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Research Article

MULTIPLE ANTICOUNTERFEIT TECHNOLOGIES TO COMBAT COUNTERFEITING IN PHARMA INDUSTRY: AN OVERVIEW

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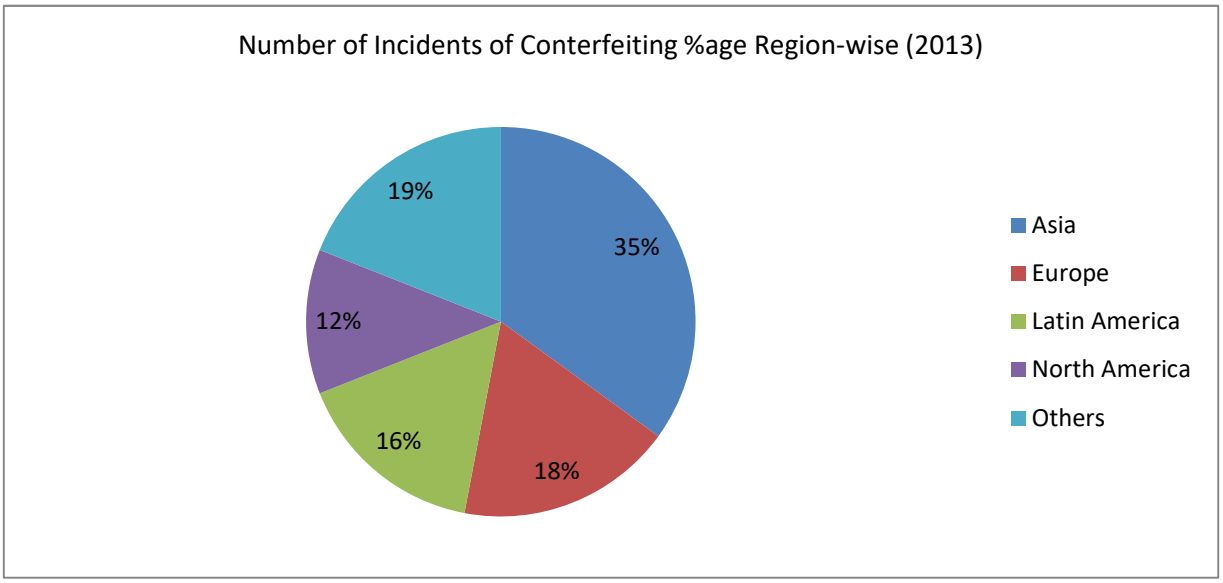
ABSTRACT
Growths of international free trade and inadequate drug regulation have led to the expansion of trade in counterfeit drugs worldwide. The problems related to safety, quality of medicine and efficacy is to measure concern in today developing scenario in develop and developing countries. This counterfeiting is overcome by technological protection. A variety of technologies came into existence like covert, overt, and track and trace technologies. This review is mainly focus on the ideal technological characteristics, existing anti-counterfeit technologies, and their adoption in different countries. The Indian government is getting sensitized about the extent of the problem and has formulated rules mandating barcodes. This counterfeit medicine can be identified by using various anti-counterfeit packaging techniques such as 2D barcodes, holograms and RFID.

