IMITATION DRUGS—A HEALTH HAZARD

Vadivel Velmurugan*, Ramadoss Karthikeyan

Vishwa Bharathi College of pharmaceutical sciences, Guntur-522009. A.P.
Vignan pharmacy college, Guntur-522013. A. P.

Summary

The Counterfeit medicines are deliberately and fraudulently mislabelled with respect to identity or source their quality is unpredictable as they may contain the wrong amount of active ingredients, wrong ingredients or no active ingredients. Since from 1990 and is a growing problem-in both developing and developed countries. One prediction is that global counterfeit drug sale will reach 75 billion by 2010. In this review, various factors, reasons, measures and role of pharmacist to counteract the counterfeiting of medicines globally for safeguarding the human lives.

Key Words**;** Counterfeit medicines, Internet sales, Measurements, Role of pharmacist

Corresponding author
Vadivel velmurugan,
Vishwa bharathi college of pharmaceutical sciences,
Perecherla, Guntur-522009. Andhra Pradesh, India.
e-mail; muruganvel75@yahoo.co.in.

Introduction

What are counterfeit medicines?

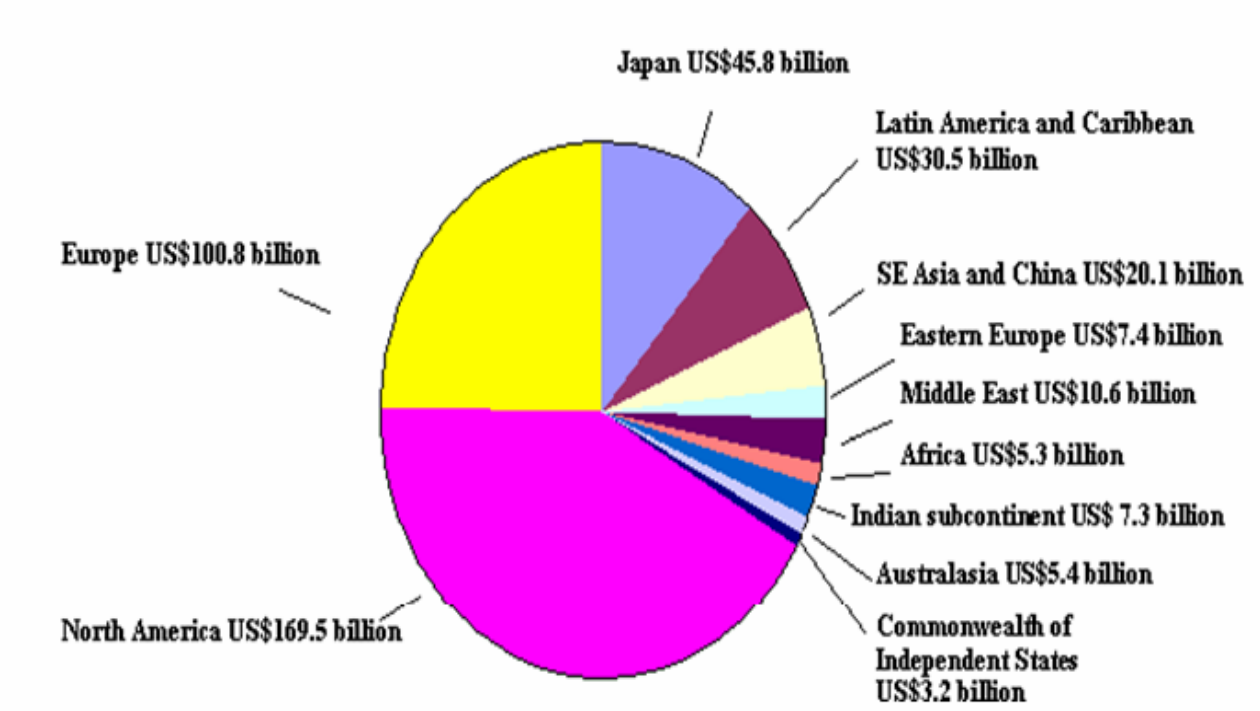
Counterfeit medicines are deliberately and fraudulently mislabelled withrespect to identity or source their quality is unpredictable as they may contain the wrong amount of active ingredients, wrong ingredients or no active ingredients. In all cases counterfeit medicines are manufactured secretly with no possibility of control. Counterfeiting occurs both with branded and generic products. It has been found that counterfeiters copy or imitate existing products but they also manufacture products that are completely invented.[1]

