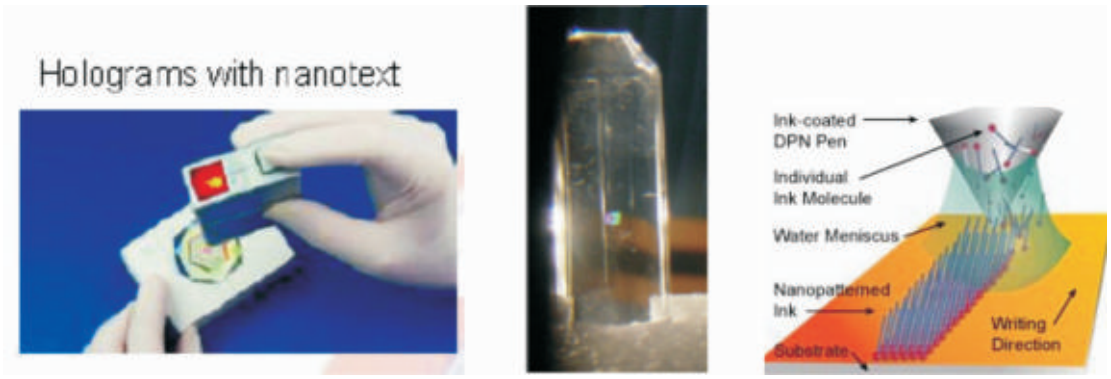
Pic: 5 Mass Serialization



I) **Bar Codes.** 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, and other possibilities include PDF417 codes. 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.

ii) **"Nano-printing" substrate** technologies allow microscopic application of UV inks allow invisible printing onto any substrate including glass vials and ampoules.

Pic: 6 Nano-prints on substrates



iii) **"Nano-printing" product** technologies allow microscopic application onto individual tablets.

Pic: 7 Nano-prints on tablets

iv) **Radio Frequency Identity (RFID) Tagging.** An RFID tag comprises of an antenna with a microchip at its centre. This contains item- specific and batch information which can be interrogated at a distance, and without requiring line of sight (unlike bar codes). The radio frequency used determines the range and sensitivity, but no one specification suits all applications. Some systems are able to capture multiple records for a mixture of different products, but there are some issues around orientation of the tags and absorbance of the radio signal by liquids and foils. But one clear advantage of RFID is that it has the potential to be fully automated in warehouses and even through to pharmacies, without requiring manual intervention. Specifications for equipment and data standards are being developed. The cost of tags remains a significant barrier to individual pack application, as does the availability of the application and verification equipment if it is to be implemented to pharmacy level. Robustness of the tags during

application and handling through to end of life is another issue, as trials to date indicate a significant failure rate. However there is optimism that a printed version may be developed. Privacy issues and susceptibility to deliberate adulteration must also be addressed prior to widespread implementation.

Pic: 8 RFID Tags

v) **Unique surface marking or topography.** There are several methods for applying a pseudo-random image to each item in a batch, such as a pattern of lines or dots in one area of the carton, and then scanning the signature into the batch database via secure algorithms, for later authentication. Alternatively, the pack surface provides a unique fingerprint when scanned by a dedicated laser device, which enables each pack to be registered into the database at batch manufacture, and which is impossible to replicate or falsify. Unique pack serialization has the potential to deliver robust solutions to fraud and counterfeiting of pharmaceuticals, but is not yet fully developed. Barcode systems use proven existing technology, but lack the advantage of automation and remote scanning possible with RFID. But RFID systems are not yet proven or robust, and standards need to be agreed and defined. RFID tags may be vulnerable to deliberate and invisible alteration or corruption.

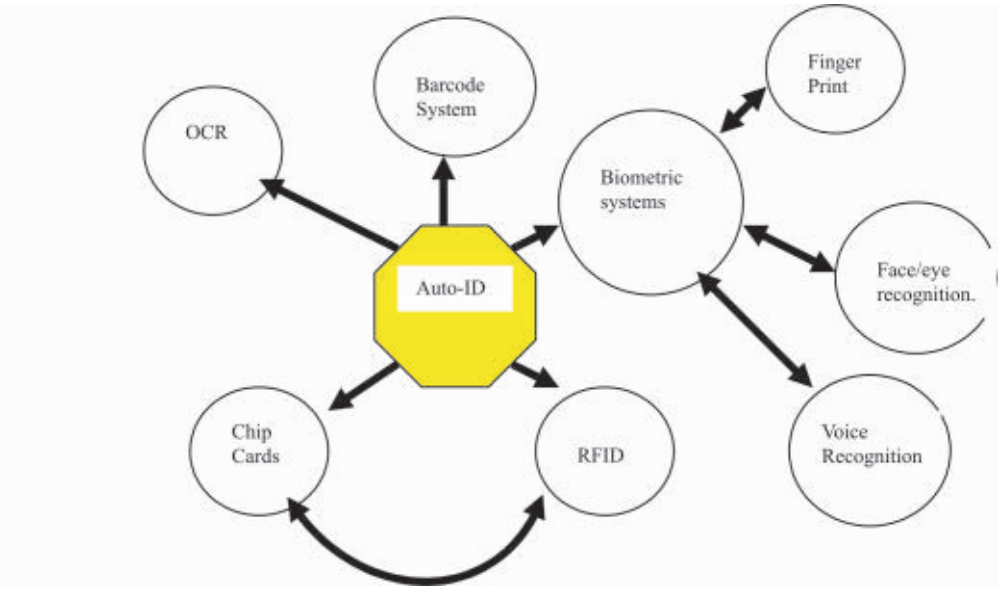
D.2 Auto Identification systems.

Smart packaging or auto identification systems are defined as small inexpensive label or tags that are attached onto primary packaging (e.g. treys, pouches bottles) or often onto secondary packaging(e.g. shipping containers) to facilitate communication through-out the supply chain for safety enhancements. Auto identification systems as per Ustandao[19] are classified as optical character recognition (OCR), barcode system, chip cards, biometric systems and RFID as shown in Fig.6.Data carriers such as barcode labels and RFID tags are used to store and transmit data. Packaging indicators such as time temperature indicators, gas indicators, biosensors are used to monitor the external environment and whenever appropriate issue warnings.

Pic: 9 Auto Identification of tags and barcodes with scanners, readers and phone

[19] Ustanso A.(2005).RFID technology: A Paradigm shift in business Process,35th International conference on Computers and Industrial engineering,2065-2070

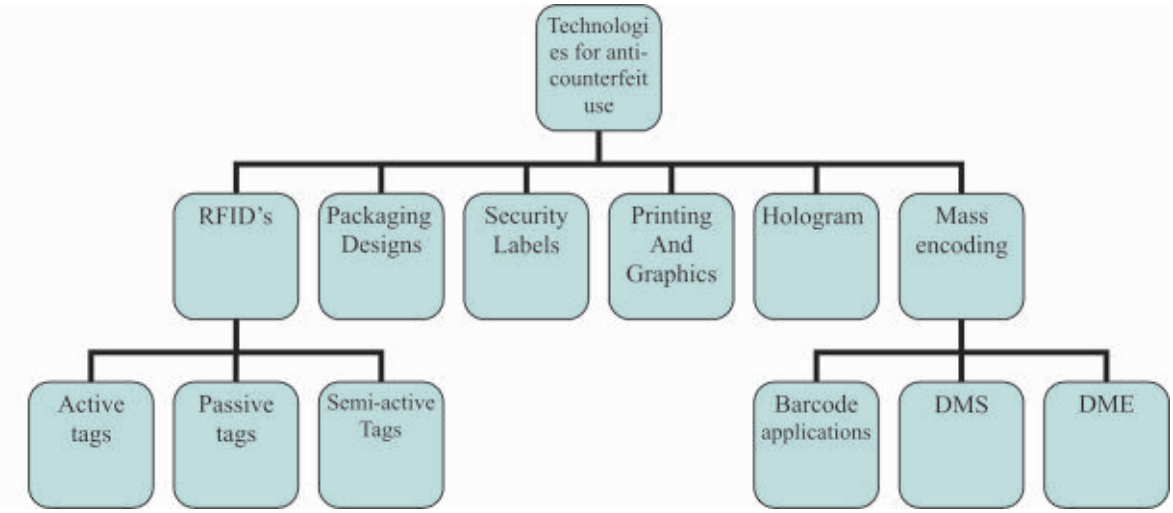
Fig: 6 Classifications of auto identification systems



5.2 EXISTING TECHNOLOGIES: OPTIONS

The current numbers of anti-counterfeiting solutions are many and new options are introduced in the market with some variations. An attempt is made to classify the technologies as shown at Fig-7, for easy understanding and comparison for their applications on product packaging.