Keywords: Anticounterfeit; RFID; 2D barcodes

INTRODUCTION
Nowadays counterfeiting is growing problem in both develop and developing countries. The increased counterfeiting of pharmaceutical products in recent years has develop into a global healthcare crisis affecting patients the world over. This increased in counterfeiting mostly affect the patients as the therapeutic effect is not achived and also the toxicity is increased. Materials such as cement, gypsum, industrial solvents and lead based road paints have been identified in counterfeit pharmaceuticals[1]. The drugs which contains the counterfeit materials it leads to decreased levels of bioavailability and the development of resistant strains of a disease[2]. In other cases, unrelated pharmaceutical products have been altered or repackaged so they can be passed off as a more profitable product. Common over the counter pain relievers such as aspirin have been used in this way[3]. An additional, to this the most subtle aspect of pharmaceutical counterfeiting involves the use of authentic product, often referred to as illegal diversion. Illegal diversion can occur at any stage within the drug supply chain, from the manufacturer to the individual retailer, and may involve product which is past its expiry date and slated for disposal. This diversion represents challenge for the analysis of the final products for their testing, autthotification of finished products, there physical and chemical identifications. The branding of pharmaceutical products are most important due to their high market share their ease of productions and ample profit margins[4]. The counterfeit is mostly related to product security. This counterfeiting is mostly related to the products which are sidetracked from their distribution channel or expired their shelf life. And this problem is mostly related to their repackaging or modification of products[5, 6]. This type of products are mislabeled with respect to their identity, sources. The counterfeiting of medicine is applicable to both branded and generic products According to reports in 2012developing country near about 30% of the medicines sold as a counterfeit, among which 50% are sold online. In USA 75 billion revenue are generated by this type of medicine in2010 and 13% growth is expected in future. The counterfeiting with refence to packaging is not problem in isolation. Duplication i.e., copying labels , packaging , products ,instruction and usage information, substitution, tampering by Counterfeiting with reference to packaging is not a problem in identification ;in packaging they mainly counterfeit the product by duplication it includes labels copying, products packaging, use, and instruction information, counterfeit with respect to substitution it includes substitution, tampering etc.



Countries like mostly Asian country and elsewhere where most of the products are outsourced have very poor track record of government control and safety regarding products[7, 8, 9].

Categories of Counterfeits[10]

There are five basic categories of counterfeits which are having lack of standards with respect to safety, eminences and efficacy. The categories includes as follows:

Completely fraudulent counterfeit: These types of medications mostly are the placebo type having no active ingredients. In few cases the ingredients are mostly poisons. This type of medications includes significant risk near about 40% of drug are in circulation with no active ingredients. It some cases it also include diluted active ingredients.

Expired medications: in this type of medication the counterfeiting are done by re packaging and reselling. In this the risk is significant with respect to the health because the active ingredients are not stable and the viability of drug is not known. The medication prepared by using unknown raw materials and inferior ingredients and manufacturing processes. This type of medications are extremely hazardous given their lack of regulation, quality control or processes. These medications are primarily produced to infringe on a pharmaceutical manufacturers patent with the quality and efficacy of the medication is completely unknown. Counterfeiting can apply to both branded and generic products. In wealthy developed countries, expensive drugs such as hormones, steroids, and antihistamines are frequently counterfeited due to lifestyle preferences. While in developing countries, those used to treat life threatening conditions such as malaria, TB, and HIV/AIDS are chosen to be imitated due to their relatively high costs.

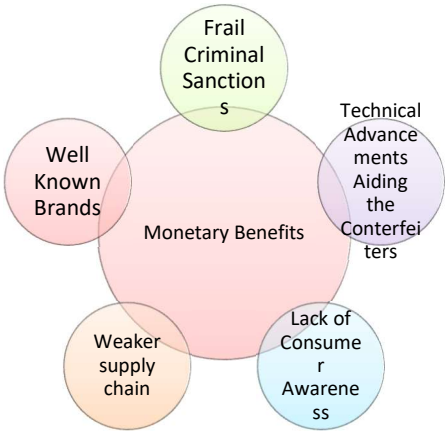


Fig 1: Drivers of Counterfeiting or factors affecting for counterfeits

The primary reasons for the rapid increase of counterfeit and adulterated medications include[10]: The high price of pharmaceuticals worldwide. Medications have become a global currency. Pharmaceuticals increase in value over time, are relatively easy to reproduce, relatively easy to transport and relatively easy to distribute. The technology to reproduce reasonably near identical or reasonable forgeries of all the components of a medication including labels, containers, form, and ingredients is now widely available worldwide. The ease of even relatively unsophisticated counterfeiters to take legitimate or expired medications, dilute and/or alter and repackage and re-introduce into the supply chain. The Globalization of the world's economy specifically as it relates to the pharmaceutical industry as a whole, including the access to raw materials, manufacturing, supply chain and dispensing. The ease of use of the Internet which provides individuals and sophisticated organizations a relative anonymous access to direct consumers worldwide. Insufficient, weak or inconsistent laws, regulations and standards which govern the pharmaceutical supply chain globally. From manufacturing to dispensing, current regulations do

