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Review Article

ANTI-COUNTERFEIT PACKAGING IN PHARMA INDUSTRY: REVIEW

MALI D. K.*, MITKARE S. S., MOON R. S

School of Pharmacy, S.R.T.M. University, Nanded, Maharashtra, India Email: dkmalipharma@gmail.com

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ABSTRACT

Problems related to safety, efficacy & quality of medicines exists in many places around the world today, not just developing countries but in developed countries as well. Counterfeiting can apply to both branded and generic products and counterfeit products include products with correct ingredients or with fake packaging. Counterfeit drugs may lead to death in severe cases such as heart attack, epilepsy, angina pectoris, in such condition anti-counterfeit drugs acts as weapon to avoid tragedy.

It is very difficult to identify counterfeits from genuine products. Hence anti-counterfeit packaging techniques such as 2-D barcodes, holograms & RFID can be used to protect patient from counterfeit medicines.

Keywords: Anti-Counterfeiting, Barcodes, Hologram, RFID

INTRODUCTION

According to WHO definition "A counterfeit pharmaceuticals product is a product that is deliberately and fraudulently mislabeled with respect to identity and / or source. Counterfeit products may include products with correct ingredients, wrong ingredients, without active ingredients, with the incorrect quantity of active ingredient or with fake packaging" [1].

Counterfeiting mechanisms

There are five different types of counterfeit mechanisms in which drugs are manufactured or distributed without proper regulatory approval and do not meet the determined standards of safety, quality, and efficacy:

1. No active ingredient (43 %)
2. Low levels of active ingredient (21 %)
3. Poor quality drugs (24 %)
4. Wrong ingredients (2 %)
5. Wrong packaging or source (7 %) [2]

Global extent of counterfeiting of drugs

The problem of counterfeit drugs is global in nature. Although it is difficult to obtain precise figures, estimates put counterfeits at more than 10 percent of the global medicines market. It is known to affect both developed and developing countries. A WHO survey of counterfeit medicines reports from 20 countries between January 1999 and October 2000 found that 60 percent of counterfeit medicines cases occurred in poor countries and 40 percent in industrialized countries. The largest numbers of reports are related to antibiotics, antiprotozoals, hormones and steroids[3]. In 2006, the WHO established the "International Medical Products Anti Counterfeiting Taskforce (IMPACT)". Among other things, the European Commission is an active member of IMPACT and has specifically co-funded and supported WHO in the development of the recommendation "Principles and Elements for National Legislation against Counterfeit Medical Products"[4].

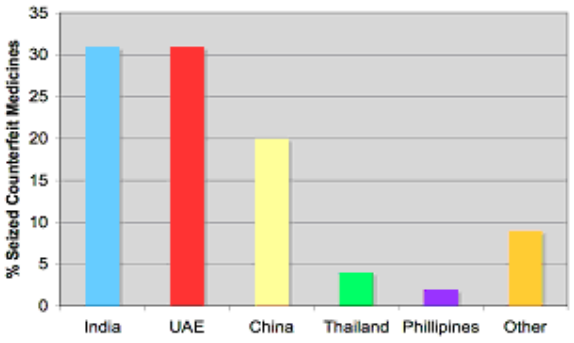

Fig. 1: Breakdown of source of counterfeit drugs seized by European customs officials [3]

Counterfeiting of drugs in India

According to a report by the Organization for Economic Cooperation and Development, 75% of fake drugs supplied world over have origins in India, followed by 7% from Egypt and 6% from China. India is also a leading source of high quality generic and patent drugs in legitimate commerce worldwide. Since drugs made in India are sold around the world, the country's substandard drug trade represents a grave public health threat that extends far beyond the subcontinent[5].

