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Review Article

Traditional and Herbal Medicines: Opportunities and Challenges

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ABSTRACT

Background: Since ancient times natural herbs were extensively used for the treatment and prevention of various ailments and in past few decades, due to an extensive research in traditional system of medicine various herbal medicines have been developed for the prevention and treatment of diseases, which are environmentally, organically safe and inexpensive. Indian sub-continent has a good capability to tackle the task of meeting the worldwide demand for such products due to its rich wealth in case of herbal medicine. Historically, Indian people conventionally played a vital role in the development and management of these biological sources and also preserve their pertinent data that were accumulated via trial and error over centuries. **Objectives:** Due to tremendous global resurgence in traditional and alternative healthcare systems, the market for herbal medicines has grown at an impressive rate and therefore has great economic importance. However, the primary barriers to the expansion of herbal medicine include biodiversity loss, over-exploitation and improper use of medicinal plants, industrialization, biopiracy, and a lack of regulation and infrastructure. For the expansion of herbal medicine usage in the twenty-first century, conservation, proper research based on traditional knowledge, quality control of herbal medicine, and correct documentation are required. **Methods:** The desired and encouraging testifying items for systematically evaluated reviews and meta-analysis (PRISMA) standards were opted. A literature exploration was accomplished utilizing SCIENCE DIRECT, SCOPUS and GOOGLE SCHOLAR to locate articles for the present scenario about traditional and herbal medicines. **Conclusion:** The availability and type of conventional medicine safety and effectiveness data are far from sufficient to fulfil the requirements required to support its use globally. This review paper examines the restrictions and issues associated with conservation, science and technology, regulatory constraints, potential usage of herbal medicines, the drug production industry, safety and efficacy, and the prospects for traditional remedies on a nationally and internationally scale.

Key words: Traditional medicines, Herbal medicines, Healthcare system, Regulatory constraints, Traditional Knowledge, Quality control.

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INTRODUCTION

Herbal therapy, an oldest kind of medicare known to humans and involves the use of entire plant or plant part, for the treatment of various debilitating diseases[1,2] or to support good health.[3] Various herbal formulations are available that have been shown to alleviate the symptoms of a variety of ailments, ranging from depression to cold and flu.[4] WHO has prescribed specific criteria for the evaluation of safety, potency and quality of herbal remedies? It was estimated that around 80% of people throughout the world are using herbal formulation as a primary health care system[5] and is tremendously increase day by day, due to toxicity and adverse reactions associated with modern allopathic drugs, which has also led to rapid rise in herbal drug manufacturers.[6] Herbal products have gained wide acceptability as valuable agents like antimicrobial,[7] antifertility,[8] antidiabetic, antiarthritic, antiageing, antidepressant,[9] sedative, antispasmodic, antianxiety, anti-inflammatory, analgesic,[10] vasodilatory, anti-HIV, hepatoprotective,[11] treatment of cirrhosis, acne, asthma, menopause, impotence, gall stones, migraine, alzheimer's disease chronic fatigue, and memory enhancing activities.[2]

Natural herbs were extensively used for the treatment and prevention of various ailments since ancient times. Based on pros and cons in this field leads to the generation of new herbal remedies which are beneficial for health, with no or minimal side effects.[12] The collected rich knowledge about natural products has progressively developed into various systems including traditional Indian medicine, European medicine, Japanese Kampo, traditional Chinese medicine,[13] or traditional Arabic and Islamic medicine and folk medicines, which includes not only herbal treatments but also pharmaceuticals derived from minerals and metals e.g. Mercury, Gandhaka (purified sulfur oxide), Gold, Silver etc. or Animals e.g. Ivory, Antler of deer, horns of animals etc. or Physical procedures (Panchkarma).[14]