not provide an effective prevention, in terms of enforcement and penalties, to deter counterfeiters. Internationally, nationally and locally the regulations and law enforcement efforts are not focused on catching and properly punishing this type of criminal activity. The reward versus the risk is very high. Sophisticated, global organized crime networks have realized the high return of this crime and have become increasingly involved in counterfeiting medications. Given the penalties and enforcement, it is now a higher return to counterfeit legitimate medications than to manufacture and distribute illicit drugs.

Effects of Counterfeits[11]

The counterfeiting of pharmaceuticals has serious consequences for consumers, health care providers, drug manufacturers, and governments. Consumers can be affected when there is illness or death, as has already happened on several occasions in the developing world. Health-care providers are in a particularly difficult situation as there can be a decline in confidence in public health systems, health care professionals and in government agencies involved in distributing drugs.

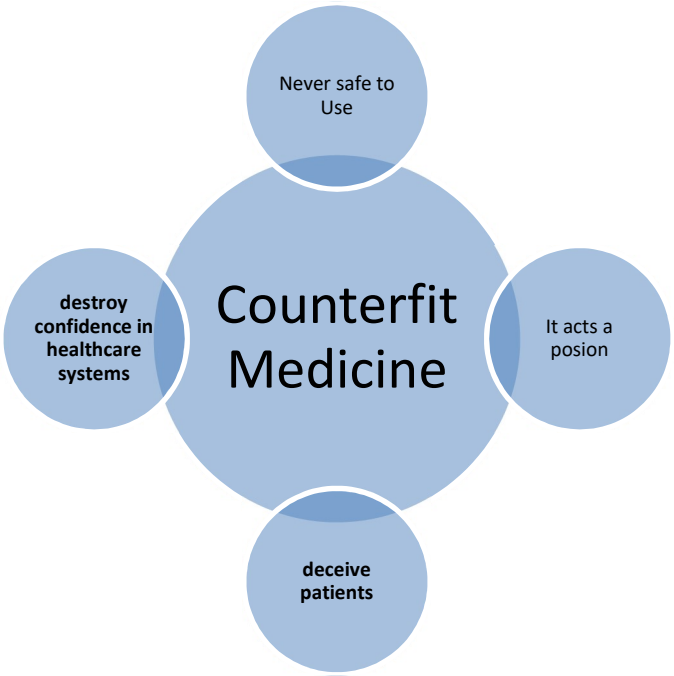


Fig 2: Adverse Health Effect of Counterfeit[12]

Need for anti-counterfeit technologies [13,14]

Counterfeiting of medicine lead to drug recalls, liability suit, brand loyalty is being compromised also consumers perceive additional risks when using a fake company product. The use of anti-counterfeit technologies is the preventive measure for identifying production of a counterfeit drug by employing these technologies, by using anticounterfeit technology companies can ensure that drugs in the supply chain are legitimate and safe for patients. The main purpose of this type of technology is to authenticate an item, either by the investigator or by the investigator or by the public. The second and most important function may be to act as prevention to anyone considering counterfeiting a product based on the difficulty or cost involved set against the likelihood of detection, and therefore prosecution. It must be stressed that security devices on packaging components provide no assurance as to the authenticity of the contents, which may have been substituted or adulterated. Security devices alone do not reduce counterfeits but are designed to make them easier to detect.