Fig: 7 Classification based on current Technologies



A. RFID. Radio Frequency identification is hardly a new concept. For some, RFID is already a mainstream technology-it is used everyday to pay tolls, secure building access, catch shop lifters etc. It allows identification of objects through a wireless communications in a fixed frequency band. Three essential components in any RFID system are: the tag, the reader and the software. The tag is an Integrated circuit containing a unique tracking identifier, called an electronic product code (EPC), which is transmitted via E.M. waves in the radio spectrum. The reader captures the transmitted signal and provides the network connectivity between tag data and the system

software. The software can be tailor made for the purpose of anti-counterfeiting. For their use on Packages and LSCM, probably Wal-Mart becomes the pioneer. For their track and trace usage, RFID tags are used in different ways:

a) **Passive tag:** When RFID tag is within the interrogation zone of the reader (i.e. interrogator) equipment; sufficient power is extracted from the interrogator to power up the tag or circuit, or a special reflective material. It then responds by transmitting data back to the interrogator.

b) **Active tag:** Such tags incorporate a battery to increase range for collating data, tag to tag communication, etc. But these are much more expensive.

c) **Semi-active tag.** In these tags battery is used to back up the memory and data, but not to boost the range. With some active RFID tags, the battery is only used when interrogated or when sending a homing pulse at fixed intervals to reduce cost and size.

B. Packaging design: Materials/Substrates and other design options

a) **Substrates.** There are variety of substrates used in the design of packages with intent to provide counterfeit and tamper evident features starting from litho paper, polystyrenes, destructive vinyl's, acetate films synthetic paper and coatings etc. There are many ways of incorporating covert markers within a substrate, such as visible or UV fluorescing fibers, or chemical reagents in carton board or paper. Watermarks can be embedded in leaflet paper, or metallic threads interwoven in the base material, possibly including an overt OVD feature. These require a dedicated supply source and large volume production, which, if affordable, results in a very effective option. Odor. Micro-encapsulated distinctive odors can be applied as an additive to an ink or coating to provide a novel covert or semi-overt feature as well as sound chips creates special opportunities in the design.

Pic: 10 Special grade of paper used as label stock

b) **Packaging designs** like sealed cartons, aerosol containers have inherent strength against counterfeiting

c) **Sealing systems.** Special caps as the outer tamper evident system or the foil seal offers that offer an internal tamper evident feature are commonly used for processed food and FMCG products. Sealing options are:

a) **Induction.** A process where heat is applied just where needed, around the edge of the aluminum foil inner liner. As a sustained downward pressure of 50-150 phi) is exerted on the cap, an electronic

b) **Conduction** Foil closures are stamped from a roll of foil/polymer laminate and fed into the chute.

c) **Lever-lidded tins.** The pilfer resistance of lever lidded metal containers can be dramatically improved by the inclusion of a tagged foil diaphragm which can be formed into the lid assembly prior to attaching to the can body.

d) **Secure Packaging Tapes:** A simplest features providing Tamper evident and theft protection at the level of secondary packaging, boxes and logistics containers. The secure packaging tape is equipped with a highly aggressive adhesive and features a unique design. The continuously varying serrated edge, rhombic pattern and semi-transparent finish indicates clearly that tape has been cut through and pasted over again.

e) **Tear tapes/ bands:** These provide excellent features at the levels of transport or the secondary packs

Pic: 11. Tear tape applied as a security feature on a corrugated box.

f) **Lined cartons.** As an efficient replacement for secured containers like the metal cans, these packs have the internal flexible liner and the external semi rigid paper carton. However as a security feature the liner carton is attached to the paper carton during manufacturing stage on special machines and thereby product filling is done directly on the special filling lines.

Pic: 12. A liner carton

C. Security labels: Construction and substrate features

Tamper evident and security labels play an important role in providing some relief to the consumers against fakes. In Self Adhesive Labels the substrate mostly performs as a complimentary interaction of the substrate and the pressure sensitive adhesive. While passive security labels have been extensively used today one can find a greater application of functional labels such as printing plus EAS serving as anti theft. Some label options are:

a) **Paper labels with Security Cuts:** The substrate used for these labels is ordinary coated/uncoated paper. The security features are built in by the label printer at the converting stage. With the help of a special cutting die the face material is given cuts at various angles so that any way one tries to remove these labels the paper will tear off. A general purpose permanent adhesive works fine with such labels. Care is taken to ensure that the adhesive will adhere well and firmly to the surface on which the label has to be applied.

b) **Destructible Labels:** Needs a special substrate designed for the purpose. Most of the high-end applications use a specially made Cellulose Acetate film. The film is very intricately designed that it has adequate strength to undergo conversion into Label stocks in roll form. It is available both in clear and opaque formats. This is further converted into labels using aggressive pressure sensitive adhesives. These labels can be automatically dispensed on automatic label dispensers. These labels when attempted to be removed, break up into very small fragmented pieces. These days' cost effective vinyls are being used instead of the Acetate film. There is also development on this front using a combination of various synthetic polymers such that the end substrate has very low inherent strength.

c) **Void Labels and Tapes:** These are perhaps the most important of the tamper evident security labels. These substrates have text built into them and when as a self adhesive label they are removed, they exhibit the word VOID both in the removed film and the adhesive layer left behind. These substrates gain importance since there can be customization built into the labels produced with it. One can use polyester or BOPP as face materials. Variety of colors, even metallization is possible. The text VOID could be replaced by the customers brand, emblem or a message, which would normally be invisible till the label is opened. Due to the versatility of things that can be done with the product, these label substrates have found widespread usage worldwide. However in India the volumes still need to pick up. This perhaps can be attributed to the cost cutting measures always haunting the marketing managers. These substrates can even be designed to work as tapes for the final outer corrugated cartons to prevent pilferage.

Pic:13.Void Label leves mark when tampered/removed

d) **Self destructing paper label:** These labels are very similar to destructible labels mentioned earlier. Only in this case the substrate used is a very weak strength paper of low grammage. This paper is also heavily loaded with fillers creating a weak and brittle paper. Labels made from such papers fragment into pieces when attempted to be removed. However converting is a very tricky issue when using these substrates due to the lack of strength. These papers are very difficult to source as most of the paper mills are trying to develop papers that are very high in strength. This goes against their target specifications.

e) **Holographic labels:** These labels form a very large and important part of the security label market and are an ideal choice for product authentication. The holographic foil that is an optically variable device is largely made using a polyester film base. The optical interaction of the holographic image and the human eye makes it ideal for brand promotion and security. These products reveal the holographic image when tilted in light. The image so revealed can be customized to the need of the brand owners to make the maximum impact. The hologram production involves development of complex origination process and a

lot of innovation to make it difficult for counterfeiters to duplicate. Many holograms are designed such that besides offering brand authentication they also have tamper evident properties. The top polyester layer has a special coating that if the hologram is attempted to be removed, the top layer peels off leaving the hologram behind on the product.

Pic:14. Holographic Labels -options

Clear to Cyan Technology | Angular Image Technology | Transparent Holography | Laser Visible Technology | OVD

f) **Multi layered labels:** The face stock of these labels is laminates of different substrates depending on the requirement of the security label. These can be film to film or film to paper or other coatings. Here the layers are designed such that on separation they either exhibit tamper evidence by way of a one layer getting fiber tear or by complete separation and exhibiting a design or message. The various layers are bonded together by adhesive or heat seal coatings depending on the requirement of the design of the label. This segment of substrates can be vast and can be designed to the requirements of the user and can go on offering variants as per the imagination of the designer or producer.