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In Indian traditional medicinal system, Ayurveda is the most oldest (6000 BC) and best organized traditional health care system still practiced which include prophylactic and therapeutic measures as the key components.[15] Charak Samhita and Sushrut Samhita (100–500 BC) are the two oldest known Hindu texts which describe the detailed classification, pharmacological and therapeutics characteristics of around 700 plants.[16] In southern part of India, Siddha system of medicine was originated which dates back to approx. 3000 BC-2000 BC.[17] Hippocrates laid the basics of Unani system and later by Galen and was introduced in India by Arabs and Persians in eleventh century.[18]

OPPORTUNITIES

Globlization: Traditional health care system is gaining popularity and is still increasing worldwide due to public curiosity about herbal drugs and its marvelous acceptance for their beneficial properties with least or no side effects against various challenging health related problems. 60% of world's population now utilizes herbal/conventional remedies as primary curative agents for the management of elevated temperature due to malaria. 80% African people, 30-50% Chinese, 48% Australian, 70% Canadian, 80% Germans, 42% USA and 39% Belgium and 76% French people prefer herbal/alternative medication as first choice for treating various ailments.[19] In San Francisco, London and South Africa, 75% HIV positive/AIDS patients use herbal medicines. In terms of health professionals and low-cost, the status of using herbal products are steadily increasing and countries like Malaysia now spent more on prime health care medicines than allopathic drugs.[20]

It is estimated that the majority of people in developing countries rely on traditional goods as their primary mode of Medicare, and therapeutic applications, which include the use of herbs, are treasured as an intrinsic part of those countries' cultures.[21]

Herbal treatments have also been extensively adopted in many industrialised nations, and are now gaining extreme importance in Europian Union, Australia, North America and in United Kingdoms.[22]

Factors Influencing Accelerated Herbal Medicine Acceptance and Self-Medication

The latest revival of public curiosity in herbal preparations has been ascribed to numerous factors such as:

- Efficacy of plant medicines,
- Increasing interest of consumers in alternative medicines and natural therapies.
- Erroneous trust about the superiority of herbal remedies over manufactured products,
- Inadequate or ineffective results from conventional medicines and trust on efficacy of herbal product.
- Expensive cost and adverse effects of most pharmaceutical medicaments.
- Enhancement in the safety and quality of herbal medicines by incorporating latest scientific technology.
- Patients' treat herbal medicines as alternative treatment, believing that their physician doesn't identified their problem properly.
- Self-medication[23]

In addition, the advertising policies and the hard work by numerous producers and their legislative bodies have extremely propelled these merchandises into spotlight. Consumer's awareness regarding herbal product was prominently improved by using mass media like radio and television broadcasts[24]

For normal or healthy growth and development, people of every age are advised to take herbs or herbal products. For example children consume herbs for their important dietary content. To manage stress and prevent or slow aging in young people and older person use herbal products due to its anti-aging or revitalizing properties. Women use herbal products due to its slimming and beautifying property.[25]

This helps to explain why herbal medicine sales are increasing and account for a sizable percentage of the worldwide medication industry. As a result, India has a fantastic

Government support for Promotion, gradual integration of ITM

In India, promotion of traditional medicines is supported by secured government policy which includes planned research development related to traditional herbs. Ministry of AYUSH is responsible for general education, governance, regulation, growth and development of traditional system of medicines in India and abroad. The budg *et al* lotted for such ministry also increases gradually over the years. In 2017-18 the budg *et al* lotted was 1428.7 crores, which was more than double than that in 2013-14.[26] The various objectives of AYUSH includes

- To deliver cheap AYUSH services and drugs which are harmless and potent?
- To guarantee the readiness and authenticity of raw materials as essential by pharmacopoeial standards and to increase the value of AYUSH pharmaceuticals, for domestic and/or export purpose.
- Utilization of AYUSH in healthcare system and national programmes, to build a large infrastructure of dispensaries, hospitals and physicians.
- To produce opportunity for the growth and development of Indian Systems of Medicines and application of their potential, power and revival of their glory.