Effective Anti-Counterfeiting Strategy [13,14,15,16]

An anti-counterfeiting strategy helps to effectively detect counterfeit products, increase audit compliance, and enhance supply chain management capabilities. This strategy can identify the multiple solutions for meeting a company's requirements via Radio Frequency Identification Devices (RFID), dosage unit-level security, ePedigrees, label security, nanotechnology, and other capable solutions to combat counterfeiting of drug products. A single product is not capable of protection of companies from counterfeiting of Drugs, but the multilevel approach provides the safeguard to the supply chain, prevent the brand from erosion and increases the capital. This causes a markebly reduction in the number of counterfeit products in the market and improving patient safety. It also leads to increase product identification and authenticity. Apart from this increased audit compliance by reducing the supply chain issues such as time to account and inventory tracking. Therefore, this leads to an increased bottom-line by effectively locating its products within the supply chain from manufacturer to patients. This enables the drug manufacturer to

increase revenues for legitimate drugs in the marketplace.

Characteristics of Ideal Anti-counterfeit Technology[12, 13, 15, 17,18]

This type of anti-counterfeiting technology includes: It should possess a high level of security, higher product application and authentication speed, proven standards. It should be difficult to remove and reapply, easy to check, have automatic authentication, be useable by consumers, and must be legally compliant by the industries. The governments strengthen their drug regulatory authorities and their powers to enforce drug regulations and laws. Drugs registration process in India is needs to be strengthened for all drugs which is produced in country and imported in country. Apart from this those drugs which are imported to the country must be assessed for its safety, efficacy, and quality. IN FDA report they mentioned some of comprehensive measures need to be taken to prevent counterfeiting of drugs it includes: Use of new technologies to protect drug supply chain. Acceptance and enforcement of anti-counterfeiting laws and regulations. Increase in enalties to deter counterfeiting Use of secure business practices by all participants in the drug supply chain Educating the consumers, patients, and health professionals. Collaboration with global stakeholders to prevent global counterfeiting of drugs.

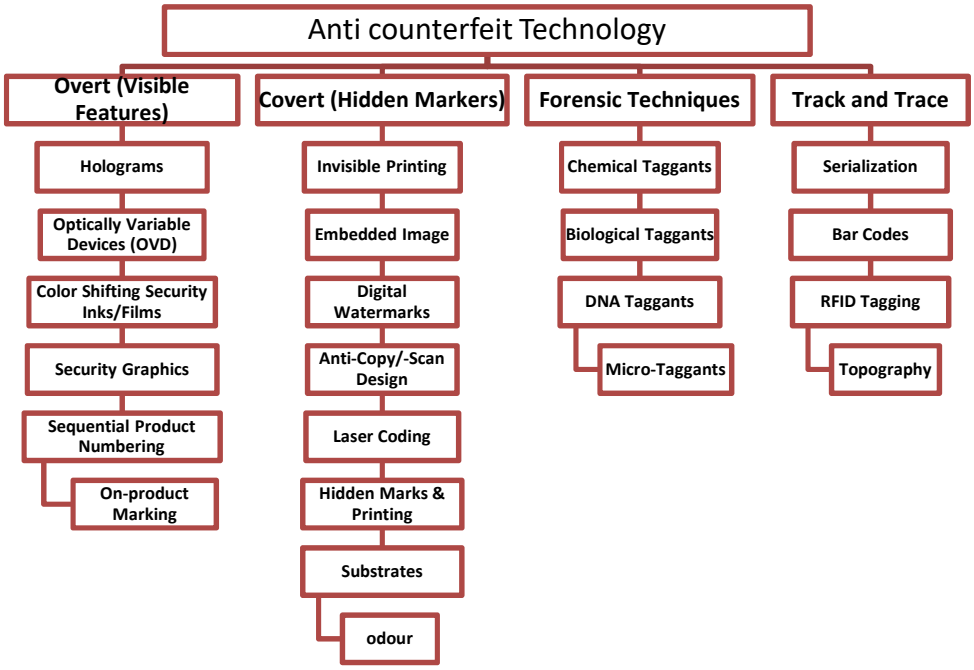


Fig 3: Anti-counter fit Technology

Different kinds of anti counterfeit technologies[19]