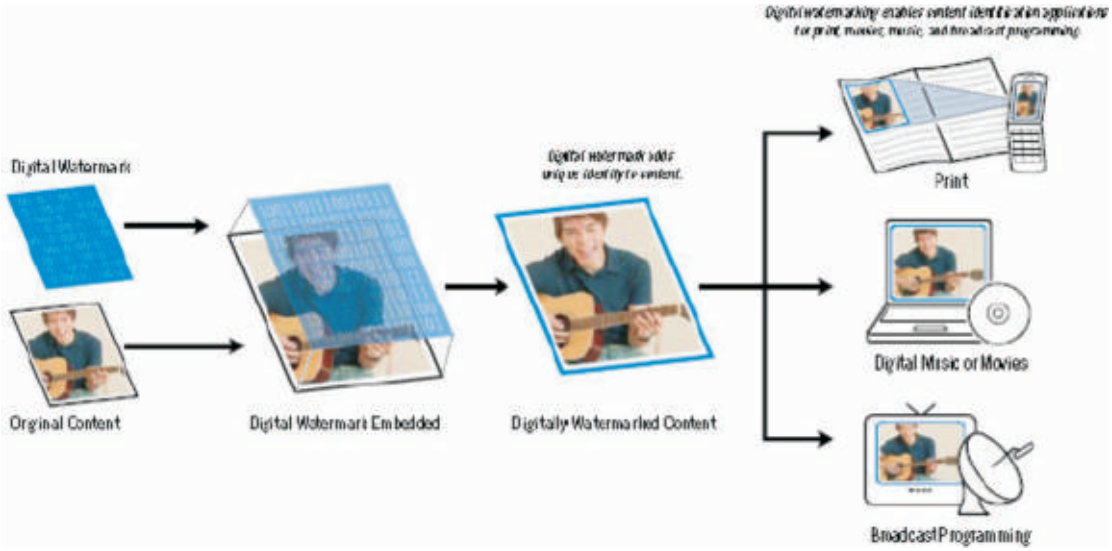
g) **Transfer labels:** The substrate in this case consists of either BOPP or Polyester. The film has a release coat over which the matter is printed and then adhesive coated. Such labels when applied and peeled off, the clear top layer comes off leaving the printed matter behind. This can also be designed such that some printing is subsurface and remains behind and some printed matter is on the top and comes off with the top layer.

h) **UV fibers in paper:** Here the substrate is paper and the security is built in at the paper mill during the paper making process. UV light sensitive fibers are incorporated into the pulp and evenly distributed in the paper. When Labels made from such paper are exposed to UV light, the fibers glow indicating the genuineness of the labels. The volumes required for these substrates have to be large enough to allow the paper mill to produce a batch full of pulp that would eventually be converted into paper for security labels. The color of the fibers can be selected as per the wish or need.

i) **Security threads:** Thin micronic threads are introduced in the substrates either at the label stock making stage or they are separately built into two layers of paper laminated together. These threads can also be sensitive to UV light. These will glow under UV light. Most people are aware of this security as it is a part of our currency notes.

j) **Water Mark:** These are marks that you can see as an image in the paper when you hold it against light. These are also built into the paper at the paper making stage in a paper mill. Again here the volume has to be large enough to justify incorporating the markings in the paper making process. However some converters do print these with inks where security requirements are not of a very strict nature.

Pic:15. Digital Water Mark -options



k) **RFID:** Radio frequency identification remains the most interesting development in security labels in recent times. Basically the micro chip has to be placed under the label and programmed. The uses of such labels are diverse. As for security, unbilled items attempted to be taken out of the exit gates would trigger off security alarms. The technology to implant the RFID chip into the self adhesive laminate is quite diverse and fast changing. A multilayer laminate where the top layer is paper and the chip is sandwiched between the top layer and foam is adhesive coated and laminated to a release liner. The foam in the laminate provides a flat surface for printing on top as otherwise the printing would not be possible on the uneven surface formed as a result of insertion of the chip. There are others who delaminate the label stock and place the RFID chip and relaminate, this is done in line as part of the label printing and converting process. It is a matter of time when substrates with chips in-built into them will be commercially available for label stock producers to use just as they use ordinary paper or film. As of now the cost at the entry level into this field is prohibitive for smaller players as the technology and equipment are too expensive and changing very fast.

l) **Barcodes, Consecutive and sequential numbering, Labels with DNA inks, Labels with Micro Taggants, Security Inks:** These are processes that are not a part of the basic construction of the substrate of security labels but they are put on the label during the label printing and converting process. Barcodes for instance, most of us recognize as a band of black vertical lines of varying thickness. These barcodes have a whole lot of information built into them. It is a regular accepted fact now that most of the retail stores use these for billing, accounting, inventory control, logistics, etc. For barcodes to be effectively printed, substrates need to be given primer or basecoats that will facilitate proper printing of the barcodes and their sensing by the sensors reading and transmitting information to the computers. It is unfortunate that the rhetoric created for the RFID coming in, has left the trusted workhorse barcodes in neglect. The bar code failure rate is almost zero compared to the 5-12% of RFID.

Consecutive and sequential numbering is again done as a part of the label printing or finishing process. This does not provide a very high level of security. In fact it is generally used as a security enhancing process. A label that has other security features is given this numbering to further enhance the level of security. One of the biggest users of this process is the state excise departments who apart from having various security features in their seals also number them in an evident effort to keep a track on the labels in the supply chain.

When we talk of labels with DNA features, these are DNA-embedded biotechnology security applications using plant DNA. These are proprietary formulations and processes and can be verified by laboratory DNA analysis. This is used for very high level of security and anti counterfeiting measures. Micro-taggants are microscopic Identification Particles that are traceable and play an important part in anti-counterfeit technology. Micro-taggants are highly versatile in their use and application. In basic form, Micro-taggants are a unique numeric code sequence in a multiple colored layer format. In more complex forms, Micro-taggants deliver multiple layers of security through the incorporation of several taggant technologies. These can be used in inks coatings, adhesives and paper making. The simplest form of taggants can be identified from their different colors. Other taggants can be energy sensitive, fluorescent, magnetic, etc.

Many printers also prefer to rely upon the security inks. These vary from the normal UV sensitive inks, thermochromic inks, luminescent, fluorescent inks, etc. The UV sensitive fibers are available in various colors and they glow under UV light even though they are invisible to naked eye. The thermochromic inks change color with change of temperature. You could have a bottle of soft drink with a label that would read," Chilled!" when it is say less then 10 degrees and the words disappear when the temperature rises. Alternatively a hot cup of coffee would provide a safety feature if the label showed, "HOT" when the temperature rose.

The scope of security labels and brand protection solutions are wide and no, one solution can be a permanent solution, and however the development and innovation does not come about due to hesitation on the part of the users in avoiding to spend more. Sometime back Jet airways in Mumbai undertook an exercise to upgrade their security labels that they use during baggage scanning. Though many innovations were suggested but the airlines decided to stay with the simplest paper stickers with security cuts as they did not want to pay more then what they were already paying. I was recently visiting a large automotive spare parts manufacturer. I was surprised to note that one of the marketing people actually expressed that I should suggest one security solution that would last them for a long long time say five years. This is not possible as the counterfeiter works overtime to make duplicates and fakes and continuous innovations are required to produce security solutions that become a deterrent for the counterfeiters. Giving them so much time would make us fall into a trap facilitated by time we ourselves give to the counterfeiters. Designing a security label needs application of mind, time and money. We have to reconcile to the fact that providing security solutions is an ongoing process because looking at the security label we can say that if someone can make it then someone can also fake it.

D. Coding, Printing and Graphics:

a) **Coding and marking.** For a long time regulatory compliance drove the need for coding and marking on the packaged products starting with best before date. However, with increasing awareness and greater printing and marking options like ink jet coding, laser coding and electrolytic etching for metal marking on can decide their use to evolve an overall anti-counterfeit feature. These provide the opportunities for online coding with flexibility, programmable options, time saving and low running costs. Depending on the exact requirements one can go for the Touch dry contact coding, non contact coding or the permanent laser coding etc.

Traceability and counterfeiting measures can be improved by using a variable data on the labels i.e. to create unique marking of the packages, which can be made cost effective by using digital printing technology for producing on demand short run packed products.

Pic: 16. Ink jet coded bottle

b) **Security graphics.** Fine line color printing, similar to banknote printing, incorporating a range of overt and covert design elements such as guilloches, line modulation and line emboss. They may be used as background in a discrete zone such as an overprint area, or as complete pack graphics, and can be printed by normal offset lithography or for increased security by intaglio printing. Subtle use of pastel "spot" colors makes the design more difficult to scan and reproduce, and security is further enhanced by the incorporation of a range of covert design elements, such as micro-text and latent images.

