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DANGEROUS WORLD OF COUNTERFEIT DRUGS – PHARMACIST’S ROLE AND ITS PREVENTION

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ABSTRACT: Escalating social evil and global problem for pharmaceutical scientist world-wide is counterfeiting of drugs. Fraudulent representation of medication with an intention to deceptively represent its origin, authenticity and effectiveness is a counterfeited faked drug which is a potential massacre. The prominent role of drug is patient life-saving, but a drug being counterfeit encounters additive danger to patient. Global scenario indicates India accounts for one third of counterfeit drugs world-wide, being existence since 1982. It is spreading its roots in top most selling drugs like steroids, anticancer etc. This review provides an insight into the planning of counterfeit-free world by implementation of WHO guidelines, updating training programs for pharmacist, adapting innovating methods. The counterfeiters use sophisticated technology for huge profit and less trade risking for counterfeiting of drugs. This difficult task can be overcome by different diagnostic patterns like digital imaging, radio frequency identification (RFID), holographic labels, infra-red inks, supply chain tracking, chemical fingerprints. In spite of increasing globalization and cross border trading, pharmacists play a major role in curbing the menace of proliferating counterfeit drug by holding the hands of all nations and enlightening a flawless path in pharmaceutical industry.

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INTRODUCTION: Counterfeiting of drug is an age-old practice and dangerous scenario prevailing in the 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 include both branded and generic drugs containing the insufficient active ingredient or wrong or incorrect 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 10%.

The counterfeited drug which has no therapeutic value is the main reason for the prolonged illness, increased spreading of the pathogen, and may also lead to death.

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 people. Recent trends to combat the spreading of the counterfeiting of drugs include radio frequency identification, holographic labels, Raman spectroscopy, nanotags, chemical fingerprints.

Types of Counterfeiting:

- Deceptive – consumer unaware of purchased product
- Non-deceptive – intention of customer to buy the medication owing to low cost.

Reasons for Counterfeiting: The trouble shooting problem of the counterfeiting mainly arises due to the following reasons:

- 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 scenario: India accounts for 35% in fake drug import FDA claims the fake drug consumption may go upto 30% and 40% globally by extending its wings lucratively in the midst of pharmaceutical drugs. India is fast becoming the capital for counterfeit drugs. International policy network (IPN) states 7, 00, 000 deaths from malaria and TB arise in 2010 due to counterfeiting. Contamination of heparin by Chinese counterfeiters in 2007-2008 killed 149 patients in USA. According to WHO reports about \$ 182000 worth of counterfeit drug for diabetes, blood pressure, cancer were seized in china, almost 2000 people were arrested. In 2010 council of Europe drafted mediclme convention constitutes binding international standard for criminalizing manufacture and distinct of counterfeit drug ¹⁻².

Incidences/Influences of Counterfeiting:

- In 1995 in Nigeria about 2500 people died of meningitis epidemic due to inoculation of fake vaccines.
- In 1995 in Haiti about 89 people died on usage of paracetamol cough syrup contaminated with diethylene glycol. In India in 1998 about 30 infants died of paracetamol cough syrup contamination with diethylene glycol.
- In 2001 in India about 660kg of counterfeited drugs and 1000kg of raw material and boxes containing labels of another company were seized.
- In Myanmar in December 2003 approximately 5 million capsules of amoxicillin, ampicillin were seized.
- The wide spread of counterfeit drug is mainly through the on-line pharmacies. FDA has also warned of the 24 websites selling the counterfeited drug.
- The list of drugs mainly counterfeited includes prescription drugs such as anti-infective, antianaemic, antineoplastic and schizophrenic ³⁻⁵.

The examples are Combivir, Lipitor, Lamisil, Epogen, Risperdol, Gamimmune, Trigivir, Sustiva.

