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Herbal Drug Adulteration: A Threat to Safety, Efficacy, and Global Herbal Trade

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Abstract: ***Approximately 80% of the population in developing countries depends on traditional medicines for their primary healthcare needs due to their affordability and accessibility. Historically, medicinal plants were used directly through ingestion or topical application. In modern times, however, these plants are processed and marketed in different forms such as crude drugs, powders, tinctures, teas, capsules, tablets, syrups, and various herbal formulations. Globally, more than 50,000 plant species are utilized for medicinal purposes, with countries such as China and India being major contributors to the diversity and use of medicinal plants. The increasing popularity of herbal medicines has also spread to Western countries, where plant-based remedies are often perceived as natural and safer alternatives to synthetic drugs. Despite their widespread use, the rapid expansion of the herbal medicine market has resulted in growing concerns about adulteration, substitution, and misidentification of medicinal plants. These problems arise mainly due to high demand, limited availability of authentic plant materials, morphological similarities among species, and taxonomic ambiguities. Adulteration involves the mixing or replacement of genuine plant material with inferior, defective, or harmful substances that do not meet quality standards. Such practices may reduce the therapeutic effectiveness of herbal medicines and can sometimes pose health risks. Furthermore, contamination of herbal products with pesticides, insecticides, heavy metals, or synthetic substances presents additional safety concerns. Therefore, proper identification, authentication, and strict quality control measures are essential to ensure the safety, efficacy, and reliability of herbal medicines.***

Keywords: Adulteration, Substitution, Medicinal Plants, Herbal Drugs, Authentication

1. Introduction

The significance of medicinal plants to humankind is undeniable. Since ancient times, people have relied on medicinal plants to maintain health and prevent or treat various diseases and ailments. The therapeutic properties of numerous medicinal plants have been well documented, leading to the development of diverse traditional systems of medicine, such as Ayurveda in India and Traditional Chinese Medicine in China[18]. Medicinal plants also serve as the primary source of raw materials for the preparation of herbal drugs[39, 22, 10, 35]. Approximately 80% of the population in developing countries depends primarily on traditional medicines for their basic healthcare needs[22,42,11] , largely because they are more affordable and accessible[33,18]. In earlier times, medicinal plants were used directly through ingestion or topical application. In the modern era, however, they are commercially available in various forms such as crude drugs, powders, tinctures, teas, capsules, tablets, syrups, and other herbal formulations[4,48].

More than 50,000 medicinal plant species are utilized in the preparation of drugs and health products, with China (11,146 species) and India (about 7,500 species) being the leading contributors[22,11]. The growing interest in herbal medicines is also evident in Western countries, as these remedies are plant-derived, natural, and generally considered safer than many synthetic drugs[17,52]. Notably, about 118 of the top 150 prescription drugs in the United States are derived from natural sources, and over 1,300 medicinal plant species are used in Europe, of which nearly 90% are harvested from the wild[11].The therapeutic efficacy of medicinal plants is mainly attributed to their bioactive secondary metabolites, including alkaloids, terpenoids, steroids, flavonoids, and other phytochemicals, which are responsible for a wide range of pharmacological activities[61].

2. Present Scenario of the Herbal Trade Industry

The global use of medicinal plants as sources of natural health products and herbal drugs has increased markedly in recent years[39]. Over the past few decades, the herbal medicine and dietary supplement sectors have experienced remarkable expansion, evolving into a multibillion-dollar industry that contributes significantly to the global economy[43]. More than 1,000 companies utilize nearly 29,000 herbal substances, generating annual revenues exceeding US$60 billion, with raw materials predominantly sourced from biodiversity-rich regions of Asia, Africa, and South America[21,41,54]. According to the World Health Organization, the herbal product market generated approximately US$14 billion in China in 2005 and about US$5 billion in Western Europe during 2003–2004 (WHO 2008). Furthermore, projections have suggested that the global herbal drug market could reach between US$62 billion and US$5 trillion by 2050[27]. The international trade in herbal products is steadily expanding across both developing and developed countries, reflecting the growing demand for plant-based medicines and natural therapeutic alternatives[24].

3. Cases of Health Threats due to Incorrect Herbal Identification

Several life-threatening cases due to unauthenticated herbal intake have been reported, some of which are outlined below:

1) **Aconite poisoning**- Cases of Aconite poisoning are common in Asian countries due to their wide usage in traditional medicines[7,8]. During 2006-2010, 156 cases of Aconite poisoning were reported in China[6], and 45 cases of Aconite poisoning were reported in Hong Kong alone, of which three proved fatal[62]. Cases of compromised cardiovascular arrhythmia and shock due to aconite poisoning have also been reported in India[28]. Cases of

compromised cardiovascular arrhythmia and shock due to aconite poisoning have also been reported in India[28].