E. Holograms

Were used first for promotional purposes during 80's and saw a phenomenal growth by 1996.Probably the most familiar overt feature is the "dove" hologram which has been used to protect credit cards for many years. A hologram normally incorporates an image with some illusion of 3-dimensional construction, or of apparent depth and special separation. Holograms and similar optically variable devices (OVD) can be made more effective when incorporated in a tamper evident feature, or as an integral part of the primary pack (e.g. blister foil). They can be incorporated into tear bands in over wrap films, or as threads embedded into paper substrates and hence may be usefully employed on secondary/ transport packs. Several processes can be used to incorporate holograms into packaging; flexible, folding cartons or bottles. Methods include pressure sensitive, shrink, or glue applied labels; hot stamping; web transfer and lamination. Essentially selection options for the hologram are the Image and Media. The right combination of the two components produces a successful anti-counterfeiting marking that meets the desired objective.

a) **Image choices** are in the form of Parallex, 3-D perception, switching images, animated images, dynamic color effects, micro text, fine line patterns, machine readable image, Hidden image readable through special reader.

b) **Media or the form of delivery** has the choices: tamper evident, frangible, paper labels, induction wads, shrink sleeves, hot stamping foils, aluminum foils, PVC films, Hologram tape/thread.

c) **Optically Variable Devices (OVD):** OVDs also include a wide range of alternative devices, similar to holograms, but often without any 3D component. Generally they involve image flips or transitions, often including color transformations or monochromatic contrasts. Like holograms, they are generally made up of a transparent film which serves as the image carrier, plus a reflective backing layer which is normally a

very thin layer of aluminum. Other metals such as copper may be used to give a characteristic hue for specialist security applications. Extra security may be added by the process of partial de-metallization, whereby some of the reflective layer is chemically removed to give an intricate outline to the image, as can be seen on many banknotes. Alternatively the reflective layer can be so thin as to be transparent, resulting in a clear film with more of a ghost reflective image visible under certain angles of viewing and illumination. DOVID's (differentially optically variable image devices that can not be copied by electronic means are being used in decorative packaging and brand enhancement with security. DOVID's are generated through micro embossing, dot matrix mastering, photo resist interference, lithography, electron beam lithography and classical holography.

d. **Color shifting security inks and films:** These can show positive changes in color according to the angle viewing angle, and can be effective either as an overt graphic element or by incorporation in a security seal. Color shifting pigments are finely ground metallic laminates which need to be laid down in a thick opaque film to achieve the optical effect, and are therefore better suited to printing techniques such as gravure and screen printing rather than lithographic printing. Their security value lies in the specificity and dynamics of the color change (e.g. from blue to gold), combined with the difficulty and expense involved in manufacture. They are only available from a limited number of pigment suppliers, via a few specialist ink manufacturers. Positive authentication may involve forensic (microscopic) examination and embedded taggants. Color shifting films have been used for security applications, involving multi-layer deposition of thin films to build up a structure with unique diffractive properties, and vibrant color transitions. They can be applied as security seals or tamper evident labels.

e) **Sequential product numbering:** Unique sequential numbering of each pack or label in a batch can make counterfeits easier to detect in the supply chain. If printed visibly, it provides a semi-overt means of authentication by reference to a secure database, because duplicates or invalid numbers will be rejected. The main disadvantages of sequential numbering are that the sequence is predictable and easily replicated, and end users require some means of access to the database. The more secure option is serialization by means of a pseudo-random non-repeating sequence, and this is discussed in the Track and Trace section.

f) **On-product marking:** On-product marking technologies allow for special images or codes to be placed on conventional oral dosage forms. These overt technologies can be difficult to replicate and offer a security technology at the pill level. This added layer of security is effective even when products are separated from the original package.

g) **Invisible Printing:** Using special inks, invisible markings can be printed on almost any substrate, and which only appear under certain conditions, such as via UV or IR illumination. They can be formulated to show different colors with illumination at different wavelengths.

h) **Embedded Image:** An invisible image can be embedded within the pack graphics which can only be viewed using a special filter, and cannot be reproduced by normal scanning means. The effects can be quite dramatic, and yet well hidden.

i) **Digital Watermarks:** Invisible data can be digitally encoded within graphics elements and verified by means of a reader and special software. The data can be captured using webcam, mobile phone or other scanning equipment, but the digital information is not visible to the human eye, and attempts to replicate it will be detected by virtue of the degradation of the embedded data.

j) **Hidden Marks and Printing:** Special marks and print may be applied in such a way that escapes attention

and is not easy to copy. Their effectiveness relies on a combination of secrecy and subtlety.

k) **Anti-copy or Anti-scan design:** Fine line background patterns appear as uniform tones, but when scanned or copied reveal a latent image which was not previously visible. Commonly used on secure documents to prevent photocopying, they may be applied to product packaging as a background tint.

l) **Laser Coding** The application of batch variable details by lasers coding requires special and expensive equipment, and results in recognizable artifacts which may be difficult to simulate. Laser codes can be applied to cartons and labels, and plastic and metal components.

F. FORENSIC Markers

a) **Chemical taggants.** Trace chemicals which can only be detected by highly specific reagent systems, but not normally detectable by conventional analysis.

b) **Biological taggants.** A biological marker can be incorporated at extremely low levels (parts per million or lower) in product formulations or coatings, or invisibly applied to packaging components. At such low levels they are undetectable by normal analytical methods, and require highly specific "lock and key" reagent kits to authenticate.

c) **DNA taggants.** Highly specific DNA "lock and key" reagent systems can be applied to packaging by a variety of printing methods. They require a "mirror image" recombinant strand to effect the pairing, and this reaction is detectable by a dedicated device. Security is further assured by hiding the marker and reagent pair in a matrix of random DNA strands, but the test is tuned to work only with one recombinant pair.

d) **Isotope ratios.** Naturally occurring isotopes can be highly characteristic of the source of a compound, and accurately determined by laser fluorescence or magnetic resonance techniques. These can provide a "fingerprint" of one or more of the product constituents, or alternatively a specific marker can be added with its own unique signature. Detection requires highly specialist laboratory equipment.

e) **Micro-taggants.** Micro-taggants are microscopic particles containing coded information to uniquely identify each variant by examination under a microscope. This may take the form of alphanumeric data depicted on small flakes or threads, or of fragments of multicolored multilayered laminates with a signature color combination. These can be embedded into adhesives, or directly applied to packaging components as spots or threads.

f) **"Nano-Printing"** technologies allow microscopic application onto individual tablets. UV inks allow invisible printing onto any substrate including glass vials and ampoules and provide an excellent security.

G. Mass Encoding

Individual products are encoded in an overt manner either through a barcode or a human readable form. Coding therefore becomes the essence in design process. Encoded products need the support of software solutions that permit product tracking through the various nodes in the LSCM operations. Options adopted for encoding are:

a) **Barcodes:** Barcode is a series of parallel, adjacent bars and spaces used to encode the small string of data. 2-D codes are also available now with possibility to encode large amount of information that makes it an option for anti-counterfeiting. Bar-coding when used with GS-1 standards, permit universal and unique identification of goods, services, assets etc. A bar code reader (scanner) decodes the bar code using intensity of the light reflected. While Package printing gives emphasis to product appeal and acceptance

by the consumer, barcodes captures the specific information that may contain information related to track and trace traceability, inventory management, security, identification etc. Bar-coding provides the means for automatic data capture of information. When used with international numbering standards, it permits universal and unique identification and security of packaged products. Barcoding works essentially with the optically scanning devices e.g. for the UPC bar code scanners use a helium neon (red) laser emitting at 660 nanometers to determine the contrast between the reflected light from the dark bars and light spaces. For their use as a system they also need the decoders, software's for coding. Universally GS-1 barcodes provide an access that could operate with countries/users who are the members of GS-1. However, due to some specific reason many retail chains use their proprietary codes. Use of barcodes as anti counterfeit option is attempted especially with the possibilities to go for 2-D codes.

Pic:17. 2-D barcode

Pic:18. A barcode

b) **Digital mass serialization (DMS).** The technology includes the generation of a random, pseudo random code in a sequential manner by the technology provider entered into their or the customers data base for later verification. These codes are provided to customers who in turn can apply them in different ways. These codes can be printed on the labels and then affixed on the product or can be used in a covert way on a pack. The authentication process involves matching the unique code on a product to those stored in the data base. If the code is present in the data base, then the then the product is authentic. This technology needs to be integrated with proper protocols and SOP's for its success with security features to its data base since it could be the weakest link in the technology[20].

c) **Digital Mass encryption (DME).** In all respects it is similar to the DMS except for the way code is generated. In this process encrypted codes (defined)[21] are produced by a cryptographic algorithm. These codes themselves do not carry or contain any product or logistical information. No need for maintaining a data base is also envisaged in this system.

H. Surveillance Technologies. Systems which can give signals when products are being stolen form part of this technology. Three main technologies used for electronic surveillance are;

a) Radio frequency

b) Acoustic-Magnetic

c) Electro-magnetic

[20] Generic drug industry in India; the counterfeit spin.Nitin Shukla and Tanushree Sangal Journal of IPR Vol 14,May 2009,pp 136-240

[21] Wikipedia

World Forecast for brand protection by healthcare industry

Packaging is a major aspect of differentiation in most consumable goods; where differentiation competition is intense then prices are low, and packaging provides a marketing advantage at the point of sale. Packaging is also a major cost component in the majority of consumable products. For example, 48 cents out of every dollar (48%) of coke's product cost is from packaging[22] of the total market, 60% lies in the areas of primary containers and flexible packaging-the containers and wrappers that give immediate protection to the packaged product. Along with the key trends for the brand enhancements that includes printing, high quality graphics and the design features; demand for security features including anti-counterfeit and tamper evident design is gaining a huge interest of brand Managers. Data presented at Table 3 indicates the importance of each technology in value terms as well as the CAGR indicates the interest that is shown in the development and use of RFID technology.