Policies articulated by AYUSH for healthcare system include

- Addition of numerous traditional drugs (*i.e. Ayush Ghutti, Bal Rasayana*, *Soubhagya Shunthi*, *Ajwain Ark*, *Pudina Ark*, *Punarnavadi Mandoor* and *Tel Ksheerbala.*) in the Nationwide Reproductive and Child Health (NRCH) Programme.
- To find various methods for in cooperation of AYUSH remedies in systems like ICDS-AYUSH, Janani Suraksha Yojana (JSY-AYUSH), early breastfeeding, growth monitoring of children, ante and post natal care, etc
- In cooperation of AYUSH drug (*i.e. Punarnavadi mandoor*) for treating of anemia during pregnancy.
- Certify the availability of AYUSH remedies to principal healthcare centers.
- Use of AYUSH physicians in National Reproductive and Child Health and Population stabilisation projects.
- Using the Indian system of traditional medicine's accessible resources in community healthcare projects (NRHM). Instituting Ayurveda physicians and paramedics, for example.
- Promoting Indian Traditional system of medicines globally by collaborating and establishing research in foreign institute and also by conducting seminar and conferences.
- Center for Research on Indian Systems of Medicine (CRISM) an Indo-US joint center opened by AYUSH in 2008 at the University of Mississippi in the United States.
- Organizations of India providing various progrmmes related to Ayurveda for the students of various foreign countries like Japan, Italy, Russia, USA, Australia, Netherlands, South Africa, Canada,

Brazil, Germany, Hungary, Ukraine, France, Poland, Switzerland, Sri Lanka etc.

- In the field of Ayurveda education, therapy, and research, India and Russia have signed a Memorandum of Understanding.[27]

Opportunities in field of Research, industry, education and practice

The current time hot area of research on traditional medicines is based on preclinical or clinical studies, exploration on standardization and development of herbal products. Conventional herbal remedies is being intensively researched, developed, and promoted by a variety of government and private research facilities, organisations, and universities.

1. Central Council for Research in Ayurvedic Sciences,
2. Central Council for Research in Unani Medicine,
3. Central Council for Research in Siddha,
4. Central Council for Research in Yoga and Naturopathy,
5. Council for Scientific and Industrial Research (CSIR),
6. Central Drug Research Institute (CDRI),
7. RRL, Jammu.

Council for Scientific and Industrial Research and its related laboratories are engaged in developing novel herbal drugs or preparations. In this field, significant advancements have been made by Central Drug Research Institute (CDRI) which include:

- Gugulipid an anti-hyperlipidemic and anti-atherosclerosis drug was developed and marketed by CDRI (Guglip®, Cipla Ltd).[28]
- Antimalarial drug "arteether" a semisynthetic derivative of artemisinin, marketed under trade name E-Mal by Themis Chemicals Ltd., Mumbai.[29]
- Saponins rich local spermicidal cream "Consap" from *Sapindus mukorossi*.[30]
- Hepatoprotective agent Picroliv an iridoid glycoside was developed, which is a mixture of 60% picroside I and kutoside isolated from *Picrorhiza serrate*.
- Memory enhancer herbal preparation of plant *B. monnieri*.[31]
- Gum resin, a NSAID isolated from *Boswellia serrata* was commercialized by RRL Jammu under trade name (Sallaki® Gufic).

Various CSIR labs throughout the country have created several herbal ache relievers, antifungal treatments, and anti-dandruff hair products. Recently, scientists from CSIR-NBRI and CSIR-CIMAP collaborated to develop BGR-34, an anti-diabetic medication.[32] An attempt has been initiated to discover new formulations and new drugs, on the project called "Golden Triangle partnership" among AYUSH, CSIR and ICMR.

Based on traditional information, global pharmaceutical firms and scientists furnished with latest scientific knowledge and technology in order to rediscover herbal plants as a supplier of novel drugs. New techniques and technologies have changed the evolution of drug discovery from herbal plants and turned into a vital tool for the analysis of traditional medicines. Using latest instruments and methods in research has helped to separate and develop novel phytoconstituents found in conventional formulation or plants.[33] Therefore, these novel methods became an important device to assess and to retain the standards of traditional preparations, discovering new medications, determining mechanisms, pharmacokinetic and toxicity profile and also used in synthetic and semisynthetic procedures for the manufacturing of natural constituents.

