FOOD AND DRUG COUNTERFEITING IN THE DEVELOPING NATIONS; THE IMPLICATIONS AND WAY-OUT

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ABSTRACT

Compared with developed nations, food and drug counterfeiting in the developing nations have become serious economic and social problem. A comparative analysis was carried out between the serialization technique as used in the developed nations and the SMS verification technique practiced in developing nations. The objective of this study is to review the anti-counterfeit technology solutions to ensure a lasting and effective preventive measure against counterfeiting in the developing nations. The result shows that using serialization technique with data career to trace and track food and drug supply chains proved to be a better solution than the SMS verification technique as used in some developing nations. To ensure maximum authenticity and global success in the counterfeit war, we recommend that the serialization technique with data career should be adopted.

Keywords: Bar-code, Counterfeit, Data Career, Food and Drug, Serialization, SMS Verification.

INTRODUCTION

Counterfeited drugs are drugs that are not authentic and have been manufactured using incorrect quantities, or incorrect ingredients, to either reduce the potency, or nullify the potency of drugs altogether, and the same is applicable to food counterfeit. Addition of harmful ingredients could also lead to counterfeiting, and may cause serious health effects amongst the patient population. As counterfeiters have started working cross borders, the counterfeited drugs have become difficult to identify, and have become a public health risk for people living across communities and borders (Ankur, 2009; Au, 2012).

Food and drug counterfeiting have become an economic and social problem for decades since they affect human beings directly due to the unavoidable importance of food and drug to live. The World Health Organization (WHO) has discovered a terrific growth rate in food and drug faking especially in the developing nations (P-ORG, 2012; Harris *et al.,* 2012) which has caused alarming rate of ill-health and eventually deaths amongst all level of human development. Most countries have developed strategies to fight the growth of food and drug counterfeiting. Recently, the SMS verification method (Obinna, 2010; Nana, 2011) was confirmed efficient in some developing countries, but it was not implemented on all drugs. Moreover, food counterfeit is almost neglected in the fight against counterfeit, thereby posing greater threat to the societies.

The objective of this research is to study the anti-counterfeit technology solutions to include all drugs and foods counterfeit to ensure a long lasting and effective preventive measure to reduce and eventually stop food and drug counterfeiting especially in the developing nations.

OVERVIEW

Fake Food

According to Au Fait, Counterfeit or fake food usually means substituting a cheaper food for what a food item is claimed or labeled to be. For example, selling salmon under the label of wild salmon when really it is farmed, or pen-raised salmon, is one form of counterfeiting food (Figure 1). Mislabeling tilapia, which is a cheap fish as red snapper which is a more expensive fish. Another way

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food is counterfeited or faked is when cheaper ingredients are added as filler without telling the consumer. Examples are adding grain, pink slime, or sawdust to ground beef, adding soybean oil to what is labeled as extra virgin olive oil (Figure 2), or adding melamine to milk, as the Chinese did (Au, 2012).

The melamine caused the hospitalization of 900 American babies for kidney problems and 6 of those babies died. It is not just an economic issue where cheaper ingredients are added to foods, or substituted for what the label says the ingredients are so that a manufacturer or seller can make more money. Counterfeit food can be dangerous to your health and to the health of your children (Au, 2012).

Figure 1. Mislabeling fish (Source: GettyIMages.com)

Figure 2. Extra virgin olive oil with 90% soybean or peanut oil (Source: Photobucket.com)

Counterfeit Drug

Based on Mark Davison presentation, a counterfeit medication or a counterfeit drug is a medication or pharmaceutical product which is produced and sold with the intent to deceptively represent its origin, authenticity or effectiveness. A counterfeit drug may contain inappropriate quantities of active ingredients, or none, may be improperly processed within the body (e.g., absorption by the body), may contain ingredients that are not on the label (which may or may not be harmful), or may be supplied with inaccurate or fake packaging and labeling. Medicines which are deliberately mislabeled to deceive consumers—including mislabeled but otherwise genuine generic drugs—are counterfeit. Counterfeit drugs are related to pharma fraud. Drug manufacturers and distributors are increasingly investing in countermeasures, such as traceability and authentication technologies, to try to minimize the impact of counterfeit drugs (Mark, 2011).

The Scale of the Problem

It has been estimated that up to 15% of all sold drugs are fake, and in parts of Africa and Asia this figure exceeds 50% (Cockburn, 2002; BBC News, 2003; WHO, 1992; WHO, 1998; Newton *et al.,* 2002; Saywell *et al.,* 2002; Newton *et al.,* 2001). The Federal Drug Administration (FDA) estimates that fake drugs comprise approximately 10% of the global medicine market. This estimate suggests

annual criminal sales in excess of US$35,000,000,000 (Cockburn, 2002; BBC News, 2003). According to FDA report in 2009 (Figure 3), the number of drug cases opened by the Office of Criminal Investigation (OCI) has arisen sharply in the past 5-7 years.