Table: 3. World Forecast market for Brand security by technologies 2005-12 ($ million)

Security features	2005	2006	2007	2012	CAGR % 2007-12
DOVID's	1018.9	1128.3	1263.5	2041.8	10.1
RFID	82.2	95.1	109.9	415.1	30.2
Taggants	396.7	453.7	526.2	963.4	12.9
Security inks & coatings	930.0	1038.6	1176.9	2235.0	13.7
Security substrates	800.0	868.9	955.8	1419.6	8.2
Security printing	1066.7	1145.4	1240.0	2328.3	13.4
Total	4530.0	5005.6	5597.3	10086.6	12.5

Note: includes Data-matrix & 2-D barcodes, track and trace protection, watermarks etc.
Source: Pira International Ltd.

[22] The future of Global Packaging. Pira international ltd./WPO 2005

5.3 NEW PACKAGING TECHNOLOGIES: OPTIONS

One of the key analyses of the package system on a pharmaceutical product is the simplicity of printed matter particularly on the lidding foils used in a unit dose blister pack. The printing technologies employed are conventional and hence it is very easy for an imitator to get a similar printed lidding material without much effort. Secondly, the print inputs do not encompass a blend of technologies which can enable a considerable level of deterrence for an imitator to wrongfully duplicate an original product. The new packaging technologies are targeted to challenge the counterfeiter's convenience and create a capability of print matter which can provide overt, covert and ultra-covert security features more specifically detailed as below:

a) Complex graphic image printing on aluminum (lidding foils, cold-formable foils), paper and other substrates used for unit dose packaging of Medical Products

Pic:19. Complex graphic image printing

b) Metallized substrates with unique color options – capability for secure and distinctive overt brand security

PVC based blister forming film having a precise amount of metal deposition providing a classic metallic appearance. The metal layer on the PVC film and / or the second surface of the PVC substrate is further coated / laminated with specialty color lacquers, barrier polymer coatings and /or additional polymer films to create a unique and distinct multi layered metalized film.

Pic:20. Metallized substrate with unique color options

c) Image embedded on transparent or metallized substrate – capability for secure and distinctive Overt brand security

The metallized substrate is subjected to a unique process which includes employing a unique differential grating methodology resulting in creation of unique, non replicable visual effect in the from of image / pattern over the metallized surface.

Pic:21. Image embedded on transparent or metallized substrate

d) Color shifting graphic printing – capability for distinctive overt brand security

The viewing angle-dependent color shifts by changing the viewing angle of the 'security spot'.

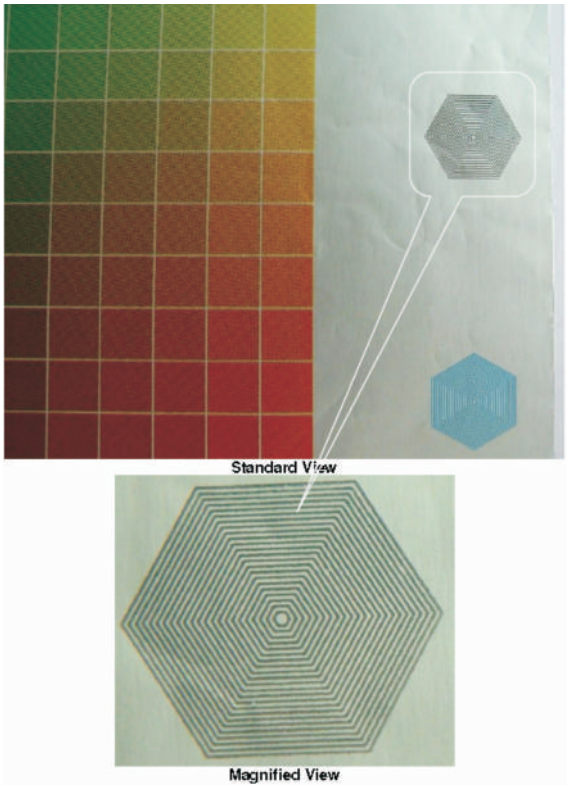
e) Micro-text printing – An Overt-Covert security feature for brand security

High clarity micro-print text on various substrates like lidding foils, paper and cold formable foils, which is legible under naked eye and on magnification.

Pic:22. Microtext print

f) Interference graphic print – with complex print details visible on magnification – An Overt-Covert security feature for brand security

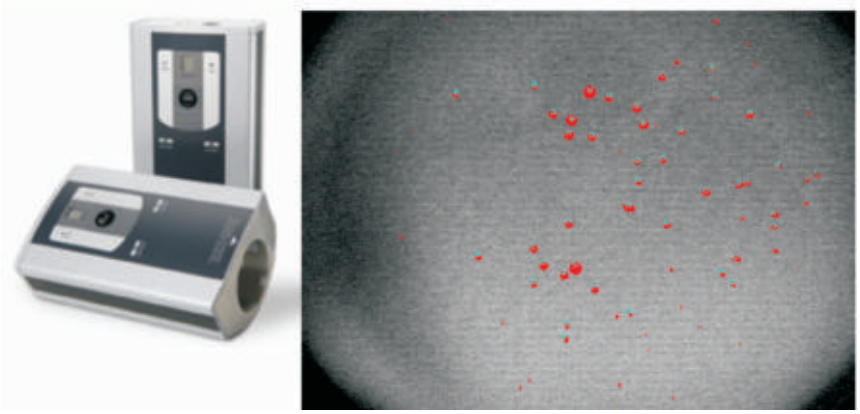
Pic:23. Interference graphic print



g) Forensic print through specific secure traceless markers read by specialized devices - An Ultra-Covert security feature for brand security

A printed Aluminum lidding foil embedded with invisible markers that are visible only under highly specialized proprietary devices and capable of highly secure forensic ultra-covert measures against counterfeiting.

Pic:24. Forensic print



h) Product Authentication cum Track-n-Trace

A tamper evident nanotag label comprising a unique fingerprint integrated with any universally used overt systems like barcodes/ RFID tags etc. that can be authenticated with the help of a secure reader which can scan the encrypted image through any universal mobility platform like GPRS / 3G / Broadband to a secure fingerprint server and authenticate as well as track-n-trace any product. This technology is capable of being integrated with any existing identity and supply chain management system such as Barcodes, RFID and their likes to achieve tailored graded levels of security.

Pic:25. Product Authentication cum Track-n-Trace

6. COMPARISON OF CURRENT ANTI-COUNTERFEITING TECHNOLOGIES

Most companies with no ability to look at their continual sales adopt anti-counterfeiting strategies to meet their sporadic sales and in no time realize that the adopted technology has failed. Possibly the failure was due to the fact that they never worked with strategies. They took the tactical solutions which were short lived. First and foremost requirement of any company with serious intentions of going for anti-counterfeit solutions for their products is the need for strategic marketing orientation. The orientation that will make the company look at their brands and the anti-counterfeit choices within the LSCM as already discussed at Section 2. In addition with the packaging paradigm already discussed earlier it must be kept in mind that any technology adopted will have a strong influence of factors related to market geographical locations, regional social dimensions, customers profile/habits and finally the security of the LSCM operating for the product. It must be understood that choosing a technology is a complex process. While not making any specific choices for the industry, general comparison of technologies with known features is attempted as given below and should be considered only for the guidance.

6.1 COMPARISON: PRODUCTS BASED ON END MARKETS

It is well known that the creation of pharmaceutical brands is a very expensive business as such there is a wider choice of technology options. On the other hand a branded product like packaged drinking water with mass consumption and huge volumes viable options could be simple.

Table: 4. Choice of anti-counterfeit technologies based on end markets needs.

RFID in Packaging: Applications with system range

End Market	Trend	Implications	Potential Solutions
Pharma	High priced prescription drugs forcing consumers to seek lower priced options via internet	Increased risk of counterfeit. ~45% of drugs bought outside US are counterfeit.	Secure Supply Chain Anti-counterfeit, tamper evidence and/or RFID traceability @ minimum cost.
Food	Increasing concern with keeping food unspoiled and safe to eat.	Prevent: Package failures. Product tampering. Bioterrorism.	Tamper band Seals Tamper Evident Closures Shrink Sleeves Product Coding RFID Case & Pallet Freshness Indicators
Beverage	Trade Diversion	Tamper Evidence and Product Authentication is increasing packaging features.	Over-the-cap closures. Shrink Sleeve. Track and trace SCM operations
Consumer Durables	Counterfeiting Theft	Brand Integrity Loss Revenue Loss	Ultra -destructible vinyls. Polyester VOID labels Holograms Security Printing Inks

At Section-5, table-3, a CAGR of 30% on RFID use is forecasted for the year 2005-2012.Clearly RFID is the technology of choice in the future to combat counterfeiting. A comparison as a function of range that indicates their use at the individual product level or during the SCM is made at Table.5.