Ayurveda, an oldest and well renowned health care system around the world and for the invention of novel drugs, traditional knowledge is a fundamental path.[34] Reverse pharmacology, based on the data obtained from scientific observations and clinical trials, new preparations are discovered as a result of this process. Reversing the routine from 'laboratory-to-clinic' to 'clinics-to-laboratories' is a major component of reverse pharmacology. In this process safety and effectiveness of the preparation becomes a subject of validation and is helpful in determining superior and safer leads.[35]

Industry

In India, above 10,000 industrialized units are present for traditional medicines and make around 1 billion US dollars net income using ISM and Herbal systems. AYUSH manufacturing units statistically showed steady annual growth in drug production since last two decades. Ayurvedic preparations are available in both classical forms (tablets, powder, medicated oil, decoction, fermented products and medicated ghee) and new drug forms like lotions, capsules, syrups, liniments, ointments, granules and creams etc. The manufacturing process in this field is regulated by Drugs and Cosmetic act (1940) and rules (1945). GMP as well as GLP for Indian system of medicines have been defined by the governing authorities, which to be followed by organizations, involved in the manufacturing of traditional and herbal drugs.[36]

Education and Practice

CCIM (Central Council of Indian Medicine) is tangled with regulation of education and training of Traditional health care system and observed a prominent rise in AYUSH training institutes since last two decade. In India, there were around 500 AYUSH undergrad campuses with admittance capabilities of over 25,000 in 2013. National Institute of Ayurveda (Jaipur), Institute of Post Graduate Teaching and Research in Ayurveda (Jamnagar), National Institute of Unani Medicine (Bengaluru), National Institute of Siddha (Chennai), All India Institute of Ayurveda, are some of India's top traditional medicine educational institutions. Various programs like Diploma Courses, Bachelor Degree, PG, PhD, Doctor of Medicine (MD) and Doctor of Surgery (MS) in different branches of traditional health care system are being offered by various organizations.[37]

In India, there are about 3100 AYUSH hospitals with 57,056 beds and above 26,000 AYUSH dispensaries are available to provide the primary healthcare services throughout the country. In Indian subcontinent, the ratio of doctor to patient is 1:1700 if just only allopathic physicians are considered, and it will increase to 1:800 on addition of AYUSH professionals, which is much better than WHO recommendation of 1:1000. Currently in India, desperate scarcity of allopathic doctors exists particularly in rural and distant places; however the practitioners of AYUSH are far more common in rural and distant places.[19]

Since past few decades, traditional medicines are gaining interest all over the world due easy accessibility, variety, religious/social acceptability, flexibility, lack of adverse effects and inexpensiveness.[38] These features provide an opportunity to incorporate such therapeutic agents in prime health services to assist the well-being of public. It is not, however, simple. Various methods have been designed for the integration of traditional medicine in primary healthcare services. A series of experiments or evaluations had demonstrated the significance of conventional treatments in chief Medi-care services.[39]

Traditional remedy plays a significant role to avoid common ailments like skin disease, injuries, fever, high BP, dehydration, liver disease, diabetes etc. in rural areas of West Bengal.[40] Similarly in Meghalaya, traditional remedies play an important role in the prevention/management of common diseases.[41] A study demonstrated the potency of Ayurvedic multimodal in osteoarthritis management; and suggested an alternative of NSAIDs in such treatment.[42] Combination of Ayurveda

with allopathic system of medicines for the treatment of osteoarthritis was also explored in various tertiary care hospitals, which was found to be efficacious in terms of minimizing the clinical manifestations, enhancing well-being and diminishing the negative effects of allopathic ache relievers. Ayurvedic curative therapies can be readily incorporated with conventional chemotherapeutic drugs and are found very effective in reducing the adverse reactions of chemotherapeutic agents and also improve patient's health.[43] Herbal remedies are essential in the management of common health related issues like fever, upper respiratory tract infection, dysentery, diarrhea, worm infestations, anemia, hepatitis, certain liver problems arthritis, gynecological diseases along with various communicable problems like malaria and HIV.[44]

Traditional and herbal medicines and Economy

Ayurveda industrialists are encouraging awareness about the efficiency and ability of traditional systems of medicine, disappointment with Allopathy, synchronized adverse effects, Government support, increasing R&D ventures, etc.