A global public health crisis

Counterfeit medicines represent an enormous public health challenge. Anyone, anywhere in the world, can come across medicines seemingly packaged in the right way but which do not contain the correct ingredients and, in the worst-case scenario, may be filled with highly toxic substances. In some countries, this is a rare occurrence, in others, it is an everyday reality. Counterfeit medicines range from random mixtures of harmful toxic substances to inactive, useless preparations. Occasionally, there can be high quality fakes that do contain the declared active ingredient. In all cases, contents of counterfeits are unreliable because their source is unknown and, by definition, always illegal. Fake drugs can cause harm to patients and sometimes lead to death. Any kind of product can be and has been counterfeited: expensive lifestyle and anticancer medicines, antibiotics, medicines for hypertension and cholesterol- lowering drugs, hormones, steroids and inexpensive generic versions of simple pain killers and antihistamines. In developing countries the most disturbing issue is the common availability of counterfeited medicines for the treatment of life-threatening conditions such as malaria, tuberculosis and HIV and AIDS.

The size of the problem

Currently, the sources of information available include reports from nongovernmental organizations, pharmaceutical companies, national drug regulatory and enforcement authorities, adhoc studies on specific geographical areas or therapeutic groups, and occasional surveys. These sources of information emphasize the complexity of making estimations.Although precise and detailed data on counterfeit medicines is difficult to obtain, Stakeholders estimate proportions ranging from around 1% of sales in developed countries to over 10% in developing countries, depending on the geographical area. That range takes into consideration both regional disparities in the presence of counterfeits, and specific global market value shares. Apart from the huge differences between regions, variations can also be dramatic within countries, i.e. city versus rural areas, city versus city. Counterfeiting is greatest in those regions where the regulatory and legal oversight is weakest. Most industrialized countries with effective regulatory systems and market control , have an extremely low proportion, i.e. less than 1% of market value.



Many countries in Africa and parts of Asia and Latin America have areas where more than 30% of the medicines on sale can be counterfeit, while other developing countries have less than 10%; overall, a reasonable estimate is between 10% and 30% . In many of the countries of the former Soviet Union the proportion of counterfeit medicines is above 20% of market value . Medicines purchased over the Internet from sites that conceal their physical address are counterfeit in over 50% of cases. The estimated ranges do not aim at providing an exact figure but rather an indication of the different possible levels of prevalence around the world. Even one single case of counterfeit medicine is not acceptable because, in addition to putting patients at risk and undermining the public confidence in their medicines, it also betrays the vulnerability of the pharmaceutical supply system and jeopardizes the credibility of national authorities[2].

Counterfeiting grows more sophisticated

Fake medical products are increasingly present even in better controlled markets, as shown in the following examples: April 2007: the United States Food and Drug Administration (FDA) issued an alert about a counterfeit antiretroviral medicine. 2006: The Dutch Healthcare Inspectorate warned consumers not to buy oseltamivir, a flu medication, through the Internet, after counterfeit capsules were found in the Netherlands containing lactose and vitamin C, and no active substance. 2006: In the United Kingdom, officials seized 5000 packets of counterfeitflu medication oseltamivir. 2006: In the United Kingdom a Recall Alert was issued on counterfeit atorvastatin, a cardiovascular medicine. 2004: In France, counterfeit contact lenses were detected by the regulatory authorities after receiving complaints from patients.