Table: 5. Packaging applications as a function of typical RFID range employed[23].

Max range (meters)	Applications Example	Purpose	Mode
40 microns	Touch outside of paper packaging to sense tag inside(like a banknote stripe)	Anti-counterfeiting and tracking	Read or read/ write. Usually disposable tag or fitted for life. Passive
A few centimeters.	Retail products tag like a label	Track and trace, EAS, and anti counterfeit	—
1 meter	Automatic sorting of air freight and courier parcels, e.g. tag like a small label	Track and trace security status updates	—
Upto 100 meters	Location of large crates, etc (large heavy tags needed)	—	Read only. Reusable tag Active

6.2 TECHNOLOGY COMPARISON.

Authentication technologies. Authentication technologies include measures such as color shifting inks, holograms, fingerprints, taggants, or chemical markers embedded in a drug or its label. The use of one or more of these measures on drugs, starting with those considered most likely to be counterfeited, is an important part of an effective anti-counterfeiting strategy. Because counterfeiters will adapt rapidly to any particular measure and because the most effective measures differ by product, the most effective use of authentication technology will vary by drug product over time.

Certain general conclusions on various technologies and options discussed earlier are made in the tabular form below:

Table: 6. Advantages /disadvantages overt technologies.

Advantages	Disadvantages
User verifiable	Require user education — not always widely understood
Newer technologies more secure	May be easily mimicked
Can add decorative appeal	May add to cost
Can be a deterrent to counterfeiters	May rely on covert features for authentication
—	May be re-used or refilled
—	May give false assurance

[23] RFID in Packaging, Dr Peter J Harrop.p-23

Overt features represent an attempt to put authentication into the hands of the general public. However, to be effective they demand public education and awareness, which is especially difficult in the most challenged developing markets. It should also be noted that the more widely used one overt security technology becomes, the more attractive it is for counterfeiters to defeat it.

Where overt features are used, experience is often that counterfeiters will apply a simple copy which mimics the genuine device, sufficiently well to confuse the average user. They also require utmost security in supply, handling and disposal procedures to avoid unauthorized diversion. They should be applied in such a way that they cannot be reused or removed without being defaced or causing damage to the pack — otherwise genuine used components may be recycled with fake contents, giving a false impression of authenticity. For this reason an overt device might be incorporated within a Tamper Evident feature for added security.

Table: 7. Advantages /disadvantages Covert technologies.

Advantages	**Disadvantages**
Can be simple and low cost to implement	Need strict secrecy — "need to know"
Needs no regulatory approval	If widely known or used, may be easy to copy
Can be easily added to or modified	More secure options add supply complexity and cost
Can be applied in-house or via component suppliers	If applied at component suppliers, greater risk of compromise

Covert features are most effective in the hands of industry specialists. They are a very valuable investigative tool, but a counterfeiter will be able to copy many of the simpler features unless they are skillfully applied and their details are kept secret. However, there is almost unlimited scope to the possibilities, given imagination and ingenuity on the part of the technologist and designer, and the costs can be minimized or even eliminated when applied in-house. In-house application also has advantages of limiting involvement of third party suppliers, who may not be trustworthy in some environments. Only the most secure covert features can be safely used in an overt context, and these generally come under the next heading of forensic markers.

Table: 8. Advantages /disadvantages Forensic technologies.

Advantages	**Disadvantages**
High tech and secure against copying	Licensed technologies usually limited to one source
Provide positive authentication	Significant cost
May be disclosed for overt purposes	May be difficult to implement and control across many markets
	Wider use increases risk of compromise
	Unlikely to be available to authorities or public

There are some very robust and secure options available, which may enable their use to be more widely known and therefore accessible to trusted authorities and investigators. However, these tend to be subject to patent protection and therefore restricted in availability and pricing.

Table: 9. Advantages /disadvantages Serialization and Track and Trace technologies.

Advantages	**Disadvantages**
High tech and secure against copying	Significant cost to implement and monitor
May be capable of remote authentication, via phone or internet	Difficult to implement across multiple markets
May be accessible to authorities and investigators without compromise	May be vulnerable to hackers
May eliminate dispensing errors	Damaged labels may not read
Facilitates recall of defective product	Robustness of RFID tags not proven
May combat theft and fraud	Needs harmonization of standards
Benefits in supply efficiencies	Not accessible to the public
	Remote reading causes privacy issue

A number of Track and Trace applications are under development which are sector specific. The most obvious benefits are in the supply logistics, where greater transparency of inventories and demand patterns can lead to efficiency improvements and cost reductions. Another benefit is the ability to identify a product through to dispensing to the patient, enabling the elimination of medication errors and the ability to speedily recall defective product batches. But the ability to tightly control and authenticate all products through the supply chain greatly reduces the possibilities for counterfeit, stolen or diverted product entering the distribution system without being detected. It should also be noted that Track and Trace tags or labels may not necessarily be applied at the unit pack level, but may be restricted to whole cases or even pallets — thereby affording the logistics benefits but not all the safety and security gains. As has been mentioned before, a key security element lies in pack serialization.

6.3 CHOICE OF ANTI-COUNTERFEIT SOLUTIONS WITH DIFFERENT LEVELS OF PACKAGING

Table: 10. Anti-counterfeiting technologies favorable at different packaging levels.

Anti-counterfeit technologies	**Levels of Packaging**				
	Primary Sales pack	**Secondary Group pack**	**Transport pack**	**Unit load**	**Parts of pack**
Packaging design	Yes	No	No	No	No
Printing & graphics	Yes	Yes	No	No	No
Labels	Yes	No	Yes	No	No
Tamper evidence	Yes	Yes	Yes	No	No
Forensic markers	Yes	No	No	No	Yes
RFID	Yes	Yes	Yes	Yes	No
Track & trace	Yes	Yes	Yes	Yes	Yes

7. ANTI-COUNTERFEITING STRATEGIES

7.1 ANTI-COUNTERFEITING BUSINESS STRATEGY - A MUST

As already discussed in Section-2, strategy needs to be for long term benefits, should have a broad scope and operate at a higher level in the corporate hierarchy with an ultimate aim to maintain a competitive advantage. For example, seizing 2 million counterfeit parts keeps that product out of the marketplace, but did it do more than just temporarily disrupt the counterfeiters' cash flow? It is opined that a company can identify its ability to compete and accordingly should look at creating anti-counterfeit protections at each of the five primary links (inbound logistics, operations, outbound logistics, marketing and sales, services) and four supporting structures (infrastructure, human resource management, technology development and procurement). All this with considerations from social set up and consumer habits, infrastructure available and the overall environment for conducting their business.

With the three identified components i.e. the criminal, the victim and the opportunity a **"crime triangle"** possibly offers a best frame work to formulate the company's strategies developed within a framework of a detailed, integrated process consisting of several equally important steps. These include:

a) Analysis of company's counterfeit and diversion problems and prioritize to uncover the weakest link in the supply chain, complemented by identification of both internal and external problem areas like products, regions and channels etc.

b) Development of technologies and various control mechanisms best suited for the theft problems in question, including development of specialized programmes for contract manufacturers and franchise brands.

c) Deployment of a plan, designed by company's supply chain management team, to ensure that every aspect of the customers programme is implemented smoothly to effect the desired changes. An important component of this step is development and implementation of established metrics/standards by which to measure programme effectiveness. This can be done through field surveillance, data collection and feedbacks.

7.2 UNDERSTANDING OF LEVELS OF PACKAGING FOR THE PRODUCT

Each product depending on its characteristics has a specific design need for its market success. Anti-counterfeit options accordingly needs to be explored for the different levels of packaging as explained below:

a) Primary package is the first wrap or containment of the product that directly holds the product for sales. Identified as Sales Packaging[24]

b) Secondary package is a wrap or containment of the primary package. Identified as Group packaging[24]

c) Distribution package (shippers) A wrap or containment whose prime purpose is to protect the product during distribution and to provide for efficient handling. Identified as Transport packaging[24].

d) Unit load. A group of distribution packages assembled into a single unit for the purpose of mechanical handling, storage and shipping.

