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Research

Current trends in regulatory actions against misbranding and adulteration

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Abstract

Adulteration has led to many mild, moderate, severe adverse reactions in our body. They Can Be Life Threatening as Well. Adulteration Is Done with The Use of Other Crude Drugs Which Consists of Similar Properties. Every country is the victim of misbranded or adulterated drugs, which result in life threatening issues, financial loss of consumer and manufacturer and loss in trust on health system. For minimizing adulterated and misbranding drugs or not of standard quality drugs, there is urgent requirement of more stringent regulation and legal action against the problem. The adulteration and substitution of crude drug is a burning problem. substitution is helpful in places where unavailability of particular crude drug and or unwanted adverse effects of desired crude drug are there and have a choice of other drug with similar pharmacological effect and less unwanted after effects. But in most cases, it is unacceptable because the conversion of authentic drug into substandard drug may cause variety of adverse effects from mild and moderate to severe life threatening reactions. So, understanding of all the ways of adulteration and substitution is necessary to rectify this illegal act and maximizing consumers' safety. However, India has taken some preventive steps in the country to fight against the poor quality of regulatory organization drugs for protecting and promoting the public health.

Keywords: Adulteration, Crude drug, Misbranding drugs.

INTRODUCTION

An Introduction to Adulteration of drugs

A treatise published two centuries ago (in 1820) on adulterations in food and culinary materials is a proof for this practice as an age-old one. Due to adulteration, faith in herbal drugs has declined. Adulteration in market samples is one of the greatest drawbacks in promotion of herbal products. Many researchers have contributed in checking adulterations and authenticating them. It is invariably found that the adverse event reports are not due to the intended herb, but rather due to the presence of an unintended herb. Medicinal plant dealers have discovered the 'scientific' methods in creating adulteration of such a high quality that without microscopic and chemical analysis, it is very difficult to trace these adulterations.[1]

Adulteration Caused A Variety of Adverse Effects from Mild (Allergic Reactions, Pain, Mood Disturbances Etc), To Moderate (Seizures, Vomiting Etc) To Severe (Coma, Poisoning, Renal or Liver Damage) Serious Complications. Adulteration Is Similar to The Term Substitution Which Means Substituting the Original Crude Drug to Other Substances Which Are Inferior. Adulteration Is Done Intentionally and Unintentionally as Well. Sometimes Adulteration Is Done by Adding A Foreign Substance to Increase the Weight or Potency of The Materials or To Decrease the Price of The Product. Herbal Medicine Has Shown A Promising Result in Healthcare. But, Because Of Adulteration Faith in Herbal Medicine Has Declined. The Substance Which Are Replaced by The Original Crude Drugs Are Called as Adulterants. Basically, Adulteration Is A Process Which Decreases the Quality of Any Food Because Of Addition or Substitution of Foreign Substance. Researchers Have Studied That the Problems Caused in Life of People Are Mostly Because Of The Presence of Adulterants. We Need to Know All the Basics of Adulterants to Minimize the Rate of Adverse Reactions and Learn How the Adulteration Is Been Done to Rectify This Illegal Act.

The unwanted aspect of substitution lies under substandard conditions. Which sometimes become life threatening. Adulteration caused a variety of adverse effects from mild (allergic reactions, fatigue, gastrointestinal upset, mood disturbances or muscle weakness, nausea, pain, and respiratory complaints) to moderate (confusion, convulsions, dermatitis, lethargy or seizures, leucopenia, sensory disturbances, vomiting) to severe (carcinomas, cerebral oedema, coma, intracerebral haemorrhage, poisoning, metabolic acidosis, multi-organ failure, nephrotoxicity, prenatal stroke, renal or liver failure or death) life threatening effects.[2]

AIM AND OBJECTIVES

- To make provision for the prevention of adulteration of food
- To protect the public from poisonous and harmful foods
- To prevent the sale of substandard foods and
- To protect the interests of the consumers by eliminating fraudulent practices.