The WHO's Beijing proclamation on herbal products has sparked interest for the implementation of traditional health care services. Government support, growing eCommerce and growing demand has led to the development of Ayurveda and various nutrition industries for the serving the world population.

Due to growing incidence and prevalence of chronic diseases like arthritis, cardiac problems, allergy and others, the clinical practitioner prefer herbal formulations for the treatment of such diseases and also due to least side effects and lack of effectiveness of modern allopathic drugs.

Zandu Pharmaceutical Works Ltd, Hamdard labs, Baidyanath Group, Vicco Labs, Charak Pharma, Emami Group, Dabur, Patanjali Ayurved Ltd., etc. are some of the top traditional system providers. Dabur is India's largest firm, with a lion's share of the Indian Ayurveda market.

Asia Pacific region like India, Myanmar, Sri Lanka, Indonesia, Pakistan and others are known for the major contribution in ayurveda market due to their rich source of traditional herbs and among which India being the biggest industry, contributes nearly $1 billion in industrial price. In 2016, India exports Ayurvedic medicines of worth 64 million USD around the world and is expected to grow at a CAGR of 14% during 2019-2024 due to its massive potential for cultivation and export of medicinal plants. India is the leading exporter of Psyllium, Senna, powder and leaves of henna, gymnema, jojoba seed, garcenia and myrobalans.

The United States, Kazakhstan, the United Arab Emirates, Nepal, Ukraine, Japan, the Philippines, Kenya, and Mauritania are the top ayurvedic marketplaces. Due to the growing demand for natural medications and therapies, Europe, followed by France, Germany, and the United Kingdom, is the third largest market.

CHALLENGES

Influence of regulatory policies on status and safety of herbal medicines

The majority of the complications connected with the incorporation of herbal medicines have been observed to arise mostly as a result of certain governments classifying these goods as foods or dietary supplements. Virtually, herbal preparations do not require any evidence of quality, potency and safety before marketing. Hence the quality testing and manufacturing standards tend to be less challenging or organized in case of herbal medicines and even practitioners of traditional medicines in some cases are not registered or licensed. As a result, the safety of traditional and herbal remedies became a prime consideration for both the national medical experts and the public generally.[45]

Herbal remedies and associated products are launched without any required safety or toxicological assessment in most countries, due to lack of adequate tools to monitor quality control and manufacturing procedures. Such preparations are frequently reaching consumers with no need for a prescription and without recognizing potential risks associated with a herbal medicine.[46]

Based on definition and regulations applied on food and herbal preparations, in different nations, a medical herb may be classified as a meal, a therapeutic food, a nutraceutical, or an herbal cure. Therefore introducing herbal medicines in national drug regulation is a serious trouble and is also confusing both for the patients and consumers.[47] For example, in US, The Dietary Supplement Health and Education Act (DSHEA) of 1994 govern natural remedies. A dietary supplement, by definition, is a material that contains a "dietary element" for ingestion, which incorporates vitamins, minerals, herbal products, and other phytochemicals from extra toxicity studies if the herb was accessible on the market before to 1994.[48] In various countries the regulatory knowledge on herbal products is often not pooled between regulating experts and pharmacovigilance centers.[49]