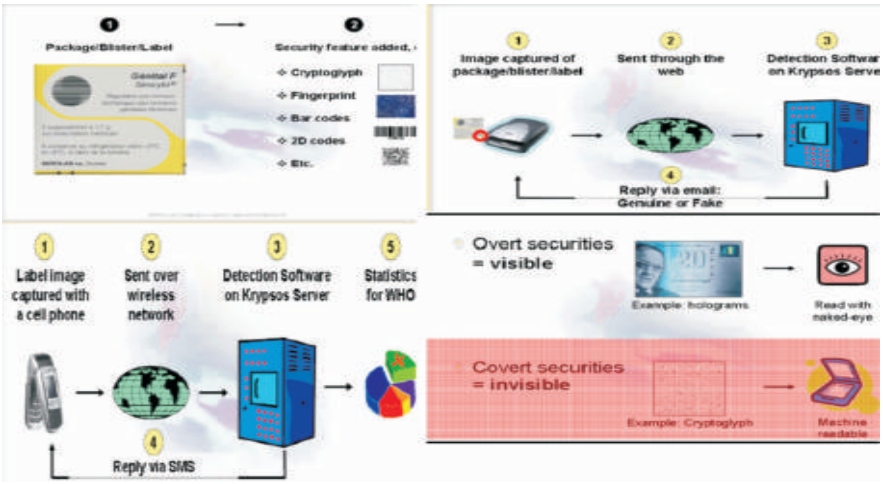
e) Staples, sleeves, closures, labels are also identified as the part of packaging[24]

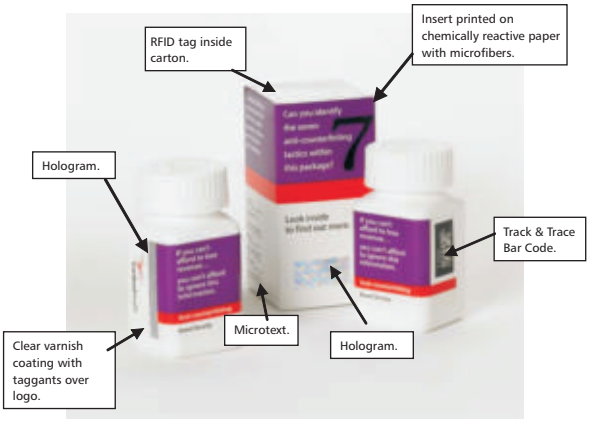
[24] As defined in European directive 2004/12/EC

7.3 "BUILDING BLOCK" SYSTEM FOR ANTI-COUNTERFEITING

Such a system uses a single security precaution but a combination of security measures. The more the components of use the harder it becomes for the counterfeiters. An anti-counterfeiting system that is designed for the primary and secondary packaging of a product is shown at Pic uses the covert, overt and track and trace features.

Pic: 26.Combination of anti-counterfeit solutions





A heat sealed foil closure on a glass rim container plus a thermoformed or injection molded plastic overcap can show a considerable cost saving over metal twist off or prize off lids. This is in itself an attractive consideration, especially in the economic climate where margins are being squeezed, but the aspect of pilfer resistance and tamper evidence is becoming increasingly important. Another example which is a combination of covert feature with Digital mass serialization adequately supported by the communication network is the Mobile Product authentication technology where Consumer has to simply scratch-off a code on the pack, send a text message through his/her mobile and obtain an instant response through a numeric code number with an alert in case the code is fake.

Public education

Products packed in their primary or the secondary packaging comes in direct contact with the consumer at the point of sales. Generally graphics and design govern the choice of purchase. Since today consumer is also health conscious, if educated could become the most important link in the product authentication. Naturally it will demand his education to compare a fake from the original. Some options are the Public service announcements and new educational partnerships with consumer and health professional organizations, to help consumers avoid buying counterfeits. Much greater efforts in enhancing the educational programs for pharmacists and other health professionals about their role in minimizing exposure to, identifying, and reporting counterfeits in case of drugs.

8. CONCLUSION AND RECOMMENDATIONS

Compliance and security features are not a cost burden? Many, particularly in SME sector believe that anti counterfeiting measures are tough and costly .However, a research undertaken[25] to see the value realization of Indian grape exports since the time EU compliance on traceability is followed by the exporters indicate much better value realization with respect to Indian Grapes in the last few years in particular. Thus by assuring safety and quality through incorporation of anti counterfeiting operations to gain consumer confidence, manufacturers can gain the competitive advantage in local and export business if actions are planned strategically.

Successful companies world over spend time and money in protecting their brands. The best defensive strategy is to integrate very technique into distribution, record keeping system and also thinking strategically.

Some proactive government departments in India have also started mandatory use of GS-1 barcodes. Delhi state excise department has mandated bar-coding for all IMFL sold in Delhi. The department needs to track and trace the movements of stocks and sales of alcoholic beverages as they move through the supply chain from the manufacturers down to the retail vendors to prevent theft and better tax collection.

As can be seen above, there is a huge range of possible solutions ranging from the very simple to the highly complex, from zero cost to highly expensive and from fragile to highly secure against counterfeiting. The wide range of options adds to the potential security by diluting the advantage gained by a counterfeiter in defeating any one system, and manufacturers should choose widely and wisely for optimum security gain.

It is unlikely that any one solution will be appropriate for all applications - the costs may not be affordable in developing markets, or for low margin products Effective protection against counterfeit products includes actions by producers, distributors, and dispensers to secure their business practices such as ensuring the legitimacy of business partners and refusing to do business with persons of unknown or dubious background, taking steps to ensure physical security, and identifying an individual or team in the organization with primary responsibility for ensuring that effective security practices are implemented. In US the wholesalers have already drafted a set of secure business practices and FDA will continue to work with other major participants of the drug supply chain to develop, implement, and disseminate such business practices, through such steps as issuing guidance and supporting the development of industry best practices. To help ensure secure business practices, FDA intends to increase its inspection efforts of re-packagers whose operating procedures place them at increased risk for the introduction of counterfeit drugs.

Development of a system that helps in ensuring that effective reporting of counterfeit products to the designated agency for rapid response to such reports is foolproof.

Counterfeit menace is a global challenge to all nations, and criminal counterfeiting operations are increasingly operating across national borders. There will be a need to work with the World Organization, Interpol, and other international public health and law enforcement organizations to develop and implement worldwide strategies to combat counterfeit drugs. Collaboration with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally is a good option.

Certain products like for drugs use is not restricted to highly developed and sophisticated societies, but is almost universal. Therefore, not all areas share the same accessibility to technological solutions, and their supply infrastructure. It is also noted that reliable and secure sources of supply may be wanting in some regions where there is a poor history of intellectual property protection. Manufacturers may be confined to using only in-house technologies in such territories.

[25] Research undertaken by the author. Extract attached as an annexure.

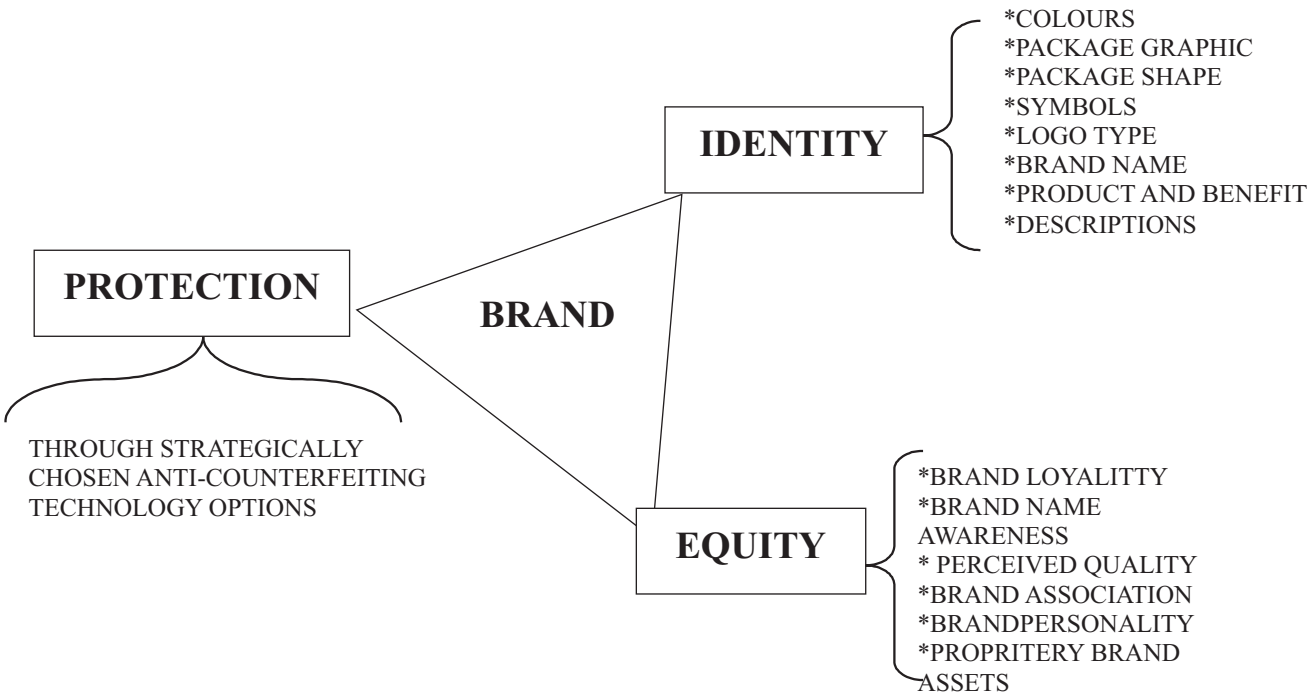
Because the capabilities of counterfeiters continue to evolve rapidly, there is no single "magic bullet" technology that provides any long-term assurance of drug security. However, a combination of rapidly improving "track and trace" technologies and product authentication technologies should provide a much greater level of security for drug products in the years ahead.

