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ETHICAL LANDSCAPE OF HERBAL MEDICINES

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ABSTRACT: Remarkable numbers of people have a false belief in naturally obtained herbal medicines as they are safe to use, omitting the fact that herbal medicines have pharmacological action like allopathic medicines. Many plants are poisonous and there is less safety data available for herbal medicines. Adverse drug reactions associated with herbal medicines are overdose and toxicity, herb interactions and hypersensitivity reactions. The potential side effects, the quantity of intake, risk of herbal medicines should be adequately developed. Herbal medicines, which are well studied, are not tested in the groups of the population like pediatrics, pregnant or breastfeeding women, geriatrics, or people with multiple co-morbidities. Many herbal medicines are under-examined, and their harmful effects sun known. The patients cannot be intimated properly about the risks and benefits unless the physician fails to show evidence about potency or side-effects of herbal medicines. The high demand for standard herbal medicines puts pressure on high-demand species and plants, leading to the extinction of selected species and plants. It is essential to take measures of the above-mentioned ethical challenges to hold respect for individual preferences and needs-preventing harm to patients, local communities, and the environment. It can be concluded that the ethical scaffolds can facilitate a consistent and structural approach. Production of herbal medicines is a global phenomenon, so the application of ethical scaffolds has worldwide importance which is based upon the values of care, respect, honesty, and fairness.

INTRODUCTION: Botanical medicine or phytotherapy involves the use of a plant's seeds, berries, roots, leaves, bark, or flowers for medicinal purposes and how plant-based medicines are used varies greatly around the world is known as herbal medicine [1]. A balanced and moderate approach to healing and individuals who use them as home remedies and over-the-counter drugs spend a huge amount of money on herbal products are often viewed as herbal medicine [2].

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The awareness of their possible side effects is minimal, making it difficult to identify the best, most appropriate therapies and promote fair use [3]. The lack of definite and complete knowledge about the composition of extracts is another black box of herbal-based treatments [4]. This article reviews the ethical challenges and approaches to herbal medicines.

Extraction: The extraction of desired chemical components from plant materials for further isolation and characterization is the first step in studying medicinal plants [5]. Pre-washing, drying plant materials or freeze-drying, grinding to obtain a homogeneous sample, improving analytic extraction kinetics, and increasing sample contact is among steps [6]. Since plant extracts are made up of various bioactive compounds or phytochemicals,

separating them is a difficult task in the detection and characterization of bioactive compounds. TLC, column chromatography, flash chromatography, Sephadex chromatography and HPLC are common isolation methods used to get pure compounds. The structures and biological activity of the pure compounds are then determined [7].

Techniques used for extraction:

1. Thin-layer chromatography.
2. High-performance liquid chromatography Immune assay.
3. Phytochemical screening assay.
4. Fourier-transform infrared spectroscopy (FTIR).

Standardization of Raw Materials: To standardize the raw materials in the production of herbal medicine, the nature of the trait of the plant product is more important. There is a significant problem in the Indian herbal industry. In typical ayurvedic formulations, 600 medicinal plant products, 2 minerals, and 50 animal products are used in the department of Ayush.

There is a possibility of contamination of medicinal plants during their growth, collection, and processing. 50% of the companies face problems during the collection of raw materials. 36% of companies face problems in quality due to the adulteration of raw materials. The major problems in Indian herbal products are substitution, adulteration and heavy metal contamination [8, 9].

Manufacture of Herbal Medicines: In the manufacturing of herbal products, the complicated part is the storage and processing due to the complex trait of the obtained plant products or extracts.

Premises and Equipment:

Storage: Separate areas are to be maintained to store herbal medicine and those areas are to be maintained well to protect from insects and other animals, including rodents. Preventive action should be done to avoid mold development and fermentation in the stored herbal products or medicines. Separate rooms are to be maintained for the raw materials and the final finished or approved herbal medicinal products to avoid unnecessary mixing. To guard the nature of the product, the storage areas to be selected with good air circulations and maintaining some free space in between the products helps in avoiding deterioration of the products. The storage areas are to be well maintained and to be kept clean. Monitoring the humidity, temperature, protection against light in the storage areas from time to time are the necessary actions.