The fraudulent practice, consisting of providing deliberately misleading information on the packaging for a particular product (hiding information on labelling, evading controversial product or service aspects, etc.) with the objective of benefiting from the confusion generated amongst potential customers.
The main objectives of the act and Rules are to protect the consumer against ill-health caused by adulteration; to restrict and control the use of food and drug additives and to confirm the nutritional standards of the food and drug. These laws are applicable for both kinds of foods whether manufactured indigenously or imported.

Factors That Create Adulteration

1. Deterioration
2. Spoilage
3. Admixture
4. Sophistication
5. Substitution
6. Inferiority

Deterioration

It Is A Process Which Decreases the Quality of Crude Drug with Actual Process of Distillation or Due to Moisture, Heat Etc. It Basically Means Decreasing the Quality of Drug by Any Physical Process.

Spoilage

Decreasing or Change in Quality of Crude Drug by The Attack of Microbes. The Crude Drug Gets Deteriorated. The Food Which Is Spoiled by The Microbial Contamination Leads to Food Poisoning and Other Related Problems.

Admixture

Addition of Similar Looking Substance to Other Original Crude Drugs by The Means of Carelessness, Lack of Knowledge, Or Ignorance. This Factor Can Come Under Unintentional Adulteration.

Sophistication

This Method Can Come Under Intentional Adulteration. It Means Adding an Inferior Substance with Less Therapeutic Activity in Place of Original Crude Drug. The Crude Drugs with Same Look A Like Powder Form Are Adulterated by This Method.

Substitution

Substituting A Different Drug in Place of The Original Crude Drug. This Can Be A Type of Intentional Adulteration. In This Factor the Substance Added Is Not Even Related to The Original Crude Frug. It Can Be Done with Lack of The Original Crude Drug. It Means When One Does Have the Original Crude Drug, He Substitutes It with The Other Substance.

Inferiority

The Original Crude Drug Is Replaced by A Substandard Drug Which Is Cheaper in Cost. The Substandard Drug Resembles the Original Crude Drug by Its Morphological, Chemical and Therapeutic Properties. In This Factor the Substandard Substance Contains Less Percentage of Chemical Constituents Than the Original Crude Drug Which Was to Be Used. Thus, The Substandard Substance Is Called as Inferior.[3]

Types of Adulteration

Adulteration in simple terms is debasement of an article. The motives for intentional adulteration are normally commercial and are originated mainly with the intension of enhancement of profits. Some of the reasons that can be cited here are scarcity of drug and its high price prevailing in market. The adulteration is done deliberately, but it may occur accidentally in some cases. Adulteration involves different conditions such as deterioration, admixture, sophistication, substitution, inferiority and spoilage. Deterioration is impairment in the quality of drug, whereas admixture is addition of one article to another due to ignorance or carelessness or by accident. Sophistication is the intentional or deliberate type of adulteration. Substitution occurs when a totally different substance is added in place of original drug. Inferiority refers to any substandard drug, and spoilage is due to the attack of microorganisms.

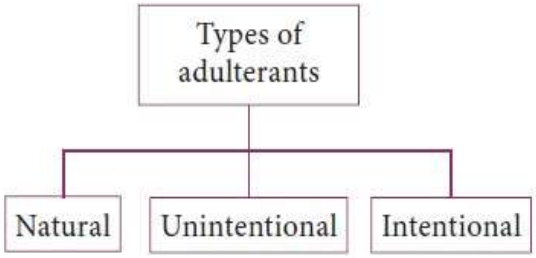

Fig 1: Types of Adulterants

1. Intentional Adulteration or Direct Adulteration
2. Unintentional or Indirect Adulteration

I. Intentional Adulteration or Direct Adulteration

In This Type of Adulteration the Inferior Substance Is Added in Place of The Original Crude Drug Intentionally. The Inferior Substance Means A Substance Which Resembles the Original Crude Drug Morphologically Are Used as An Adulterant. They Have Less Content of Constituent Which Is Responsible for The Therapeutic Activity. This Type of Adulterants Leads to Fraud and Can Cause Greater Adverse Reactions Which Can Lead to Life Threatening diseases like cancer, respiratory problems etc. many problems in india, mostly occur due to this type of adulteration.[4,5]