2) In 2011, Gilbert reported that the anti-inflammatory *Stephania tetrandra*, which was used in weight-reducing pills, was substituted with an herbal ingredient from *Aristolochia fangchi* that caused renal failure in more than hundred women taking these pills. *Aristolochia* species, produce aristolochic acids that causes nephrotoxicity and urothelial carcinoma of the upper urinary tract[3,25,45].
3) In 2008, a lady in Singapore showed symptoms of antimuscarinic poisoning after consuming a brew of *Datura metel*, a toxic herb in place of *Rhododendron molle* [31].
4) The prolonged consumption of tea adulterated with *Adenostyles alliariae*, caused severe liver diseases [16]. The adulteration of with *Aconitum*[32,12], *Datura metel* [44] and *Illicium anisatum* [26] have also known to cause neurotoxicity in the body. In 2002, 63 people in Netherlands suffered from nausea, vomiting and general uneasiness, after consuming a herbal tea containing Japanese Star anise (*Illicium anisatum*) [26].
5) Intake of the herbal 'Xenicol', supposed to be a natural weight loss formulation commercially known as "Herbal Flos Lonicerae", resulted severe adverse effects, such as, palpitations, abdominal pain, insomnia and severe gastritis on patients (http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2011/13878a-eng.php). It was later banned by the UK Medicines and Healthcare Products Regulatory Agency (MHRA). As of now, Herbal Medicinal Product (HMP) can be sold in the European Union only after receiving marketing authorization or with THM (Traditional Herbal Medicine) registration[50].
6) A two-month old infant died after consuming a Mexican herb, *Gordoloba yerba*, which is substituted by several species, such as, *Senecio longilobus* (Asteraceae), *Gnaphalium macouni* (Asteraceae) and *Verbascum thapsus* (Scrophulariaceae) [15].

The above mentioned cases strongly reflect the need for unequivocal authentication of any herbal product before it is made available to the consumers so that no such cases appear in future.

Adulteration and Substitutions

The flourishing trade of herbal market is creating situations of pervasive adulterations [54]. Faith in herbal drugs has declined due to such practices [17]. Cases of substitutions and misidentifications are a reality and have been reported in many countries[23,14]. Cases of substitutions and misidentifications are a reality and have been reported in many countries[23,14,41]. Adulteration and substitution practices are increasing because of high demand and less availability of the desired medicinal plant[29]. However, both adulteration and substitution have different roles in the therapeutic action of the herbal drugs. Generally, adulteration is more harmful than substitution as the former can be even life threatening but the latter may or may not be that detrimental. Sometimes, unintended adulterations/substitutions occur because of homonyms, that is, same vernacular name being used for two taxonomically different plants. For example, the name 'Amrita' is used for the herbal drug prepared from both *Tinospora cordifolia* and *Terminalia chebula* [29]. This happens when different workers interpret the ancient text differently, that is, sometimes giving the same Unani and Ayurvedic name to more than one plant and sometimes, giving different names to one herbal drug, that is, synonyms [19].

'**Adulteration**' may be defined as, "mixing or substituting the original drug material with inferior, defective, spurious, spoiled, useless other parts of same or different plant or harmful drug or substance which do not confirm with original standards" [47]. A drug is deemed to be adulterated if it consists, in whole or in part, of any filthy, putrid or decomposed substance (Anonymous, The Drugs and Cosmetics Act and Rule, The Drugs and Cosmetics Act 1940). One of the reasons for adulteration in India is also the undesirable conditions in which these market samples are stored for years and these often contain mixtures of other plant species[17]. There are various reasons of adulteration, species that are morphologically difficult to distinguish, taxonomic ambiguity, fraudulent substitution with cheap, less effective herbals[21]. Listed below are some of the reasons for adulterations:

1) Lack of availability of the desired plant- The populations of many of the medicinal plants are declining due to lack of cultivation or rarity of the species in their natural habitat[35]. *Hypericum perforatum* (St. Johns Wort) is cultivated and used extensively in the European markets but in India, due to lack of its availability, *H. patulum* (abundant Indo-Nepal species) is used in its place[49].
2) Similar vernacular names- In Siddha, 'Parpadagam' refers to the plant, *Mollugo pentaphylla*, whereas in Ayurveda, 'Parpata' refers to *Fumaria parviflora*. Due to this phonetic similarity, traders in south India sell *Mollugo pentaphylla* as 'Parpata/ Parpadagam', whereas in north India, *Fumaria parviflora* is sold as 'Parpata/ Parpadagam'[36]. Authentication of market samples is a must so that no confusion of nomenclature and lack of botanical identification of traded raw drug exists[36].
3) Similarity in colour- Roots of *Ventilago madraspatana* were the source of the red colored herbal, 'Ratanjot', according to the suppliers and non-timber forest product (NTFP) contractors, but more recently, *Arnebia euchroma* is used as its source[49].
4) Similarity in colour and morphology-The medicinal plant, *Mucuna pruriens* (Kaunch beej), is often adulterated with other *Mucuna* species, like, *M. deeringiana* and *M. utilis* due to the morphological similarity of their seeds[49].
5) Ignorance of authentic source- The medicinal plant, *Mesua ferrea* is the authentic source of herbal, 'Nagkesar'. However, market samples have been found to be adulterated with flowers of *Calophyllum inophyllum*. Suppliers lack knowledge about the bountiful availability of *M. ferrea* in the Western Ghats and Himalayas, and therefore collect *C. inophyllum* in its place[49].
6) Inattentive collections- *Parmelia perlata* (Shaileya) is used in Ayurveda, Siddha and Unani but the herbals of this plant are known to be mixed with other species of *Parmelia* like, *P. cirrhata* and *P. perforata* or with *Usnea* species[36].
7) Other unknown reasons- *Pueraria tuberosa* is the genuine source of the herbal, 'Vidari' and it's well known substituent is *Ipomea digitata*. Both the medicinal plants are available in abundance in the Indian subcontinent, still

for no valid reason, *Cycas circinalis*, an endangered gymnosperm, is used in the market samples[49,51].

One major reason of adulteration is the decreased availability of the desired plant due to its over-exploitation. One major reason of adulteration is the decreased availability of the desired plant due to its over-exploitation[38,1]. Sometimes, adulteration is done for monetary benefits by adding adulterants of low and cheap quality to increase the weight of herbals and decrease its price value[40].

There are various types of adulteration, for example,

1) Adulteration with substandard look-alikes- Stigmas of *Crocus sativus* (saffron) are often adulterated with dried flowers of *Carthamus tinctorius* (Safflower)[40], while papaya seeds are used as *Piper nigrum*[29].
2) Adulteration with congeneric species- In this case, the medicinal plant is adulterated with other species of the same genus. In the study performed by Sriram et al. (2010), 24% of the shops were selling other species of *Phyllanthus* in place of hepatoprotective plant, *Phyllanthus amarus*. Similarly, *Berberis aristata*, another important traded plant, is adulterated with other *Berberis* species that may have no therapeutic effect as *B. aristata* [55].
3) Harmful adulterants- Adulterants could be plant toxins, heavy metals like mercury, lead, copper and arsenic or, pharmaceutically active compounds of undetermined concentrations. There have been reports of people suffering with kidney failure, cancer of the urinary system, after consuming such adulterated products[14].
4) Replacement by exhausted drugs- usage of drugs whose medicinally active substance has already been extracted. For example, clove, fennel, etc. are sold after extraction of their volatile oils or are used for adulteration[40].
5) Adulteration of powders- Powders of similar color and texture are often adulterated, for example, *Mallotus philippensis* is adulterated with *Bixa orellana*[29].

Substitutions, on the other hand, are not deleterious, as in this case, a particular herbal is substituted or replaced by another herbal possessing similar therapeutic activity. For example, the common weed, *Cyperus rotundus* is used in place of the IUCN endangered medicinal plant, *Aconitum heterophyllum* that is used to cure fever and diarrhoea. Despite being taxonomically distant, both plants possess therapeutically similar bioactive components[60]. Reports of usage of substitutes have also been documented in the Ayurvedic texts[40]. Any substituent drug to be used is selected on the basis of its similarity in therapeutic action (Karma) and properties (Guna, Rasa, Vipaka and Virya) of the original drug[40], so that the original effect of the drug is not lost. These substituted drugs are commonly called as 'Pratinidhi dravyas', which are simply 'representatives' of the original herbal drug. A list of 'Abhava Pratinidhi Dravyas' are found in 16th-19th century Ayurveda texts, Bhavaprakasha Nighantu[13].The need for substitutions arises because of:

1) Unavailability of the desired herbal- Medicinal plants used in 'Ashtavarga' are not easily available and are mostly substituted, for example, 'Meda' (*Polygonatum verticillatum*) and 'Mahameda' (*Polygonatum cirrhifolium*) are substituted by 'Shatavari' (*Asparagus racemosus*)[34]. (i) Unavailability of the desired herbal- Medicinal plants used in 'Ashtavarga' are not easily available and are mostly substituted, for example, 'Meda' (*Polygonatum verticillatum*) and 'Mahameda' (*Polygonatum cirrhifolium*) are substituted by 'Shatavari' (*Asparagus racemosus*)[34].
2) Geographical disparities- The medicinal plant, *Premna integrifolia* is sold as 'Agnimantha' in north India, whereas, *Clerodendrum phlomidis* (Arani) possessing a similar therapeutic effect is used in south India[40].
3) Undetermined identity- Medicinal plants, *Aralia quinquefolia* and *Ipomea sepiaria* are used as the herbal, 'Lakshmana' [29].
4) Seasonal availability of the herb- *Trianthema portulacastrum* is used in the season when *Boerhavia diffusa* does not appear as some medicinal plants flower in a particular season of the year [40].
5) Cost of the drug- *Crocus sativus* (Kesar), because of its high price is known to be substituted with *Carthamus tinctorius* (Kusum)[29].

There are different varieties of substitutions. Some of these are described below:

1) Usage of different parts of the same plant- Use of roots of *Sida cordifolia* find mention in the classic therapies, such as, 'Balya, Brimhana and Shothahahra' but later scientific studies showed that even the aerial parts of this plants have equal therapeutic effects [46].
2) Using different species- The herbal, 'Gokshura' or 'Gokhura' are derived from *Tribulus terrestris* and *Pedalium murex*. The former is called 'bada gokhura', while the latter is known as 'chhota gokhura'. Both possess similar diuretic, lithotriptic, nephro and hepatoprotective activities[46]. Both *Clerodendron indicum* (Bharangi) and *Solanum xanthocarpum* (Kantakari) have antihistaminic activity and are also commonly used in diseases of respiratory system despite being taxonomically distant[46].
3) Use of species belonging to the same family- Both the species of Datura, that is, *Datura metel* and *Datura stramonium* are used in place of each other due to similar alkaloids present in them that act as bronchodilators and restrain secretion of mucous from the respiratory tract [46].
4) Same vernacular name- *Bacopa monnieri* is the real 'Brahmi' but in North India, *Centella asiatica* is traded as 'Brahmi' and, both of them are used for revitalizing nerve and brain cells and improving memory[30,38]. Due to equivocation in the names of certain medicinal plants, chemical and pharmacological information gets over-lapped[19].

In recent times, there has emerged a concept of **HERBAL DRUG TECHNOLOGY**, which is used to convert the botanical materials into medicines and also standardizes and keeps quality control with appropriate integration of scientific technology and traditional knowledge[27]. The practice of substitution is not wrong. In fact, it should be encouraged as around 300 medicinal plants are becoming endangered[47]. Alternatives for such medicinal plants should be sought. Adulteration, on the other hand is a spurious act whether, done intentionally or unintentionally. Even unrelated plant materials are used in the Indian system of medicines. For example, *Parthenium hysterophorus* (a weed) was found in

Fumaria indica (Shahtara), *Malva rotundifolia* as Brahmi, culm of different grasses as 'Chirayata'[2].

Adulteration always does not pose serious health threats but the adulterants added may be of inferior quality and thereby can be ineffective[9]. Not only identifying the botanicals, but the bioactive component involved in imparting the therapeutic value should also be investigated. Addition of the correct substituent is also important so that the benefit of taking that medicine is not hampered. Not only are adulteration and substitutions a concern, contamination of herbals by insecticides, pesticides, heavy metals or synthetic drugs is yet another challenge[37]. Safety assessment of the herbal drug becomes all the more important because as not all drugs are monoherbal, chances of harmful adulterants would be higher in case of polyherbal formulations. Many researchers, for more than the past two decades have tried to check adulteration and authenticate herbals[59,5,57,56,58,49,20]. According to WHO, fallacious use of herbal medicines is a threat to consumer safety[19]. Thus, it becomes mandatory to follow strict rules or safety protocols for authentication of raw herbal products and should be linked with both national and international trade regulators[54].

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