Most of the literature on fake drugs derives from local investigative journalism (Saywell *et al.,* 2002; Cockburn, 1989; TEMPO, 2001; Crampton, 2003; Chakravarty *et al.,* 2001; Fackler, 2002; Cockburn, 1982; Cockburn, 1984), with little scientific public health enquiry relative to the enormous scale of this criminal enterprise. The effects on patients of counterfeit medicines are difficult to detect and quantify, and are mostly hidden in public health statistics. The estimate of 192,000 patients killed by fake drugs in China in 2001 gives an indication of the scale of human suffering.

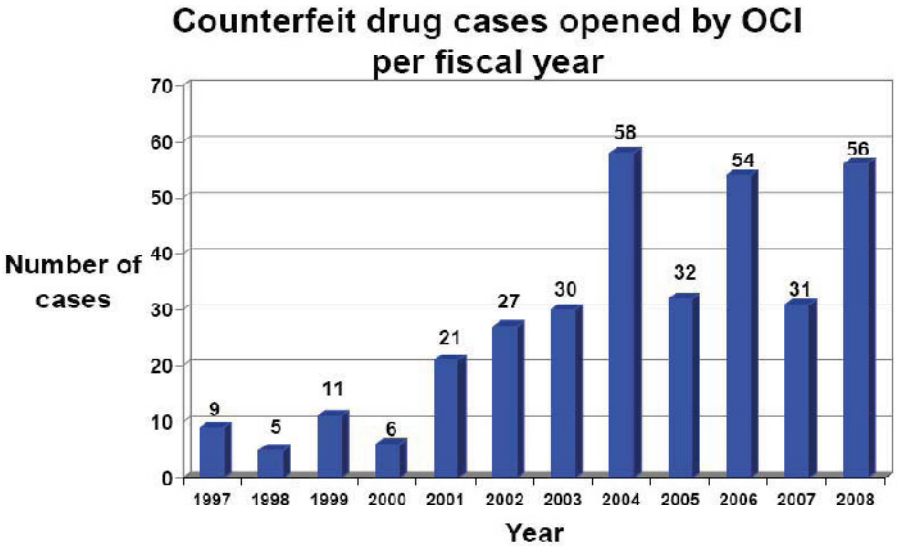

Figure 3. Counterfeit drug cases (Source: US Food and Drug Administration)

Anti-Counterfeiting

Anti-counterfeiting refers to the measures taken to prevent counterfeiting of drugs. According to FDA report in 2009, comprehensive measures need to be taken to prevent counterfeiting of drugs. Some of the measures recommended by the report are (Ankur, 2009):

1. Implementation of new technologies to protect drug supply chain.
2. Adoption and enforcement of anti-counterfeiting laws and regulations.
3. Increase in criminal penalties to deter counterfeiting
4. Adoption of secure business practices by all participants in the drug supply chain
5. Education of consumers, patients and health professionals.
6. Collaboration with global stakeholders to prevent global counterfeiting of drugs.

Anti-Counterfeit Platforms

In 2007, the world's first free-to-access anti-counterfeit platform (MPD, 2012) was established in the West African country of Ghana. The platform, dubbed m-Pedigree (MYJ, 2009), relies on existing GSM networks in that country to provide pharmaceutical consumers and patients with the means to verify whether their purchased medicines are from the original source through a free two-way SMS message, provided the manufacturer of the relevant medication has subscribed to a special scheme. Still in trial stages, the implementers of the platform announced in 2009 that they are in partnership with Ghana's Ministry of Health and the country's specialized agency responsible for drug safety, the Food and Drugs Board, to move the platform from pilot to full-deployment stage (CUS, 2009; MPD, 2012).

In 2010, NAFDAC in Nigeria launched an SMS-based anti-counterfeiting platform using technology from Sproxil (Obinna, 2010; Nana, 2011). That system was also adopted by GlaxoSmithKline (GSK) in February 2011 (Ifedigbo, 2011). In April 2011, CNN published a video highlighting Sproxil's

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solution in the fight against counterfeit drugs in Nigeria (Christian, 2011). In July 2011, Kenya's Pharmacy and Poisons Board also adopted text message-based anti-counterfeiting systems and endorsed the Sproxil solution (Phil, 2011). In early 2012 it was announced that more than one million people in Africa had checked their medicines using the text-message based verification service developed by Sproxil (SECURINGPHARMA, 2012).