In world Currently, there are a variety of measures used by Pharmaceutical Manufacturers to fight counterfeiting. Various technological approaches, ranges from the simple to complex, are available or in development, and are either routinely used or else are under review by the pharmaceutical industry. Some of anti-counterfeit packaging includes following techniques: Overt Technologies (Visible features) – This features are significantly visible to human eyes. Its prime aim is to communicate and educate the people about the authenticity of the pack, with no requirement of high-tech devices or expert knowledge. Such features will be complex or expensive to reproduce. It should be noted that overt features can add significant cost, may restrict supply availability, and require education of end users to be effective. Where overt features are used, the 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 all most security in supply, handling and disposal procedures to avoid unauthorized diversion[20,21]

Holograms

The holograms are easily identifiable, it shows manufacturer's logo, for example, the hologram techniques is primarily used as first level identification devices and are designed to enable successful authentication at the point of inspection. In Addition it includes the featurs like, such as Nano text and hidden images, can be used as second and third level techniques for trained and equipped specialists. High-security holograms cannot be reproduced by using conventional printing methods available on the market. These markers are clearly visible when viewed with a magnifier, but invisible to the naked eye. Whilst holograms offer a high level of overt security on their own, they can also be used in

combination with other security devices to provide another hurdle for would-be counterfeiters to overcome, including colour shift inks. In hologram it normally incorporates an image with some illusion of 3-dimensional construction, or of apparent depth and special separation. Holograms can be made more effective when incorporated in a tamper-evident feature, or as an integral part of the primary pack. They can be incorporated into tear bands in overwrap films, or as threads embedded into paper substrates hence may be usefully employed on secondary/ transport packs. However, some hologram labels have been easily and expertly copied or simulated, and may often rely on hidden covert elements for authentication. 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.[15], [22] A major advantage of this method is that they can be reformed under white light. The Hologram are generated from the interference patterns obtained through the contact of laser beams by either angular image or laser technology. Advantages of the hologram: It is difficult to counterfeit, It is easily recognizable to the consumer, It is cost effective and economical, It helps in tracking the product in supply chains.

Optically Variable Devices (OVD)

This type of techniques includes a wide range of alternative devices, similar to holograms, but often without any 3D component. It involves flips or transitions type of image, often including colour transformations or monochromatic contrasts. Like holograms, they are generally made up of a transparent film which serves as the image carrier, and a reflective backing layer which is normally a very thin layer of aluminum. Apart from this sometimes metals like copper may be used to provide the characteristic hue for specialist security applications.[21]

Color Shifting Security Inks/Films

In 2004, the pharmaceutical companies started using color-shifting ink that changed color when its viewing angle is changed so counterfeits can be easily recognized by members downstream within the supply chain.

Security Graphics

This is a technique with a Fine line colour printing, which is 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 overt print 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" colours make the design more difficult to scan and reproduce, and security ID further enhanced by the incorporation of a range of covert design elements, such as micro text and latent images[21].

Sequential Product Numbering

The Unique sequential numbering of each pack or label in a batch can make counterfeits very easy to detect in the supply chain. If printing is done visibly, it provides a semi-overt means of authentication by reference to a secure database, because duplicates or invalid numbers will be rejected. The disadvantages of sequential numbering are that the sequence is predictable and easily replicated, and end users require some means of access to the database.

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 end of supply chain. This on product marking is effective when it seprated from the original package.