Internet sales

In industrialized countries and to some extent in poorer countries, Internet based sales of pharmaceuticals are a major source of counterfeit medicines threatening those who seek cheaper, stigmatized or unauthorized treatments. Some Internet pharmacies are completely legal operations, set up to offer clients convenience and savings. They require patient prescriptions and deliver medications from government licensed facilities. Illegal Internet pharmacies conceal their real identity, are operated internationally, sell medications without prescriptions, and deliver products with unknown and unpredictable origins.

Prescription and over- the- counter drugs[3]

Counterfeit legal drugs include falsely –labelled drugs that were previously expired, drugs where the active ingredient is fraudulently diluted, adulterated, substituted, completely misrepresented, or sold with a false brand name.

Reasons for Counterfeit drugs

- Technology to produce everything from labels to active pharmaceutical ingredients is now widely available.
- Blockbuster "lifestyle" medicines that have created a demand for illicit use cottage industries that use unemployed skilled labour.
- Globalization of markets has made distribution of counterfeit products easier
- The internet provides counterfeiters with easy access to consumers and markets.
- An increase in self-prescribing culture
- Weak regulations, in terms of enforcement and penalities, governing the medicine distribution systems in many countries do not provide a strong enough deterrent for counterfeiters.
- Organized crime has become increasingly involved in counterfeiting as it becomes more profitable with lower risks than other drug crime.

Factors encouraging Counterfeit medicines

- Demand exceeding supply
- High Prices of medicines
- Lack of appropriate drug legislation
- Absence of or weak drug regulation
- Weak enforcement and penal sanctions
- Corruption and conflict of interest
- Inefficient cooperation between stakeholders
- Lack of regulation by exporting countries and within free trade zones.

Reports to W.H.O

- Products without active ingredients - 32.1%
- Products with incorrect quantities of Active Ingredients - 20.2%
- Products with wrong ingredients - 21.4%
- Products with correct amounts of Active Ingredients but false Packaging - 15.6%
- Copies of original products - 1%
- Products with high impurity & contaminant levels - 8.5%

Measures to combat Counterfeit medicines

- Enacting new drug laws or updating existing drug laws for prohibiting counterfeit medicines
- Establishing institutions for the regulation of medicines and clearly setting out in the drug laws, the power, duties and responsibilities of the institutions
- Training of personnel, including enforcement officers, for national drug control
- Making available necessary financial and other resources
- Ensuring that the drug laws are enforced; and
- Fostering international cooperation in the control of pharmaceutical and entering into bilateral and multilateral agreements with other governments and with international organizations such as WHO, Interpol and the world customs organization (WCO).
- Combating counterfeiting of medicines is a shared responsibility to which all interested parties have to contribute. Non-governmental organizations or community based organizations such as consumer associations should be informed about the problem of counterfeiting and the possible presence of counterfeit drugs in the national distribution chain.
- The general public should be encouraged to become involved in the fight against drug counterfeit. Education and information campaigns, directed at the general public should be established and the public should be advised to buy medicines from legitimate sources rather than from peddlers and hawkers or from market places and street.[4]
- Consumers should also be encouraged and advised to report to their prescribers or physicians any lack of improvement in their health status in spite of the treatment or any adverse reactions experienced.

Tips for evaluating product source

- Establish the integrity of the source prior to need wherever possible, establish a list of approved suppliers.
- Require that any alternative source of supply provides the following as a minimum:
- A pedigree back to the previous source