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

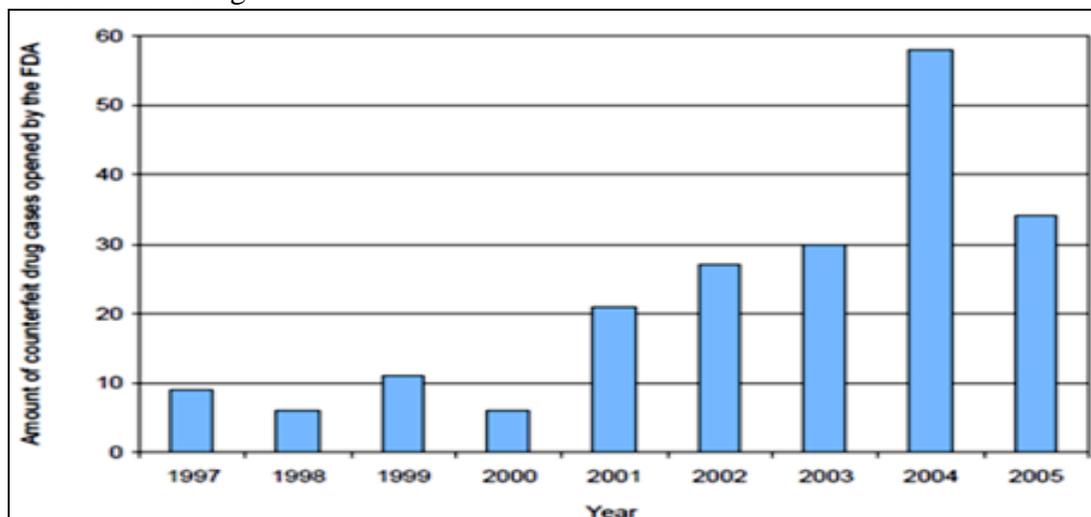


FIGURE 1: NUMBER OF COUNTERFEIT DRUG CASES REGISTERED BY FDA EVERY YEAR

Menace of Counterfeit Drugs:

- It poses a serious risk to public health.
- Eroding public confidence in genuine drugs.
- It is a curse to pharma drugs.
- Violation of rules by the drug manufacturers.
- Engulfment of patient's precious life.
- It evades the ease of detection of counterfeit drugs.
- It supersedes the business and worth of the authentic drug.
- Counterfeiting of 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 professionals⁸.

Role of Legislation to Combat 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 drug⁹. The IMPACT (international medicinal product Anti-counterfeiting taskforce) 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, health care professionals¹⁰.

Steps taken by Manufacturer to combat Counterfeiting:

- Protect the drug supply chain.
- Weigh the balance of public health campaign.
- By use of vary insiders.
- Use the Med watch form¹¹.

Detection of Counterfeit Drugs: Counterfeit drugs enter pharmaceutical market due to the existence of grey market, street drug brokers, cross border trading. According to immigration and custom enforcement (ICE) counterfeit drugs enjoy the journey 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 (RFID), 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 (MPA).

Raman Spectroscopy: Raman spectroscopy is increasingly used in the pharmaceutical field for ease of detection of the counterfeit drugs. This technique has been widely used to detect the illicit drugs such as cocaine, heroin, and ecstasy. This technique is prominently used in the identification of the active ingredients of the drug and excipients in tablets, polymorphism, imaging and mapping. Mapping is used to determine the homogeneity of the ingredient. It is also used in head space analysis of sealed vials. Raman spectrum can be recorded rapidly without any sample preparations. Raman spectroscopy is used in the qualitative analysis of various counterfeited drugs especially erectile dysfunction drugs such as Viagra®, Cialis®, Levitra®. The main principle behind it, is the comparison of Raman spectra of the genuine and the counterfeits.¹²⁻¹⁵



GENUINE VIAGRA TABLETS



COUNTERFEIT VIAGRA TABLET

FIG. 2: COMPARISON OF GENUINE VIAGRA TABLETS AND COUNTERFEIT VIAGRA TABLETS

In addition to visual inspection, Raman spectroscopy also helps in analysis of the packaging and labelling. But the spectra of the packaging of both genuine and counterfeit showed near similarity¹⁶⁻¹⁸.



GENUINE DRUG PACKAGE



COUNTERFEIT DRUG PACKAGE

FIG. 3: COMPARISON OF GENUINE DRUG PACKAGE AND COUNTERFEIT DRUG PACKAGE OF NOROMECTIN

Thus in Raman spectroscopy, with help of presence or absence of bands the counterfeits could be differentiated from genuine samples.

Tagging: Taggants are markers which can be added to the product or packaging with the help of the UV lamps or microscope to differentiate the genuine drug. There are four different types of taggants – physical, chemical, biological, spectroscopic. For spectroscopic inks which are UV absorbers are used, for biological ink with strands of specific DNA can be used, while for chemical materials which can be detected by IR spectroscopy and X-ray fluorescence can be used and the physical taggants include the microscopic plastic particles which are visible with only microscope¹⁹⁻²².

Radio Frequency Identification Technology (RFID): RFID is the most promising technology in tracing and tracking pharmaceutical supply chain. It utilizes e-pedigree system which stores and retrieves data using devices such as RFID tags or transponders. These tags are computer 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 development of standards for the identification, validation, authentication, tracking of prescription oriented drugs²²⁻²⁵.

CONCLUSION: India accounts for one third of counterfeited drug marketing, the responsibility of its erosion lies mainly on Drug Regulating Authorities, Judicial entities and all pharma companies at national and international level. Counterfeiters are becoming sophisticated thus on the simple visual inspection of drugs counterfeited drugs cannot be detected. By using various techniques such as Raman

spectroscopy, tagging, Radio frequency identification techniques counterfeits could be differentiated from genuine samples and could be discarded.

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