In 1940, traditional and unconventional medicines were introduced in India under the Act of Drug and Cosmetic Act 1940 and Drug and Cosmetic Rule, which was amended in 1959 and traditional Indian system of medicines[50] are included in the act by the Govt. The initial committee was recognized in 1962, since various specialists panels for different ISM were recognized time to time. In 1969, Unani, Ayurveda and Siddha were introduced as separate chapter under the act 13 of 1964 and was modified in 1983, 1987, 1994 and 2002 with some substitutions.[51] In 2006 and 2008 various guidelines for the evaluation and investigation of ISM drugs was granted under the 1945 Drug and Cosmetic Rule. In 1970, Central Council of Indian Medicine (CCIM) was established, responsible for developing and implementing certain norms in ISM, including as curriculum and syllabi (i.e. Unani, Siddha and Ayurveda).[52] The Sowa Rigpa medical system was subsumed into CCIM in 2012. In 2013, The Indian Medicine and Homeopathy Department (ISM & H) was founded with the goal of establishing the ISM and the Dept of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) was renamed as the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH). In 2014, however, a distinct AYUSH ministry was established.[53]

Challenges Related To Herbal Drug-Allopathic Drug Interaction

Various herbs contain a varied number of active phytoconstituents with different pharmacology, having their own metabolism and binding property. These drugs may also interact with the allopathic drugs which include pharmacokinetic or pharmacodynamics interactions. Herbal drug interaction increases with narrow therapeutic window allopathic drugs e.g. Garlic and ginger enhances bleeding in warfarin-treating patients by hindering platelets and elevating the chances of bleeding.[54] Other examples of herbal drug interaction are

1. Ephedrine interacts with beta blockers and MAO inhibitors thus increasing and prolonging sympathomimetic effect (hypertensive crisis).[55]
2. Valerian interacts with sedatives – increased CNS depression.[56]
3. Ginseng interacts with MAO inhibitors increased GABA metabolism and increased dopamine levels.[57]
4. KAVA interacts with Acetaminophen, azole antifungals increase hepatic toxicity.[58]

Challenges associated in quality control of herbal drugs

The purity of raw ingredients incorporated in the manufacturing of botanical products depends both on core (genetic) elements, and elements like ecological circumstances, good agricultural, and good collection practices (GACP), comprising selection of crop, cultivation and collection process. Since it is the mixture of all this issues, it is difficult to execute quality control of raw ingredients.[49] According to good laboratory practice (GLP), good manufacturing practice (GMP) and quality control of the raw material is necessary which can be obtained by implementing SOP during procurement of raw materials, which include proper identification, quality, storage, sanitation and cleaning methods of the crud material.[59]

Quality of the final herbal product is often a big challenge, especially with mixture herbal products due to the various challenges in determining the presence of all the herbs or raw material. Therefore the overall necessities and procedures for quality control of final products persist significantly more complications than for other pharmaceuticals. On the recommendation of WHO, institutions for quality assurance and control measures are established which governs GMP for herbal products, licensing and labeling programs for production, trade and promotion of these products in countries.[60]

***Processing and harvesting issues*:** Poor quality of herbal medications is caused by haphazard collecting, ineffective agriculture practices and propagation processes, ineffective harvesting procedures, and a lack of processing technologies.[61]

Adulteration: substitution of the original crud drug material other than the original drugs. The substitution may be unauthentic, substandard, flawed, damaged, unusable parts of same or different plant.[62] Adulteration can be carried by two ways:

- Direct or intended adulteration
- Indirect or unintended adulteration. For example:

1. With synthetically manufactured substances, e.g., adulteration of nutmeg along with basswood, beeswax with colored paraffin.
2. With substandard quality substances, e.g., *Ailanthus* as an adulterant for *Belladonna, Piper nigrum* is an adulterant for papaya.
3. With poisonous materials or drugs, e.g., Pieces of amber colored glass in colophony, limestone in asafetida, lead shot in opium, white oil in coconut oil, cocoa butter with stearin or paraffin.
4. Adulteration of powders, e.g. powder liquorice or gentian admixed with powder olive stones, under the name of cinchona etc.[63]
5. Contamination of herbal drugs with Heavy metals: Research conducted by various universities concluded that many herbal formulations contain dangerous quantity of heavy metals including lead, arsenic, mercury etc.[64]
6. Contamination of herbal formulations with synthetic medicines: U.S. FDA has found that certain herbal supplements were adulterated with available synthetic drugs like sildenafil, warfarin, indomethacin, alprazolam, estrogen etc.