Counterfeit or fake food crime has been around for decades (Au, 2012). The practice of marketing fraudulent food is getting more attention recently because attacking a group, organization, or country, by poisoning its food has become a more serious potential terrorist threat (Au, 2012). Despite the outbreak of sicknesses such as kidney problems, diabetes, cancer, liver failure, heart failure, typhoid fever and so many others in the societies especially among the young people, suspected to be as a result of consumption of fake food and drugs the anti-counterfeit measures do not include all drugs and non for food especially in the developing nations.

Electronic Traceability and Authentication Techniques

Pharmaceutical manufacturers constantly look for ways to improve drug security by reducing counterfeit and diversion in the supply chain. To date, labeling allows manufacturers to keep tabs on different lots of product, but tracking items individually becomes cumbersome in distribution and at the pharmacy. Several technologies may prove helpful in combating the counterfeit drug problem. An example is Radio Frequency Identification (RFID), which uses electronic devices to track and identify items, such as pharmaceutical products, by assigning individual serial numbers to the containers holding each product. The U.S. Food and Drug Administration (FDA) is working towards an electronic pedigree (ePedigree) system to track drugs from factory to pharmacy. This technology may prevent the diversion or counterfeiting of drugs by allowing wholesalers and pharmacists to determine the identity and dosage of individual products. Some techniques, such as Raman spectroscopy and energy-dispersive X-Ray diffraction (EDXRD) (Williams, 2007) can be used to discover counterfeit drugs while still inside their packaging (BBC, 2007).

With RFID, drugs can be tracked at the item level throughout the supply chain. Individual packages are tagged at manufacturing and then read serially, in-bulk throughout the distribution chain. The read points include tag application, case packaging, total tracking throughout distribution and item level tracking and authentication at the pharmacy. With RFID, the entire drug supply chain becomes more efficient and secure.

The SMS verification technology is an innovative use of the GSM which is now ubiquitous in our society to fight drug counterfeiting. Sproxil provides this unique service using cell phones to ensure automatic protection against counterfeiters while also capturing market intelligence in cash-based societies. To use the service, patients are advised to scratch off the silver panel on the drug (Ampiclox 500mg only) to reveal the 12 digit PIN. They are advised to send the PIN as an SMS to 38353. A response, which confirms whether the drug is authentic or fake, will be received shortly after (Ifedigbo, 2011). However, the SMS technology may be cloned in the future since it cannot be traced due to lack of data career system such as RFID. The next section briefly presents the lasting technology solutions to the food and drug supply chains using the data career.

THE TECHNOLOGY SOLUTION

The process of affixing a unique identification number to every item is called serialization. The serialized number itself could be stored in a Radio Frequency Identification (RFID) tag, a bar code, or on the package itself. There are various options available for serialization. This section details the Serialization techniques. Serialization of unique numbers is based on an encoding standard. The standard defines the way in which the information is stored or encapsulated in the unique numerical identifier (UNI) or Serialized Numerical Identifier (SNI) (Ankur, 2009).

Digital Mass Serialization

Mass serialization is the process of generating unique numeric or alphanumeric number and assigning the number to each saleable unit (item, case or pallet). The numbers can be generated in a sequential, random or pseudo-random manner (Confederation of Indian Industries (CII)). Figure 4 shows the

process of digital mass serialization. Mass serialization codes can be generated by third party solution vendors and transferred to manufacturer. The codes can be grouped in batches, and the generated batch stored in a database, which is maintained by the manufacturer or the technology solution provider. The code can be pre-printed on labels which can be affixed to the product, or the code could be printed directly on the packaging material. These numbers can also be carried by RFID or bar code symbols (Ankur, 2009).