Covert Technologies (Hidden markers)

The main Purpose of having a covert feature on pharma carton helps brand owners to identify the counterfeit product. The general public is unaware of this because it loses all of its security value if publicized. The purpose of covert features is to enable the brand owner to identify counterfeited product.[19,20]

In*visible printing*

By using special type of ink, invisible markings can be printed on almost any substrate, this invisible marking are only visible by using special conditions like IR illumination and UV by using different wavelength.

Embedded Image

Invisible images can be surrounded inside 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 well hidden.[21]

Digital Watermarks

In this techniques the data digitally fixed 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 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.[21]

Anti-Copy/Anti-Scan Design

The anti-copy/scan design are the fine lines patterns appears in as uniform tones, but when scanned or copied reveal a hidden images which were not formerly visible. Commonly used on secure

documents to prevent photocopying, the may be applied to the product packaging as a background tint.

Laser Coding

The application of batch variable details by laser 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.

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.

Substrates

The incorporation of covert markers within a substrate is done by many ways such as visible UV, fluorescing fibers, chemical reagents in carton board or paper.

Odour

Micro-encapsulated typical odour can be applied as a stabilizer to an ink or coating to provide a novel covert or semi-overt feature. 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.

Forensic Techniques

The difference lies in the usage of scientific methodologies like laboratory testing or dedicated field test kits for authentication. 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 require for authentication.

Chemical taggants

Trace chemicals which can only be detected by highly specific reagent systems, but not normally detectable by conventional analysis.21

Biological taggants

This types of markers are included in very low levels in product formulations or packaging components. At this levels, this biological tangent are not able to detect by normal analytical methods for its detection it requires very highly specific "lock and key" reagent kits to authenticate.21

DNA taggants

A very specific DNA "lock and key" reagent systems can be applied to packaging by a variety of printing methods. They also need "mirror image" recombinant strand to effect the pairing, these reactions are detectable by a special dedicated device. The safety and security is confirmed 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.21,23

Micro-taggants.

These are microscopic particles containing coded information to uniquely identify each variant by examination under a microscope. This data may be in the form of the alphanumeric type depicted on small flakes or threads, or of fragments of multicolored multi-layered laminates with a signature color combination. These can be embedded into adhesives, or directly applied to packaging components as spots or threads.21

Track and Trace

This type of technology used during the manufacturing of products. The unique ness of this techniques is it last till last point of supply chain. A large number of research is going on this technique, the techniques involves the assignment of unique identification to each unit during its manufacturing.22 [8, 30]. This type of techniques are useful in various functions: tracking of item throughout the supply chain and authentication of data at any time in any place is also done through it. The techniques are having large number of benefit with a most transparent and reduced the costt, it also helpful for the elimination of medication with error and helpful for the speedily recall defective product

Serialization

In track and trace techniques it is not possible to copying or falsification. The sequrity is enhanced by the inclusion of unique and random sterilization, and non-sequential numbering is introduced at entry level of product. Apart from this if the sequential sterilization is used then it is very risky in sequrity point of view as this sequential sterilization is predictable. Packs of cancelled and expired medicines are also track by this type of techniques.[21,24]

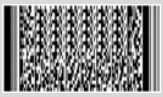
Barcodes

This is useful for pharmaceutical industry to access the product throughout the supply chain. In barcode various levels of information's are covered it includes national drug code, expiry date and lot no of products. 1-D and 2-D types of Barcodes are mostly used in pharmaceutical industry. The 2D bar coding is available in three types of formats [Figure 2]. It includes Linear, scripted and data matrix type of formatting[28].