Counterfeit cases

Counterfeit medicine	Country / Year	Report
Influenza (flu)	United states of America, 2009	Federal agencies have come across contaminated, counterfeit, and sub potent influenza products. FDA with U. S. Customs and Border Protection has intercepted products claimed to be generic versions of the influenza drug Tamiflu, but which actually contained vitamin C and other substances not shown to be effective in treating or preventing influenza[6].
Anti-diabetic traditional medicine (used to lower blood sugar)	China, 2009	Contained six times the normal dose of glibenclamide (two people died, nine people hospitalized) [7].
Metakelfin (antimalerial)	United Republic of Tanzania, 2009	Discovered in 40 pharmacies: lacked sufficient active ingredient[8].
Counterfeit Cialis (tadafil) with glyburide	Singapore, 2008	150 nondiabetic patients with severe hypoglycemia were admitted to the five public hospitals in Singapore. Seven patients remained comatose as a result of prolonged neuroglycopenia and four subsequently died[9].

Viagra & Cialis (for erectile dysfunction)	Thailand, 2008	Smuggled into Thailand from an unknown source in an unknown country[10].
Xenical (for fighting obesity)	United States of America, 2007	Contained no active ingredients and sold via internet sites operated outside the USA (FDA Warns Consumers about Counterfeit drugs from Multiple Internet Sellers[11].
Zypexa (for treating bipolar disorder and schizophrenia)	United Kingdom, 2007	Detected in the legal supply chain: lacked sufficient active ingredient (Recall of counterfeit Zyprex batches.)[12]
Lipitor (for lowering cholesterol)	United Kingdom, 2006	Detected in the legal supply: lacked sufficient active ingredient[13].
Meningitis Vaccine	Nigeria, 2005	60,000 patients were said to have been received counterfeit vaccine[14].
Contraceptive Tablets	Brazil, 1998	Resulted in 200 unwanted pregnancies[15].

Methodology

Anti-counterfeit packaging includes following techniques:

1. 2-D Barcodes
2. Holograms
3. RFID

2-D Barcodes / Mass encryption technology

Barcodes are used in the pharmaceutical industry to identify product throughout the supply chain. Different levels of information can be carried in a barcode, including such items as National Drug Code (NDC), Lot Number, and Expiration Date. There are several different types of bar codes, and the standards for what those bar codes should look like and how they are to be used. These are the Uniform Code Council (UCC) and the Health Industry Business Communications Council (HIBCC).

2-D Barcodes are present in following formats

A. Linear format
B. Scripted format
C. 2-D data matrix format

Fig. 2: National Drug Code (NDC) and National Health Related Items Code (NHRIC) for pharmaceutical products

Fig. 3: Encrypted codes can be displayed in scripted format (top) or by way of 2-D Data Matrix barcode format (bottom)

In addition to the encryption and decryption of the codes, the software that supports this technology allows brand owners to fully manage their supply chain, i.e., track-and-trace[5]. A major advantage that mass encryption enjoys over all other currently available technologies is that it empowers the consumer to authenticate a drug.

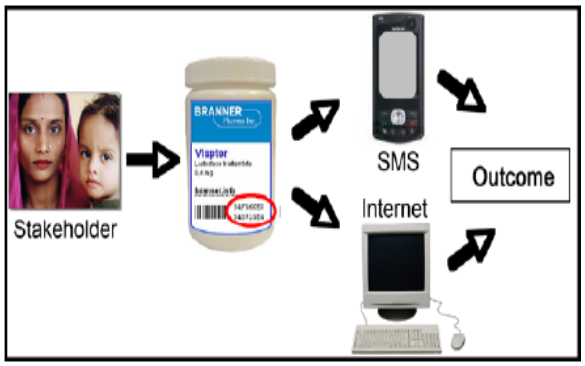

Fig. 4: Authentication process by consumer involving either SMS or internet

Furthermore, because the technology is software based, it is extremely cost effective. For example, the cost of protecting all drugs in a high-volume setting is less than five paisa per code and can actually be reduced to even mere fractions of a paisa for ultra-high volumes[16].

In Ghana, a new service called M-Pedigree allows people to send serial numbers (embedded under a scratchpad on drug packets they have bought) by text message. Within seconds they will receive a text message from the manufacturer telling them whether the product is genuine[17].

