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Counterfeit drugs – Role of Pharmacist's and its Prevention –A Review

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Abstract: The growth of pharmaceutical counterfeiting is a major public health problem. The basic role of drug is patient life-saving, but a drug being counterfeit encounters additive danger to human population. Global scenario represents that India accounts for one third of counterfeit drugs world-wide, being existence since 1982. According to recent investigation a massive increase in counterfeit drug sales have been found to over $85 billion globally in 2012, an increase of more than 95% from 2006.This represents % 25 of the size of the legitimate pharmaceutical industry. It is spreading by leaps and bounds in major selling drugs classes like steroids, anticancer, antiviral, erectile dysfunctions, anti malarial etc. This short review describes the planning of counterfeit-free world by implementation of WHO parameters, updating training programs for pharmacist and utilizing innovating methods. This paper discuss about latest diagnostic patterns to reduce the counterfeiting culture across the globe like radio frequency identification (RFID), digital imaging, holographic labels, infra-red inks, supply chain tracking, chemical fingerprints, etc. Inspite of increasing globalization and cross border trading, pharmacists play a significant role in defeating counterfeit drug strategies.
Keywords: counterfeit drugs; holographic labels; digital imaging; radio frequency identification.

INTRODUCTION:

Counterfeiting of drug is an old tradition and dangerous scenario in this world. According to WHO, the counterfeiting can be defined as "one which is deliberately and fraudulently mislabeled with respect to the identity or source". Counterfeiting drugs possess both generic and branded drugs containing the insufficient active ingredient or incorrect or wrong ingredients or without active ingredients or with fake packaging. The international federation of pharmaceutical manufacturers estimated that the world trade of counterfeit drug accounts for about 20%. Counterfeited drugs are not substandard drugs since they never meet all the standards similar to the authentic drug. It serves as an obstacle in restoring health and life saving of human population. Recent techniques to reduce the spreading of the counterfeiting of drugs include radio frequency identification, Raman spectroscopy, holographic labels, nanotags, chemical fingerprints.

Types of Counterfeiting:

Deceptive – unawareness of consumers product purchasing

Non-deceptive – low cost mentality of consumers of purchase products.

Reasons for Counterfeiting of drugs:

The problem of counterfeiting mainly produced due to the following factors:

- Reduced revenue tax of pharmaceuticals.
- Low cost.
- Use of non-prescription drugs.
- Less trade risking.
- Enormous benefits or profits for the manufacturers.
- Lucrative selling of pharmaceuticals.
- Reduced legislation or law enforcement.
- Carelessness of the manufacturer.

Global situation:

India accounts for 45% in fake drug import FDA claims the fake drug consumption may go up to 40% and 50% worldwide by extending its wings in the midst of pharmaceutical drugs. India is fast becoming the hub for counterfeit drugs. International policy network states 9, 00, 000 deaths from malaria and TB arise in 2012 due to counterfeiting of drugs. Contamination of heparin by Chinese counterfeiters in 2008-2009 killed 155 patients in USA. According to WHO reports about $ 202000 worth of counterfeit drug for diabetes,cancer,blood pressure were seized in china, almost 2500 people were arrested. In 2011 council of Europe drafted medicine convention constitutes binding international standard for criminalizing manufacture and distinct of counterfeit drug [1-2]

Incidences/Influences of Counterfeiting:

- In 1995 in Nigeria about 3000 people died of meningitis epidemic due to fake vaccines.
- In 1995 in Haiti, 95 people died on usage of paracetamol cough syrup contaminated with diethylene glycol. In India in 1998 about 40 infants died of paracetamol cough syrup contamination with diethylene glycol.
- In 2001 in India about 700kg of counterfeited drugs and 1000kg of raw material and boxes containing labels of another company were seized.
- In Myanmar in December 2003 approximately 4.5 million capsules of amoxicillin, ampicillin were seized.
- The large increment of counterfeit drug is mainly due to the on-line pharmacies. FDA has also warned of the 25 websites selling the counterfeited drug.
- The list of drugs mainly counterfeited includes prescription drugs such as anti-infective, antianaemic, antineoplastic, lifestyle drugs [3-5.]

The following data was submitted as an investigation report by FDA[6].

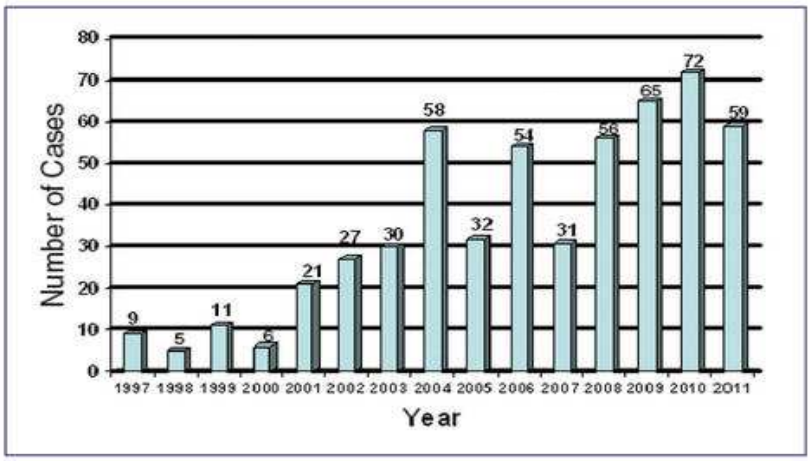

Figure 1. Number of Drug Counterfeit Cases Opened by FDA's Office of Criminal Investigations per Fiscal Year[3]