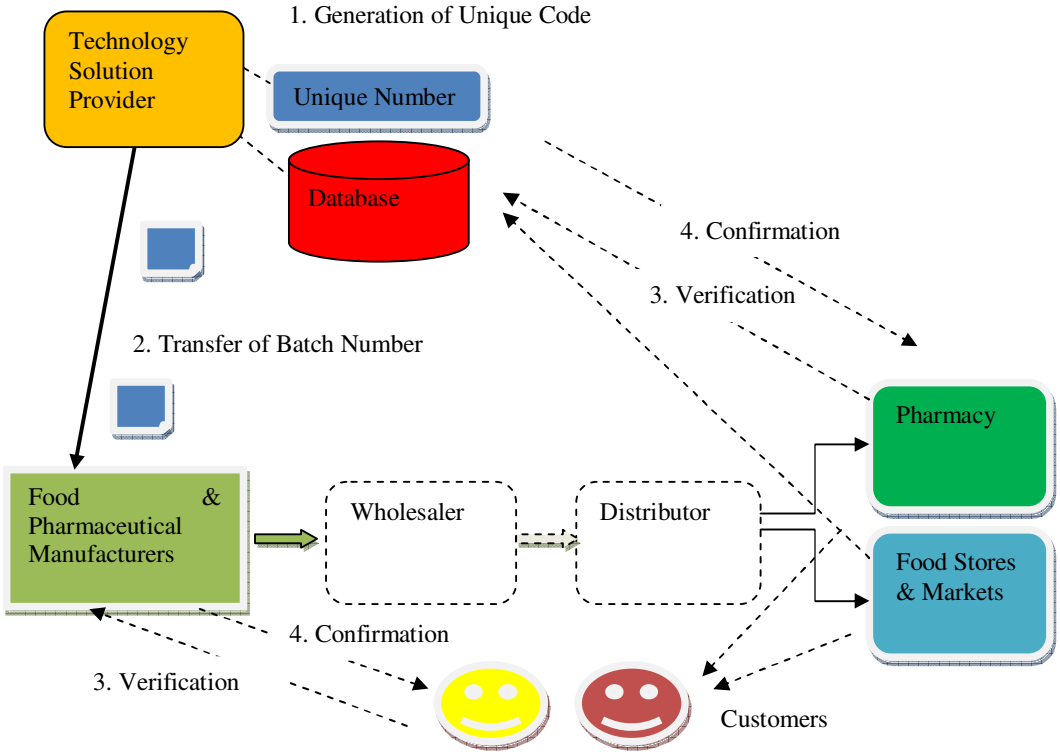

Figure 4. Digital Mass Serialization using Database

The codes are verified by end-consumers or at the point of sale. Codes can be read visually if they are printed directly, and can be read using bar code scanner if the bar code data carrier option is used. 2D bar-codes can also be read by mobile phones that have in-built bar code readers. The code can be transferred through text-message, web based portal or through automated telephonic means. The process of authentication involves verification of the number in the database. If the number is present in the repository, then it means that the product is authentic else it is a counterfeited product. Mass serialization, and the resulting verification of the product empowers consumer to verify the product. In addition to the supply chain stakeholder based security personnel, guarding and validating the authenticity of the drug, a huge customer base is added to the validation group, and thereby increases the vigilance initiatives. The mass serialization system should have business rules to accommodate the following (Ankur, 2009): Flag duplicate validation of the product from multiple consumers, and Flag failed authentication of product.

Digital Mass Encryption

Digital Mass Encryption (DME) is very similar to Digital Mass Serialization. However in DME (Figure 5), a database is not required for persistence of unique serial numbers. The unique serial numbers generated are encrypted using cryptographic algorithms. The algorithm is also required for decryption of the encrypted number. This technology was coined by Kezzler AS, a Norwegian company, and has been used by the firm to protect the supply chain from counterfeiting issues. To ensure that the code is not authenticated more than once, business rules should be built into the DME system. Multiple failures of authentications should lead to flagging, and thus would provide manufacturers with key information about the counterfeited product.

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Both DMS and DME technologies are cost-effective solutions for the counterfeiting issue. The technologies on a standalone basis do not meet the requirements of track and trace, but provide a potent means to prevent counterfeiting cases. Both the technologies can use data carrier options of bar code or RFID, or just the printing of the code on the package itself (Ankur, 2009).