Production: During the process of sampling, weighing, mixing, and processing herbal medication preparation, certain arrangements are to be made to keep clean to avoid cross-contamination by using certain techniques such as dust extraction and dedicated premises. The release of undesirable substances during the production process can be only avoided when the filtering material and types of equipment used in the manufacturing are compatible with the extraction solvent so that the product won't be affected for the time being and to be noted that the production of herbal medicine is to be in according to the guidelines of GMP and marketing authorization dossier. Quality assurance is an important factor in checking the active substance or the product from time to time by audit trails. It is also important for a manufacturer to check the quality of raw materials used in the production by knowing their collection practices and agricultural environment.

Documenting the Procedures or Selection Criteria Involved in the Manufacturing of Herbal Products:

- The binomial name of the plant is to be known.
- Details of the source of the plant.
- Part of the plant used in the manufacturing if, in case of using dried plant products, the drying system should be specified.
- A complete data about the herbal substance is to be described along with its macroscopic as well as microscopic description are to be specified clearly. Identification tests for active herbal compounds are to be indicated.
- The water content for herbal substances. Assay of constituents.

- Test for toxic metals. Test for foreign materials.

Adulteration or substitution or foreign particles such as metal glass pieces, animal parts, stones to be avoided by examining the products and having a clear picture of every container containing the herbal products are to be labelled with the instructions and the ingredients used. Since medicinal plants are so diverse, sampling them requires careful attention and experience. The documents can be used to identify each batch. A plant material comparison sample is needed, particularly in those cases where the herbal product is not included in any member state's pharmacopeia [10].

Toxicity and Adverse Drug Effects of Some Herbal Medicines: In many countries, without any safety and toxicological evaluation, many herbal medicines are put into the market [11]. Another problem is that many countries lack effective machinery to regulate manufacturing practices and quality standards. The herbal medicines are available to people without a prescription, and many products' hazardous effects are recognized. The concept that herbal drugs are safe and devoid of adverse effects is misleading [12]. The adverse effects and interactions are may due to the wrong identification and wrong labelling of herbal plants.

Herbal Plants and Adverse Effects:

- Aritlochiafanechi- Development of sub-acute interstitial fibrosis of kidney which is known as 'Chinese herbs nephropathy [13].
- Ephedra-Associated with many cardiovascular and CNS adverse effects [14].
- Tussilapofarfara-This plant has been demonstrated to be hepatotoxic [15].
- Allium Saativum- diaphoresis, light-headedness, dermatitis, spinal epidural hematoma [16].
- Hyyericumperforatum (St. John's wort) - depressive symptoms, allergic reactions, fatigue, dry mouth, hyperesthesia, myasis, syndrome of dyspnoea, photosensitivity [17].
- Pipermethysticum- headache, dizziness, GI discomfort, localized numbness after oral ingestion, dry and redness of the eye [18].

Storage: Medicinal plant storage and conservation aim to prevent quality degradation by preserving aspects such as temperature and humidity, as well as to prevent microorganisms, fungi, and insects from attacking the plants during the storage time. The metabolic rate of medicinal plants must be decreased during storage to prevent them from deteriorating. This can be accomplished by lowering the product's water content to safe levels, cooling, or storing medicinal plants in a changed atmosphere.

In terms of medicinal plant production, the post-harvest process is critical. Drying and storing the stock is critical in this step to preserve the physical and chemical characteristics of the fresh factory. If not done correctly, drying will compromise the content of active ingredients, whereas improper storage can result in material degradation, whether for physical or biological reasons [19, 20]. Medicinal plants are sometimes processed for long periods before being used as a raw material to produce a variety of goods [21]. On the other hand, Improper storage can cause physical, chemical, and microbiological changes [22, 23].

The storage time for medicinal plants is one year, according to ANVISA [24]. However, if the producer offers a longer-term validity, it could be approved.