1D (Linear) Bar Code Symbologies

Bar Code	Image	Characters	Format	Common Applications
Code 39		[a-z];[0-9];[-,s /+ %]	wide/narrow, checkdigit	Extensively used in industry, authorities, Package Tracking, Health Industry Bar Code Council (HIBCC)
Code 128		128 Alphanumeric	multiwidth, checkdigit	Package Tracking, Patient Bracelets, Medication, Inventory Control
Codabar		20 Numeric + punctuation	wide/narrow, checkdigit	Patient Bracelets, Medication
UPC		10 Numeric	multi width check digit	Product Packaging

2D Symbologies

Data Matrix		Alphanumeric	28.5% - 62.5% error correction	Manufacturing part tracking, medication, patient bracelets, etc.
PDF417		2710 characters	error correction	Manufacturing part tracking, Package Tracking, Patient Bracelets, Medication,

Script format

These are high-density linear or 2-dimensional bar codes incorporated for product identification till last in supply chain, which is useful for scanning and for references to the central database. This type of coding systems are consist of 1cm square or smaller and contains about 1 Kb with some "redundancy" or error correction. These 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 dentities 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.21

RFID Tagging

This RFID tag consisit of anantenna with a microchip at centre. It contains product specific and batch information which is printed on specific distance and without sight line. It mostly useful for determination of range and sensitivity but not suit for all applications. Many systems are useful 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. One of the most important advantages of these techniques is that it is fully automated for warehouses and pharmacies. But one of the major disadvatege of this techniques is that cost. Strength of the tags during handling and application of products is not viable this is another issue related to it[25].

Fig: 8 RFID Tags

Technologies	Advantages		Disadvantages	
Overt Technologies/Features	-Visible to user & the consumer c -Increases the decorative packaging appeal -It can be a deterrent to the counterfeiters -Newer technology is more secure.		Requires to be backed by additional anti-counterfeiting techniques like covert technologies for enhanced security -may add significant cost to the manufacturer. -it may give false assurance -it may be reused or refilled. -it required user education because it is not always understood. -it may be easily mimicked	
Covert Technologies	It is simple & low cost(e.g. Anti-Scan design) to implement. It can be incorporated in house or via component supplier. Regulatory approval not required. Facilitates easy addition & modification.		It can be easily copied hence required strict secrecy. If technology is applied by the component supplier, then there is grater risk of compromise.	
Forensic Techniques	High tech & provides better security against copying. Used for product/ packaging authentication. Provide positive authentication. - May be disclosed for overt purpose		Licensed (patented protected) technology & hence suppliers of this particular technology is limitedto one source. Wider use of the technology results in increased risk of counterfeit. Unlikely to be available to authorities or public. -wider use increased risk of compromise.	
Track and trace	High tech & provides better security against copying. -It may also be authorized by investigators without compromise. Helps to eliminate dispensing errors & speedy recall of defective products. Remote authentication is possible via phone or internet. - May eliminate dispensing errors -Facilitated recall of defective product - May combat theft and fraud - Benefits in supply efficiencies		Involves significant cost to implement and monitor. Difficult to implement & access control to different markers e.g Labels . It is required for optimum result standards needs be harmonized. - Difficult to implement across multiple market - May be vulnerable to hackers - Damaged labels may not read - Robustness of RFID tags not proven - Not assessable to a public -remote reading causes privacy issues.	

This technology is wireless data collection technology using radio signals for identifying objects. In this product is tag which contains transponders that emit a massage which is read by specially design RFID readers. The RFID Tags are stored in the form of numbers and from the numbers reader receives the information from the data base and take action acoorinding to program set by the company. It mostly a wireless communications in fixed frequency band. The RFID system consist of three important parts it includes Software, Tag, and reader. Out of these the tag is an integrated circuit containing unique tracking identifier which is known as electronic product code, this electronic product code is transmitted via Electromagnetic waves in radio spectrum. These waves are captured by signals and provides network connectivity between data and system software. Software are design in such way that which is suitable for anti-counterfeting[29]. Various kinds of track and trace RFID tags are as follows.

Active tag: This type of tags are incorporate on a battery which increase the tag to tag communication and also used for the increasing the range of collecting data etc. one of the main disadvantage of this type of tag is that it is not an economical tag.

Passive Tag: This type of tag is used when tag is within the interrogation zone of reader equipment, sufficient power is extracted from the interrogator to the tag or circuit or a special reflective material. It then responds by transmitting data back to the interrogator.