Intentional adulteration may be due to the following reasons:

adulteration using manufactured substances

- substitution using inferior commercial varieties
- substitution using exhausted drugs
- substitution of superficially similar inferior natural substances
- adulteration using the vegetative part of the same plant
- addition of toxic materials
- adulteration of powders
- addition of synthetic principles

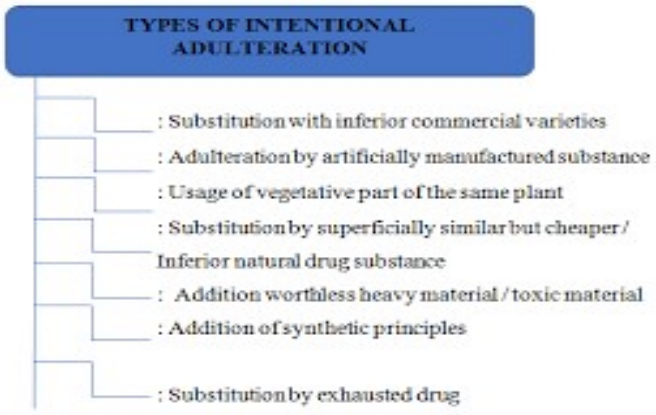

Fig 2: Types of Intentional Adulteration

Types of Intentional Adulteration

Substitution with Inferior Commercial Varieties[6]

In This Type of Intentional Adulteration, The Original Crude Drugs Are Replaced by An Inferior Drug / Substance That Resembles the Morphological Property, Chemical Constituents (But Not Much), Therapeutic Activity of Original Crude Drug. This Is Done as The Substances Are Cheaply Available, And Non-Toxic in Nature.

Adulteration by Artificially Manufactured Substance

Artificial Substances Are Produced or Made in Such type that they look similar to that of the Original Crude Drug. Usage of Vegetative Part of The Same Plant

- Presence of Vegetative Part of The Same Original Crude Drug Comes Under Adulteration Due to Faulty Collection.
- Basically, The Parts of The Plant Attached with The Original Crude Drug Also Is Collected.
- They Look A Like with The Crude Drug So They Aren't Properly Differentiated and Used.
- The Vegetative Part Collected Doesn't Contain Much of Therapeutic Activity or The Therapeutic Activity Is Negligible.

Substitution by Superficially Similar but Cheaper / Inferior Natural Drug Substances

In This Type of Adulteration, The Adulterant's Morphological Character Is Similar to The Original Crude Drug. They May or May Not Be Similar with Their Chemical or Therapeutic Property.

Addition Worthless Heavy Material / Toxic Material

In This Type of Adulteration, The Substance Used in Place of Original Crude Drug Are Toxic in Nature or Else Heavy. To Increase Weight Heave Substances Are Used in Place of Original Crude Drugs.

Addition of Synthetic Principles

Synthetic Substances Are Used in Place of Original Crude Drugs. They Are Prepared Based on Their Therapeutics Properties.

Substitution by Exhausted Drug

In This Type of Adulteration, The Exhausted Constituents Are Used Again After Extraction. This Is Done for The Substances Whose Taste or Appearance Are Not Purely Destroyed and They Are Adulterated by Using Flavouring & Colouring Agents.