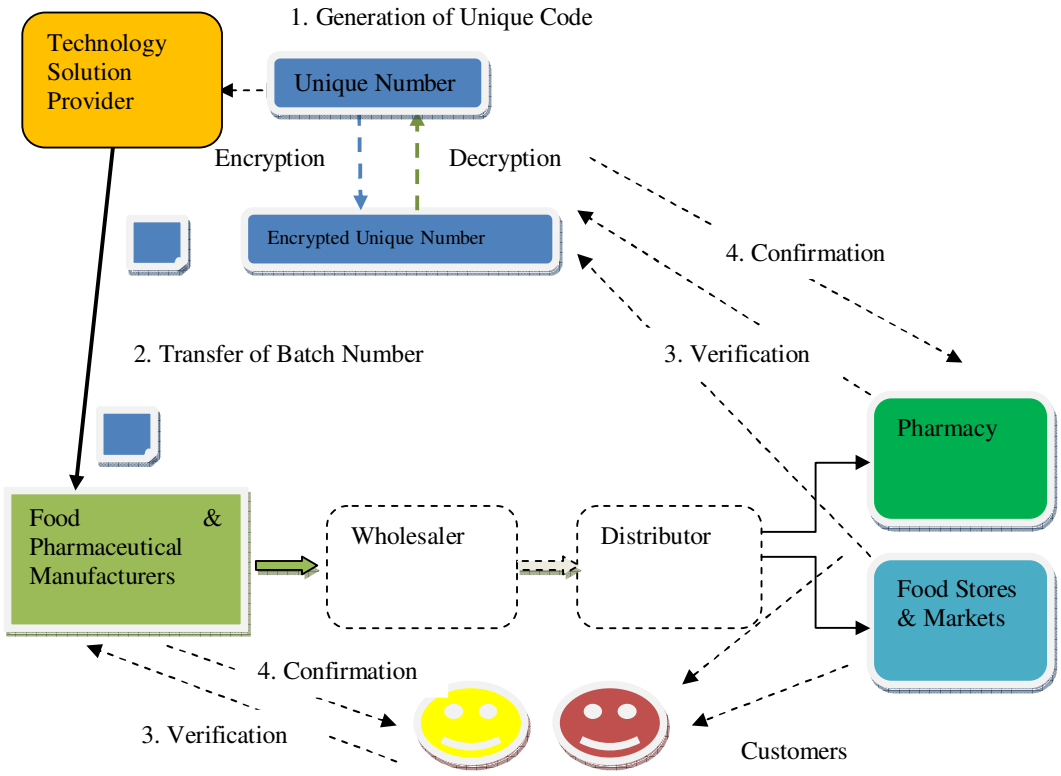

Figure 5. Digital Mass Serialization using Encryption

Data Carrier Options Compared with Non-Data Career

For any kind of serialization of a unique identifier, a data carrier is needed to hold the identifier. Options that have been widely considered for carrying SNI are a) Barcode and b) RFID (Ankur, 2009). However, the Non-Data Career such as the Short Messaging System (SMS) verification cannot be traced but the end user of the product scratches the seal covering the unique serial number and sends it to the Technology Solution Providers (TSP) for verification. Table 1 compares the data career and the non-data career options.

Table 1. Comparing the serialization technology solutions

	Bar Code	RFID	Non-Data Career
Readability	Line of Sight Technology	Tag information can be scanned from various angles	GSM network
	Bar codes are not re-writable	RFID tags are re-writable	Not re-writable
	Cannot be read in bulk	Can be read in bulk	Non readable
	Can limit the speed of operations	Have higher operational efficiency	Have higher operational efficiency
	Labor intensive	Not labor intensive	Not labor intensive
Cost	Low	High	Very low
Durability	Strong	Very strong	May be vulnerable in the future

RESULTS AND ANALYSIS

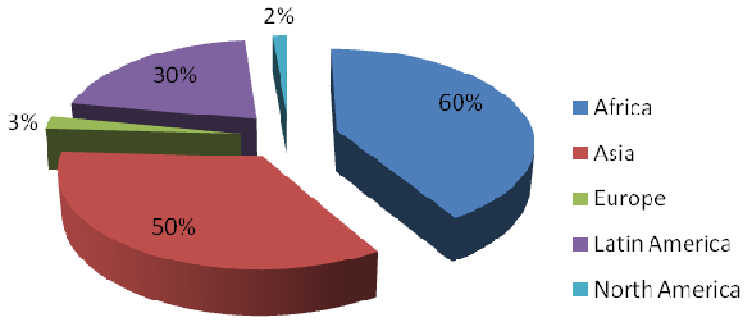

Figure 6: Drug Counterfeit level in the Continents (Source: P-ORG, 2012; Harris *et al.*, 2012)

From the result, Africa, Asia, and Latin America recorded the highest drug counterfeit in the world at 60%, 50%, and 30% respectively. Europe and North America recorded the lowest at 3% and 2% respectively. This shows that the developing countries have not deployed the proper anti-counterfeit technology and measures already in use in the developed countries. The North American countries have deployed full serialization technology with data career (RFID) system and planned to include every drug, confirming the data career serialization technology as the best solution to drug and food counterfeit.

CONCLUSION

The electronic anti-counterfeit measures will aid in realizing a creditable level of food and drug authenticity if properly implemented and checked by the various levels of governance in the developing countries. The SMS Verification technology proved a little effective in some developing nations, but the serialization technique with RFID as the data career adopted in the developed nations such as North America, is more effective as confirmed in the result in Figure 6.

It was concluded that the low level of drug counterfeit recorded in the developed countries is attributed to the level of technology solutions adopted ensuring maximum traceability and authenticity of all pharmaceutical products. It was recommended that the developing nations should deploy the full serialization technology with data career (especially RFID) system on all drugs and foods.

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