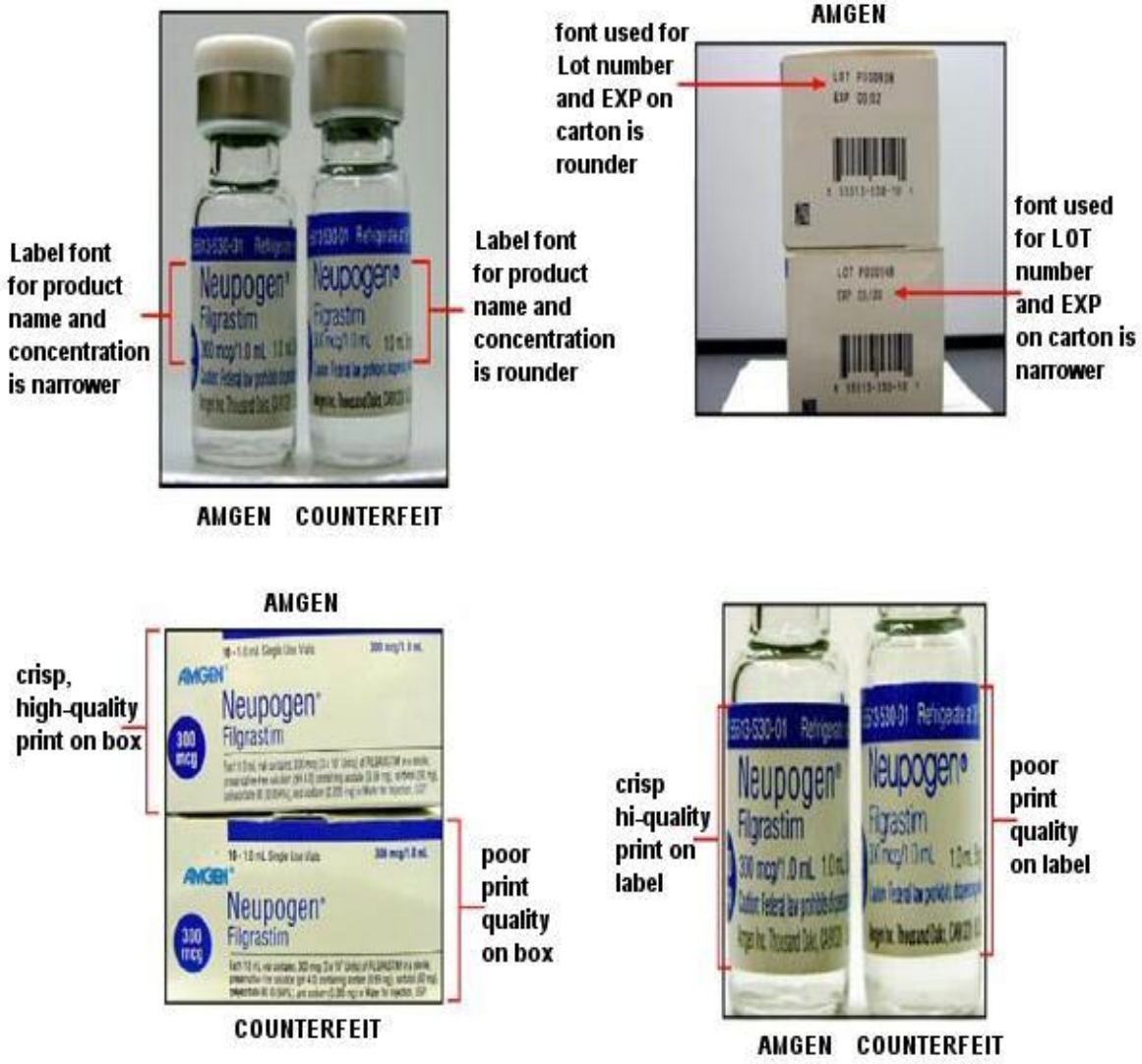
- Certification that is not a diverted product
- Certification that any actions by the alternative source will not alter any original manufacture warranties or guarantees
- Certification that the product has been stored and handled consistent with product labeling requirements.