Clinical Research on Herbal Drugs a Need: Herbal supplements have been an essential part of public health care all over the world [25]. Several studies on conventional and complementary medicine have shown that they are widely used [26]. Clinical studies of these herbal drugs, on the other hand, should be promoted to broaden their approval. It is recommended that single and reliable batches of formulations be used to show the effectiveness of clinical trials [27]. While herbal practitioners and adherents do not need clinical trials, it has become essential for large-scale acceptance and survival on the international market alongside modern medicines [28].

Recommendation for the Enhancement of Ethical Practice in Herbal Medicine: The influencing factor worldwide in the usage of herbal medicine is all about the unequal distribution of the quality and availability of herbal medicines. To enhance the usage of herbal medicine, case safety

reports and adverse events are reported to WHO to monitor the safety of all drugs [29]. The quality on comparing with the conventional medicines differs with the herbal medicine so, a practitioner needs to describe evidence gap or variations in reliability; this data helps the medical professionals, nursing and pharmaceutical programs to improve their standard in ethics through the development of safety profile data's and also make easy to communicate or intimate the patient about the usage, adverse events or precautionary action about the medicinal products [30]. Researches in herbal medicines are limited. Ethical standards in herbal preparation can only be obtained with more research. Distinguishing with the existing conventional treatment can reveal information about the products' safety index and efficacy, cost [31].

Ethical Challenges on Herbal Medicines: Finance, ethical standardization, quality control of the product, design of the study, regulatory requirements before initiating the new drug to conduct clinical trials are considered to be issues for the research on herbal drugs. Operational guidelines on regulatory requirements were issued by World Health Organization in 2005 to support the clinical trials on herbal products [32]. The product standardization process is the main challenge in herbal medicine preparation. It is necessary to avoid microbial contaminations and mycotoxins contamination. To standardize the manufacturers of the raw materials, use traditional, physical, chemical and physiochemical methods as the researches are less in India because the enterprises operating is in small and medium scale. Market-based studies are also less because of less or no reference standard product availability [33].

People believe that herbal products are safer to use because they are naturally obtained plant products. But it should be known that herbal preparation has pharmacological effects like synthetic Pharmaceutical preparations. So, plant species can be toxic and can also produce severe adverse effects, including overdose effects, herb interactions, allergic reactions and contamination with other products; hence using or avoiding those products with drug safety profiles can eliminate the adverse effects [34]. The herbal products interact with the results of laboratory tests [35].

In many countries, people get unlicensed herbal products upon using them; they may expose to an adverse reaction to be educated that all the herbal products are to be taken under the supervision of the practitioners [36]. To enter into the market, the products should undergo the various phases in a clinical trial, but most herbal products do not undergo any clinical trials because the usage of herbal products is from hundreds or thousands of years back. The dosing in paediatrics, pregnant women, lactating women, elderly patients and people having multiple co-morbidities and potential side effects of herbal preparations are to be developed and studied [37, 38] since there are fewer researches on herbal preparation their harmful effects are unknown and also lead to danger [39, 40]. Environmental factors and communities also challenge the herbal products on their production and delivery [41]. Raw materials uncontrollably obtained from the wild are considered superior products and have high demand, resulting in the extinction of certain plant species [42].

CONCLUSION: To conclude, there are various limitations in the production and management of herbal medicine. The first and foremost is the lack of information on the safety index of the medicines. The medicines cannot be given to the patients without knowing the adverse effect or toxicity that leads to danger. The usage of herbal medicines in an increased demand may also lead to the extinction of the plant species. There is less information or research on herbal medicine, so more research on herbal medicine preparation and their efficacy, adverse effects, interactions, contraindications and dosing in the different populations at various phases in clinical trials were to be done.

Complete supervision should be done from the collection of raw materials; storage areas are to be done. The herbal products are to be kept away from microbial contaminations and to be provided with well-aerated storage space. The standard procedure should be maintained in the production of herbal medicines as well a complete data regarding the plant should be kept maintained if; in case any adverse events occurred it should be recorded from time to time.

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