II. Unintentional Or Indirect Adulteration

This Type of Adulteration Is Often Done Because Of Lack of Knowledge, Carelessness, Non-Availability of The Original Crude Drug, Confusion Etc. It Doesn't Mean That the Person Who Is the Manufacturer or The Supplier Is Doing It with Bad Intention or To Harm Others. Confusion Occurs Due to Same Morphological Property, Same Look A Like Shape. Lack of Knowledge Is Due to Not Having Information About the Original Crude Drug. Sometimes During Collection Excess Vegetative Part Is Also Collected Without Knowing. So, This Carelessness Also Leads to Unintentional Adulteration. Similarity in Colour of The Crude Drugs Also Leads to This Type of Adulteration.[3]

Unintentional adulteration may be due to the following reasons:

- confusion in vernacular names between indigenous systems of medicine and local dialects
- lack of knowledge about the authentic plant
- no availability of the authentic plant
- similarity in morphology and or aroma
- careless collection
- other unknown reasons

Name confusion

In ayurveda, 'Parpatta' refers to *Fumaria parviflora*. In siddha, 'Parpadagam' refers to *Mollugo pentaphylla*. Owing to the similarity in the names in traditional systems of medicine, these two herbs are often interchanged or adulterated or substituted. Because of the popularity of siddha medicine in some parts of south India, traders in these regions supply *M. pentaphylla* as Parpatta/Parpadagam and the north Indian suppliers supply *F. parviflora*. These two can be easily identified by the presence of pale yellow to mild brown-coloured, thin wiry stems and small simple leaves of *M. pentaphylla* and black to dark brown-coloured, digitate leaves with narrow segments of *F.parviflora*. *Casuarina equisetifolia* for *Tamarix indica* and *Aerva lanata* for *Bergenia ciliata* are some other examples of adulterations due to confusion in names.

Lack of knowledge about authentic source

'Nagakesar' is one of the important drugs in ayurveda. The authentic source is *Mesua ferrea*. However, market samples are adulterated with flowers of *Calophyllum inophyllum*. Though the authentic plant is available in plenty throughout the Western Ghats and parts of the Himalayas, suppliers are unaware of it. There may also be some restrictions in forest collection. Due to these reasons, *C. inophyllum* (which is in the plains) is sold as Nagakesar. Authentic flowers can be easily identified by the presence of two-celled ovary, whereas in case of spurious flowers they are single celled.

Similarity in morphology

Mucuna pruriens is the best example for unknown authentic plant and similarity in morphology. It is adulterated with other similar papilionaceae seeds. *M. utilis* (sold as white variety) and *M. deeringiana* (sold as bigger variety) are popular adulterants. Apart from this, *M. cochinchinensis, Canavalia virosa* and *C. ensiformis* are also sold in Indian markets. Authentic seeds are up to 1 cm in length with shining mosaic pattern of black and brown colour on their surface. *M. deeringiana* and *M. utilis* are bigger (1.5–2 cm) in size. *M. deeringiana* is dull black, whereas *M. utilis* is white or buff coloured.

Lack of authentic plant

Hypericum perforatum is cultivated and sold in European markets. In India, availability of this species is very limited. However, the abundant Indo-Nepal species *H. patulum* is sold in the name of *H. perforatum*. Market sample is a whole plant with flowers, and it is easy to identify them taxonomically. Anatomically, stem transverse section of *H. perforatum* has compressed thin phloem, hollow pith and absence of calcium oxalate crystals. On the otherhand, *H. patulum* has broader phloem, partially hollow pith and presence of calcium oxalate crystals.

Similarity in colour

It is well known that in course of time, drug materials get changed to or substituted with other plant species. 'Ratanjot' is a recent-day example. On discussion with suppliers and nontimer forest product (NTFP) contractors, it came to be known that in the past, roots of *Ventilago madraspatana* were collected from Western Ghats, as the only source of 'Ratanjot'. However, that is not the practice now. It is clearly known that *Arnebia euchroma var euchroma* is the present source. Similarity in yielding a red dye, *A. euchroma* substitutes *V. madraspatana*. The description to identify these two is unnecessary because of the absence of *V. madraspatana* in market. Whatever is available in the market, in the name of Ratanjot, was originated from *A. euchroma.*

Careless collections

Some of the herbal adulterations are due to the carelessness of herbal collectors and suppliers. *Parmelia perlata* is used in ayurveda, unani and siddha. It is also used as grocery. Market samples showed it to be admixed with other species (*P. perforata* and *P. cirrhata*). Sometimes, Usnea sp. is also mixed with them. Authentic plants can be identified by their thallus nature.