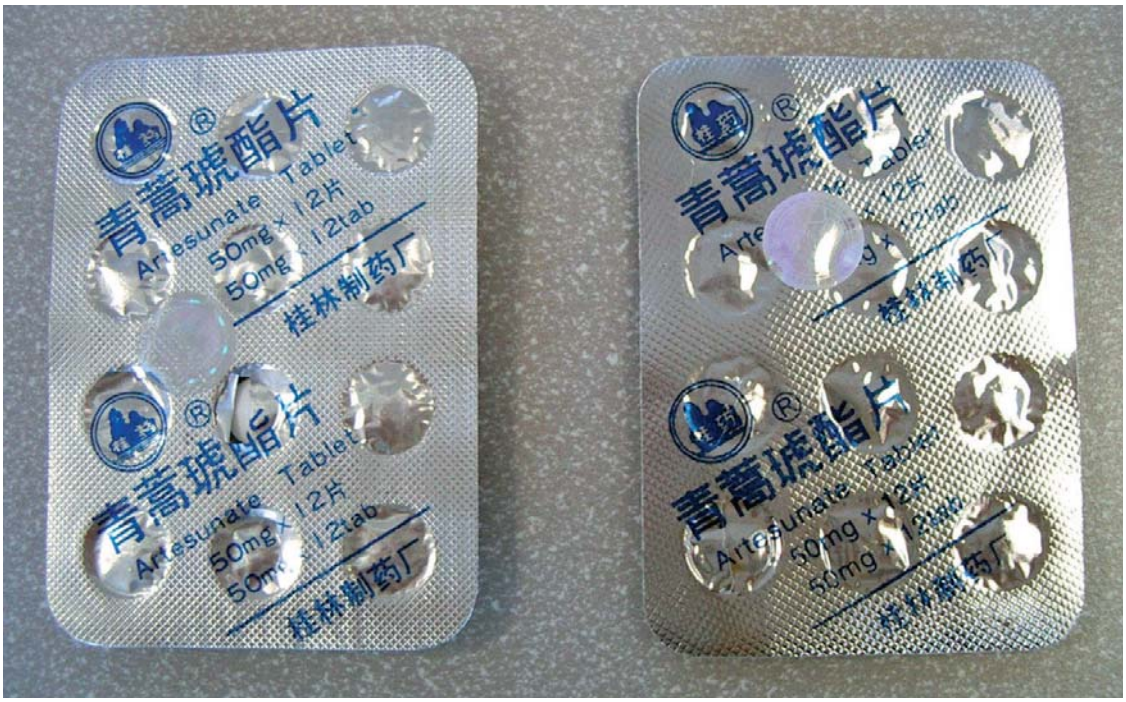
If a product is being offered at an unusually cheap price, treat with extra caution. Consider developing a list of key pharmaceutical products that will not be purchased from sources other than the manufacturer, or authorized distribution channel.

- Look for sings of a removed or switched product label One common practice by counterfeiters is to remove the original label and replace it with a counterfeit label. To do this, they use lighter fluid, acetone or some other solvent which may leave a tacky residue on the container. Also, the label may be faded or disclosured along the edges due to the solvent.
- Look for an altered expiry date Counterfeiters commonly purchase "short-dated" products and then alter the labels.
- Look for subtle changes in the products package (compare with previously purchased products), not withstanding legitimate parallel imported products
- Examine the package for differences in paper texture, size and thickness of the labels, also the gloss or finish on the paper. Look for differences in fonts and font sizes, print colour or raised print. Examine all printing on flaps and surfaces of the box in comparison with previously purchased products where possible. Look for over security features such as holograms or colour shifting inks. Finally, look for breaks or tears in the sealing tape and seals.
- Look for variations in the size of the container not withstanding legitimate parallel imported products Look for differences in container length, diameters and shapes. Examine for variations in diameters of bottle openings or lids. Examine for variations in the thickness of glass or plastic containers and for variations in container colour tints.
- Listen to patients The majority of counterfeit medicines are first detected by patients.

- Compare the physical characteristics of the product Look at colour, tablet or capsule markings, shape and thickness of the medicine. You can also weigh the product to see if there are wide variations.

Difference between Genuine & Counterfeit medicines





Can you tell which one is fake?

How can you avoid buying Counterfeit products?

The best way to avoid counterfeit drugs is to purchase prescription medicines at your local pharmacy from a reputable pharmacist whom you know. Before you fill your presentation online, always see your doctor and get a written prescription first. You should also use an online pharmacy certified by the National Association of Board of Pharmacy (NABP) when you buy prescription medicines online. This association helps ensure the quality and safety of every online prescription. The NABP verified Internet Pharmacy practice sites (VIPPS) program only certifies pharmacies that meet state licensing and inspection requirements. Use the VIPPS certified pharmacy list to choose a VIPPS – approved online pharmacy when buying prescription medicines online. Don't buy medications from online pharmacies that aren't licensed in your country or that offer to write prescriptions or sell medications without prescriptions.