Semi-active tag: These types of tags are used to back up 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.21 companies like Pfizer (Viagra), Purdue Pharma (Oxycontin) and GSK (Trizivir) have implemented

RFID technology for specific brands of their product[19].

Regulatory Outlook

Various regulatory guidelines are frame regarding the quality assurances of the pharmaceutical products. These committee are mainly focused on the role of packaging in relation to the stability of products The United States Food and Drug Administration (USFDA) enforces rule 21 CFR Part 211 [2], which specifies the current good manufacturing process for final and finished pharmaceutical products. Within this it mainly focused on the rules mandates that tamper evident packaing should be used for the over the counter products for human used. As the number of cases in counterfeiting is increases day by date the USFDA urged and form a task force regarding the counterfeiting of drug. The main aim of this force is that to create the comprehensive system of modern protective measures against counterfeit drugs.

Impacts on Industry

The pharmaceutical industry is heavily affected by the counteiting of drug. The counterfeiting of drug can be avoided by using techniques like barcodes to RIFD tags. Accessibility in markets by using the nanotechnology based approaches is likely to be limited initially due to higher cost of development.8. The ultimate victims of counterfeiting are consumers. As by paying full prices consumers get the poor quality product which will be hazardous to the health and safety. By adopting the anti-counterfeit technology one can make a added advantages like., Reduction in cost of the products Reduced the job losses due to unfair competition caused by counterfeiting; Increases in customer goodwill and confidence in products and services; 2Reduces the revenue losses to government; Reduces the cost to protect and enforce intellectual property rights.

Challenges

Cost

The cost is most important factor in the development of pharmaceutical products. For tagging-based solutions the cost of per tag is also within the limit and will limit the products with which they can be used cost-effectively. For sensing approaches, cost is a factor of the equipment required plus any changes to existing production processes.

Technology

The new nanotechnology based techniques are also generate the unique feature which can not be reproduced not only by the other user but also by the manufactures. Only the problem is come in regarding the information between the producer and end user is not resolved during the fast and secure reading.

Topography

Various methods are used for preparing the pseudo random image to each item in a batch. By applying pattern of lines or dots in one of area on carton then scan the signature into the batch wise data base via secure algorithms for lateral identifications. This topographic techniques has potential to produce the robus solution to fraud and counterfeiting of pharmaceutical products[26, 27].

Health & Safety

While developing the nano technology based anti-counterfeiting technologies. The safety concern regarding the health, enviorment is also considerd. As matarials like polymer metals , glass are bening used by the developer during the formation of anticounterfeting devies. However, while the amounts of nanomaterials used in anti-counterfeiting applications are usually very small, the possible handling of free nanoparticles during the manufacture of devices or components requires suitable procedures to be followed to limit workers' exposure. Given the potential scale and ubiquity of these new technologies, investigation of the whole life-cycle of these nano-enabled products (from manufacturing stage through use and to disposal) should be permited.

CONCLUSION

Medicines save lives and prevent diseases and epidemics only if they are safe, efficacious, of good quality, and are rationally used. The use of unsafe, substandard, ineffective, and counterfeit medicines can be harmful to the health of the patients. The use of anti-counterfeit technologies is an important policy taken up by drug manufacturers and regulatory authorities. Out of the available anti-counterfeiting technology the track and trace system and serialization are benig widly used by the manufacuters through out the world in different countries. This Counterfeit medicines have been found in every type of medicinal category, in every region of the world therefore business personnel must be educated about the implementation of good anti-counterfeit technology and make consumers aware of such strategies used. The role of Regulatory authorities must conduct checking plans and necessary measures to ensure the absence of counterfeits, increasing the penalty of the pharmaceutical counterfeiting based on the risk imposed on public health. The counterfit drug not only affect the health and economy of consumers but also leds to the harmful effect on genral public.

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