Unknown reasons

'Vidari' is another example of unknown authentic plant. It is an important ayurvedic plant used extensively. Its authentic source is *Pueraria tuberosa*, and its substitute is *Ipomoea digitata*. However, market samples are not derived from these two. It is interesting to know that an endangered gymnosperm *Cycas circinalis* is sold in plenty as Vidari. The adulterated materials originated from Kerala, India. Although both the authentic plant and its substitute are available in plenty throughout India, how *C. circinalis* became a major source for this drug is unknown. *P. tuberosa* can be easily identified by the presence of papery flake-like tubers, *I. digitata* by the presence of its concentric rings of vascular bundles and their adulterant *C. circinalis* by its leaf scars and absence of vessel elements.[7]

Misbranding or Mislabelling

Federal Food, Drug and Cosmetic Act (FFDCA) contains provisions on misbranding including some that relate to false or misleading labeling. A device's labeling misbrands the product if:

- Its labeling is false or misleading in any particular;
- It is in package form and its label fails to contain the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;
- Any required wording is not prominently displayed as compared with other wording on the device, or is not clearly stated;
- Its label does not bear adequate directions for use including warnings against use in certain pathological conditions or by children where its use may be dangerous in health or against unsafe dosage, or methods, or duration of administration or application;
- It is dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended or suggested in the labeling; or
- It does not comply with the color additives provisions listed under Section 706 of the FFDCA;
- The device's established name (if it has one), its name in an official compendium, or any common or usual name is not prominently printed in type at least half as large as that used for any proprietary name;
- The establishment is not registered with FDA as required by Section 510 of the FFDCA and has not listed the device as required by Section 510(j) of the FFDCA or obtained applicable premarket notification clearance as required by Section 510(k) of the FFDCA;
- The device is subject to a performance standard and it does not bear the labeling prescribed in that standard;
- There is a failure or refusal to comply with any requirement related to notification and other remedies prescribed under Section 518 of the FFDCA, if there is a failure to furnish any materials or information required by, or requested by the Secretary pursuant to, Section 519 of the FFDCA, or if there is a failure to furnish materials or information relating to reports and records required by Section 522 of the FFDCA; or
- There is any representation that creates an impression of official approval because of the possession by the firm of an FDA registration number.

CONCLUSION

Anyone who adulterates any drug or medical preparation in such a manner as to lessen its efficacy or change the operation, or makes it noxious, knowing that it shall be sold or used for any medicinal purpose, as if it had not gone undergone any adulteration, is said to cause adulteration. It is sufficient if the efficacy of a drug is lessened, it need not necessarily become noxious to life.

Whoever causes adulteration of the drugs shall be punished with imprisonment, which may extend to six month, or with fine, which may extend to one thousand rupees, or both. It may be observed that making as well as selling adulterated drugs is two separated crimes. Even if you have not manufactured the drugs but are only selling them you are liable to be punished for the same.

Any person knowing that the drug or the medical preparation has been adulterated, sells the same or offers it for sale, or issues it from any dispensary, or causes it to be used for medicinal purposes by any person not knowing the adulteration, is said to sell, or offer, or issue from any dispensary an adulterated drug as unadulterated.

The drug or device is misbranded if its labeling proves false or misleading in any particular. The Federal Food Drug and Cosmetic Act ("FDCA") is the federal law that establishes penalties for anyone selling misbranded products in interstate commerce. The FDCA is enforced by the Food and Drug Administration ("FDA").

The FDA has the authority to bring civil enforcement actions against parties suspected of engaging in misbranding, including warning letters, recalls, debarments, seizures, injunctions, and civil penalties.

Serious charges of misbranding could also subject the party to a criminal investigation and result in criminal penalties and jail time.

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