Techniques used to Detect Counterfeit medicines[5]

- Radio frequency identification
- Electronic pedigree
- Raman Spectroscopy
- Energy dispersive X-ray diffraction (EDXRD)
- NIR spectroscopy

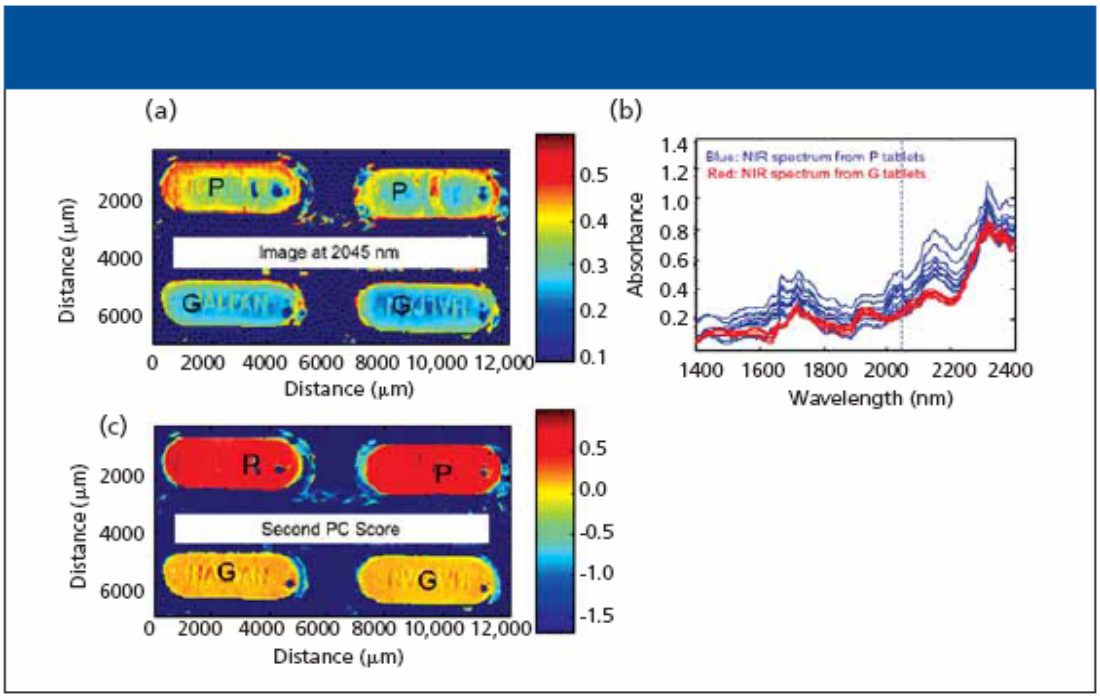
Radio Frequency Identification:
This uses electronic devices to track and identify items, such as pharmaceutical products, by assigning individual serial numbers to the containers holding each product.

Electronic Pedigree:
This system is 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.