Threat of Counterfeit Drugs:

- It possess a huge risk to public health.
- It is a negative future for pharma drugs.
- Violation of rules by the drug manufacturers.
- It evades the ease of detection of counterfeit drugs.
- It supersedes the business of the authentic drug.
- Counterfeiting drugs produce tens of billions of loss to the pharmaceutical industry[7]

Role of Pharmacist:

- In the midst of counterfeit flood, pharmacist plays a role of sailing ship to combat the counterfeit.
- Setting up of special task force in drug.
- Ensuring safety, efficacy, quality of the drug imported.
- Implementation of WHO, good pharmacy practice guidelines
- Visual inspection of the counterfeit drugs and taking necessary steps to detect the source.
- Maintaining reasonable margins for pharmacist and wholesalers.
- Updating the knowledge in training programs.
- Developing analytical method, usage of sophisticated tools to avoid counterfeiting.
- Avoiding non-regulated online pharmacy.
- Creating awareness among health professionals [8].

Role of Legislation to fight Counterfeiting:

The legislation is necessary for the manufacture and marketing of counterfeit free drug. But still there is no legislation till now for the international sale of counterfeit drug[9]. The International medicinal product Anti-counterfeiting taskforce (IMPACT) was organized in order to create awareness of the counterfeiting in February 2006. It consists of members of WHO, international organizations, drug regulatory authorities, government organizations, and health care professionals[10].

Steps taken by Manufacturer to combat Counterfeiting:

- Protect the supply chain.
- Weigh the balance of public health campaign.

- By use of vary insiders.
- Use the Med watch form[11].

Detection of Counterfeit Drugs:

Counterfeit drugs enter pharmaceutical market due to the existence of grey market, street drug brokers, cross border trading. Counterfeit drugs are spreading through mail services such as FEDEX, UPS, etc. The wide spread wings of counterfeit drugs are narrowed by following steps:

- Strengthening of drug registration in India.
- Empowering drug inspector in sample checking, inspection of packaging.
- Up-gradation of lab facilities.
- Radio frequency identification, holographic labels, IR inks, chemical finger prints, digital serial number identification chromatography.
- Issuing non –clonable ID nanotag for pharmaceutical companies.
- Notification to pharma companies regarding the use of nanotechnology.
- Usage of Scratch off card system via free product like Sproxil's mobile product Authentication.

Raman Spectroscopy:

Raman spectroscopy is widely used in the pharmaceutical field detection of the counterfeit drugs. This technique has been widely used to detect the illicit drugs such as cocaine and heroin. This method is prominently used in the determination of the active ingredients of the drug and excipients in tablets, polymorphism, mapping and imaging. Mapping is used to determine the homogeneity of the active ingredient. Raman spectrum can be recorded without any sample preparations. Raman spectroscopy is applied in the qualitative analysis of various counterfeited drugs especially erectile dysfunction drugs such as Viagra®, Cialis®, Levitra®. The main theory behind it, is the comparison of Raman spectra of the genuine and the counterfeit.[12-15]

In addition to visual inspection, Raman spectroscopy also helps in analysis of the packaging and labeling. But the spectra of the packaging of both genuine and counterfeit exhibit near similarity[16-18.]

Tagging:

Taggants are markers that can be added to the product with the help of the UV lamps or microscope to distinguish the genuine and counterfeit drug. There are four different types of taggants – physical, chemical, biological, spectroscopic. For spectroscopic, inks which are UV absorbers are employed, for biological ink with strands of specific DNA can be used, while for chemical materials that can be detected by IR spectroscopy and X-ray fluorescence can be used and the physical taggants involves the microscopic plastic particles which are visible with only microscope [19-22.]

Radio Frequency Identification Technology:

Radio frequency identification technology (RFID) is the most sophisticated technology in tracing and tracking pharmaceutical supply chain. It utilizes e-pedigree system which stores and retrieves data using devices such as RFID tags. These tags are chips embedded in package which can be activated by the radio sensors that are electronically scanned and stamped. Food, drug and cosmetic act enhances the growth of standards for the identification, validation, authentication, tracking of prescription drugs [22-25.]

CONCLUSION:

India capture one third of counterfeited drug marketing, the responsibility of this lies mainly on drug Regulating Authorities, Judicial entities and all pharmaceutical organizations at national and international level. Counterfeiters are becoming sophisticated by technologies thus on the simple visual inspection of drugs,

counterfeited drugs cannot be detected. Hence it is recommended that raman spectroscopy, Radio frequency, tagging, identification techniques, are suggested as an effective tools for fast detection of counterfeit drugs.

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