Hologram

Holographic technology is the recent emerged technology in pharmaceutical field which provide a simplified means for consumers to deduce the authenticity of a drug. The reasoning is that a blister pack or vial that contains a hologram will be seen to be a genuine product that is resistive to tampering. Holograms can be applied at the item level, such as a blister pack. The major problem, however, is that they are generally costly and not effective over the long term. For example, holograms can cost as much as 10–25 paisa, depending upon their level of sophistication[18].

Fig. 5: Two blister packages of these antimalerial drug artesunate, one genuine (right), and one counterfeit (left). A well crafted hologram is the only distinguishing feature of genuine product

Radio-frequency identification (RFID)

In a 2004 report, "Combating Counterfeit Drugs," the FDA stated that track-andtrace technologies and product authentication technologies should provide greater drug security. The FDA also said that this is a more reliable solution for ensuring drug legitimacy than current paper record keeping (pedigree) requirements[21].

RFID is a wireless data collection technology that uses radio signals for identifying objects, delivering dynamic asset supply chain contents and visualizing the entire asset lifecycle[17]. The basic premise behind RFID systems is that you mark items with tags. These tags contain transponders that emit messages readable by specialized RFID readers. Most RFID tags store some sort of identification number; for example a customer number or product SKU (stock-keeping unit) code. A reader retrieves information about the ID number from a database, and acts upon it accordingly. RFID tags can also contain writable memory, which can store information for transfer to various RFID readers in different locations. This information can track the movement of the tagged item, making that information available to each reader. RFID tags fall into two general categories, active and passive, depending on their source of electrical power. Active RFID tags contain their own power source, usually an on-board battery. Passive tags obtain power from the signal of an external reader. RFID readers also come in active and passive varieties, depending on the type of tag they read[18]. A passive-tag reader can constantly broadcast its signal or broadcast it on demand. When a tag comes within the reader's range, it receives an electromagnetic signal from the reader through the tag's antenna. The tag then stores the energy from the signal in an on-board capacitor, a process called inductive coupling.

Fig. 6: RFID placed behind label on pharmaceutical[19]

RFID and E-pedigree

EPC is a collection of interrelated standards for hardware, software, and data interfaces, together with core services operated by the EPC global (EPC global Inc., 2005). EPC global is an organization for promoting worldwide adoption and standardization of EPC technology which is a coding scheme for RFID tags. In other words, EPC global has standardized the EPC number stored in individual RFID tags.

To check the authenticity of manufactured items, enterprises can simply validate the EPC number from the EPC global network. Typically, RFID-based anti-counterfeit measures are widely adopted in the pharmaceutical industry. According to the Food and Drug Administration (FDA) of the US Government, RFID technology, coupled with the EPC and electronic pedigree (e-Pedigree) are key elements in a multilayered approach to combat the growing problem of counterfeit drugs that jeopardizes patient safety in the United States (Clara, 2004)[17].

Radio Frequency Identification (RFID) has garnered much attention in recent years as a method of supplanting the barcode[20].

List of pharmaceutical companies using RFID technology

Name of company	Product using RFID technology
Pfizer	Viagra
Purdue pharma	Oxycontin
GSK	Trizivir

CONCLUSION

To protect from counterfeit medicines patients have to check it. Now a day's pharmaceutical companies are using various anti-counterfeit packaging as barcodes, holograms. There is chance to make duplicate copies of these packaging. Hence pharmaceutical companies may use modern anti-counterfeit techniques as RFID to track and trace pharmaceutical products. Effective and efficient tracking of medical assets in healthcare facilities could be achieved by means of Radio Frequency Identification (RFID) system implementation. Benefit of RFID ultimately is in the pharmaceutical supply chain where an RFID tag attached to a consumer product could be tracked from manufacturing to the retail store right to the consumer's home. Use of RFID promotes health care system by tracking spurious and adulterated drugs. By using RFID national reputation will increase, reduction in export barrier, patient protection, brand protection can be achieved. Government should not only encourages use of RFID to pharmaceutical products by framing policies but also by making and implementing legislations.

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