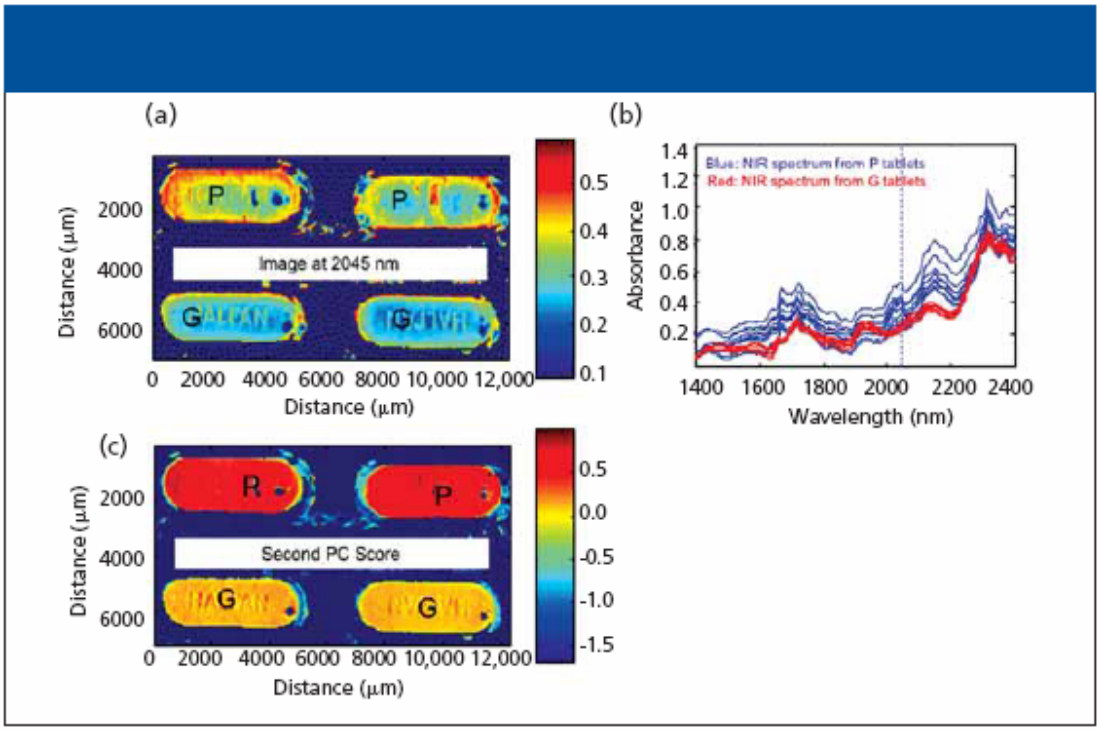
Raman Spectroscopy and EDXRD
Raman Spectroscopy and Energy Dispersive X-Ray diffraction (EDXRD) can be used to discover counterfeit drugs while still inside their packaging.

NIR Spectroscopy
The NIR technique is rapid, precise, non-destructive and costs very little to operate. "Near infrared spectroscopy is a scientific tool which has helped us understand the differences between genuine and counterfeit drugs, even those which look exactly the same to the naked eye". Depending on the choice of operating conditions, multiple samples can be compared simultaneously. Large field of view allows side-by-side comparison of real and suspect products. Furthermore, the ability to put both real and suspect samples in the same image replaces the need to run calibration data on the genuine products. Analysis can be complete in minutes.

Identifying differences between Genuine and Counterfeit medicines by NIR Spectrometer



G – Genuine, P – Paracetamol containing acetaminophine, A – Active Pharmaceutical ingredients



Blister of counterfeit (Above two tablets). Below tablet shows Genuine.

Role of Pharmacist

- Pharmacist should implement the WHO's National and Good pharmacy practices guidelines.
- Should purchase medicinal products only from reputable sources paying regard to the storage conditions before purchaser and subsequent chain supply of medicines concerned.
- Should be alert to differences in quality of packaging, labeling or leaf lets and in physical appearance of medicinal products.
- Should repeat to the state regulatory authority if he / she suspect that counterfeit medicines have been offered or supplied or even in case of absence of expected therapeutic effect.
- Should isolate and with-holds the supply of drug if it is suspected to be counterfeit in investigation to detect the source.
- Should play a major role to convince the Government to use maximum efforts to enforce all appropriate measures to prevent or minimize the manufacturing and distribution of counterfeit medicines.

Conclusion

The counterfeit medicines are health hazard unless it is controlled at the site of he manufacturing only. The drug regulatory authorities should have full force and powers to control them. The sellers should have the validated suppliers list that is the source of supply strictly to be regulated. This problem takes a huge toll in case of emergencies like epidemics because of the large demand. The people also to be educated up to some extent while purchasing the medicines.

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