Virtually all of the available solutions carry some cost and administrative burden, whereas the manufacturers' business case for cost versus benefits is extremely difficult to quantify. This is not helped by many unsubstantiated claims for the level of counterfeits in the global medicines market. The true business case is more realistically based on risk management and corporate ethical responsibility for public health and safety, except in those few areas where the counterfeit level is measurable.

Finally, there is no single solution to every problem, and a secure strategy will almost certainly involve a mixture of technologies, often in combination. An overt feature will almost certainly include a secure covert element for added security, and any one product may carry several different features on various levels of the pack and components. But as long as counterfeiters target medicines for illegal profit, a product with no form of anti-counterfeit marker represents a significant potential risk to public health and safety

In essence any anti-counterfeit technology should support the Brand through its identity, equity and the protection as shown at Fig.8.

Fig 8 Brand triad.



The ideal characteristics of a technology for delivering a 'full-proof' solution to multiple challenges that a pharmaceutical product encounters, extend from identity to reliability of its origin. The salient features of the 'Technology-of-Choice' are:

- Should be NonClonableTM (Clone proof)
- Simple to use front end with high-tech back end.
- Consistency and accuracy
- Checks and verifications – at all points and at all times
- Empowering all stakeholders including the Enforcement Agencies to carry out real-time identity, authenticity and track-n-trace.
- Capability of integration to existing processes
- Discerning features
- Ease of deployment
- Commercial viability
- Protection of Privacy
- Capable for use / integration to meet imminent and implemented needs (Patient compliance etc.)

A comprehensive End-to-End solution encompassing a hybrid of all current Anti-Counterfeit Technologies which can help the pharmaceutical manufacturer in the following ways:

- ***Protect the brand*** and product from being miss-utilized by the counterfeiters. In turn help manufacturers to prevent revenue losses and loss in brand image.
- ***Simple to use*** at the front end, the solution facilitates instantaneous authentication of product at any point in the complete supply chain.
- The solution should empower the End-Consumer to check and identify the genuine product.
- The solution should enable the manufacturer to achieve comprehensive security blanket both at the product level as well at the supply chain level.
- The solution should facilitate the manufacture to create e-pedigree of the product and help in achieving compliance.

Recommendations

While all methods for anti-counterfeiting are known to have short lives and the solutions to defeat them, the menace still must be dealt with. What is needed is an overall strategy to manage the counterfeiter's criminal intent that reduces damage to brands and health of people, at an affordable cost. Clearly first objective is to prevent the counterfeit operations. However, even after this has been done, counterfeits will still, be produced. The second objective therefore is to make surveillance strong through public participation with adequately deterrent punishments so that counterfeiter thinks twice before getting into this illegal activity. Some of the immediate issues on the subject along with the proposed actions are placed at Table: 11.

Table: 11. Recommendations.

No.	Issues	Actions proposed	Remarks
1	Authenticated data base on anti-counterfeit market in various end user sectors in the country not available	Research study needs to be undertaken for getting the magnitude and characteristics of anti-counterfeiting menace, major areas of concern and the existing system to handle such a menace.	To validate menace within the country thereby providing a base for policy interventions.
2	National policy on Counterfeits and piracy management system across end user sectors is not in existence	A clear concise and consistent national policy that is dove tailed with international policies of interest with the participation of all stakeholders	This is a necessary requirement for industry and other associated players to establish counterfeit management system and make necessary long term investments.
3	Policy action aimed at radically strengthening anti-counterfeit measures are not available	Studies on a framework for promoting anti-counterfeit efforts and support for such programmes.	Necessary to ensure safe consumption in the interest of the consumer and society.
4	Support to industry in carrying out search operations with adequate support from DM's/DC's not available:	Form expert's panel at national /state levels to make periodic raids and report for legal/ administrative immediate actions	Any neutral body with no preference or bias with the involvement of prominent Industry association could be the best choice

All the actions must ultimately lead to an Integrated anti counterfeiting management system. To make the programme successful it is necessary that IACMS designed is:

a) **Market oriented.** Any state sponsored scheme that incorporates material recycling, biological, thermal treatment or any other technologies, must recognize that it is not enough that their outputs have a market but also they must ensure their products are safe for use.

b) **Flexible.** An effective system will need the flexibility to design, adapt and operate its systems in ways which best meet current social, economic and environmental conditions. In our country these are likely to change over time and from State to State.

c) **Suitably scaled.** The need for consistency in quality and quantity of technology options, the need to support a range of management options, and the benefits of economics of scale, all suggest that IACM should be organized on a large scale, regional basis and with centralized command and control.

Consumer Education. Counterfeit menace is an issue which can be handled by the collective responsibility of Consumers who use them, Business who create them and the Regulators who have the duty to prevent them. For the success of any Plans, education programmes designed must consider following:

a) **Role of Consumers.** Consumers have to assume the role of first inspector of checking the authenticity of the product he/she buys and pays. Through adequate awareness and training if required.

b) **Role of Business.** Businesses that manufacture and use the relevant packaging and have the interest to protect their valuable brands have to bear the obligation for making their consumers aware of the anti-counterfeit features adopted by them.

c) **Role of the Government.** Government and regulatory bodies must draw up selective checking plans and devise necessary measures for selective collection of packages in their local areas for authentication followed by suitable actions. Increased criminal penalties to deter counterfeiting and more adequately punish those convicted. Such provisions should provide an added deterrent to criminals who work to counterfeit our citizens' medications. Criminal penalties need to be increased substantially and could be based on the level of risk to the public health involved in the offense.

About us

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the growth of industry in India, partnering industry and government alike through advisory and consultative processes.

CII is a non-government, not-for-profit, industry led and industry managed organisation, playing a proactive role in India's development process. Founded over 114 years ago, it is India's premier business association, with a direct membership of over 7800 organisations from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 90,000 companies from around 385 national and regional sectoral associations.

CII catalyses change by working closely with government on policy issues, enhancing efficiency, competitiveness and expanding business opportunities for industry through a range of specialised services and global linkages. It also provides a platform for sectoral consensus building and networking. Major emphasis is laid on projecting a positive image of business, assisting industry to identify and execute corporate citizenship programmes. Partnerships with over 120 NGOs across the country carry forward our initiatives in integrated and inclusive development, which include health, education, livelihood, diversity management, skill development and water, to name a few.

Complementing this vision, CII's theme for 2009-10 is 'India@75: Economy, Infrastructure and Governance.' Within the overarching agenda to facilitate India's transformation into an economically vital, technologically innovative, socially and ethically vibrant global leader by year 2022, CII's focus this year is on revival of the Economy, fast tracking Infrastructure and improved Governance.

With 64 offices in India, 9 overseas in Australia, Austria, China, France, Germany, Japan, Singapore, UK, and USA, and institutional partnerships with 213 counterpart organisations in 88 countries, CII serves as a reference point for Indian industry and the international business community.

Confederation of Indian Industry

Plot No. 249-F, Sector 18, Udyog Vihar, Phase IV, Gurgaon - 122015 (INDIA)
Phone : +91-124-4101044 / 4014060-67 • Fax : +91-124-4014057
Email : ciico@cii.in • Web : http://www.cii.in

Reach us via our Membership Helpline: 00-91-11-435 46244 / 00-91-99104 46244
CII Helpline Toll Free No.: 1800-103-1244