To control production and sale of herbal drugs or products in India, various legislative and governmental agencies are placed. Chapter IVA in 1940 Drugs and cosmetics Act pronounce guidelines for production, packing, labeling and trade of herbal remedies. Timely modification of the act is important for the advancement in Ayurveda, Siddha and Unani drugs and the latest supplement in this chapter was published in March 2013.[36] A separate board was also formed named as Ayurveda, Siddha and Unani Technical Advisory Board (ASUDTAB), who deals with technical matters involved in the regulation of ASU drugs. Similarly The Ayurveda, Siddha, and Unani Drugs Consultative Committee (ASUDCC) was also established to provide guidance on how to ensure uniformity in the implementation of the Drugs and Cosmetics Act, 1940 (which governs herbal drugs) across India.[65] GMP for Ayurveda, Siddha, and Unani pharmaceuticals was declared in 2000 under Schedule 'T' of the Indian Drugs and Cosmetics Act, 1940 and Rules, 1945. Because heavy metals are common in traditional medicines, recommendations were given for evaluating traditional formulations for heavy metal content.[66] Other criteria include the inclusion of a valid scientific name on the label, drug intake under supervision of a doctor, raw material records, additives with their respective standards, heavy metals testing, and the specification of an expiry date for traditional remedies.

Pharmacopoeial Laboratory of Indian Medicine was designed in 1970, to confirm regulation and evaluation of traditional medicines. Other government-approved laboratories are also involved in the establishment of pharmacopoeial standards, the preparation of monographs, and the development of SOPs for traditional medicines. Pharmacopoeial boards in conventional healthcare institutions are in charge of setting criteria for product quality, authenticity, and potency, as well as approving medication formularies. Pharmacopoeial Laboratories, Central Council for Research in Ayurveda and Siddha (CCRAS) laboratories, Central Council for Research in Unani Medicine (CCRUM) laboratories, Council for Scientific and Industrial Research (CSIR) laboratories, and a number of other publicly owned laboratories are engaged in the monumental task of regulating and securing the quality, standard regimens to ensure the quality and safety of polyherbal formulations.[67]

Challenges associated in monitoring herbal safety

Due to the significant increase in herbal product consumption over the last several decades, research has been conducted to monitor the good benefits as well as probable negative effects, as well as to provide scientific proof of therapeutic effectiveness and safety of herbal medicines.[68] The various adverse effects due to ingestion of herbal remedies are probably due to various factors like mistakenly using wrong species of plant, adulteration, unrecognized medicines, toxic or hazardous contaminated drugs, over dose and misuse of medicinal herbs either practitioners or buyers.

Adverse action analysis in the case of herbal products is much more complex than in the case of conventional pharmaceuticals; therefore, the evaluation of safety of medicinal herbs has become a critical concern for buyers, regulatory advisors, and medical practitioners.[69] It is also accepted that assessment of safety is complicated by various issues like geographical origin of crude material, various handling methods, administration route, challenges and interaction with other prescription drugs.[70] Moreover, authentication and collection of herbal material for therapeutic treatment poses a peculiar challenge due to lack of awareness and/or poor emphasis on the importance of taxonomy and documentation by manufacturers of herbal plants.[71]

It is critical to approve the most often used scientific nomenclature (including scientific synonyms) for herbal plants in order to eliminate the confusion caused by trivial names. For example, *Artemisia absinthium* L. has 11 distinct common names. 7 of the most popular names have nothing in common with biological name.[72]

Heliotropium europaeum (heliotrope) is frequently mistaken with *Valerian officinalis* due to common names (garden heliotrope). As a result, providing the actual biological name of the plant, the component utilised, and the manufacturer's name, as well as adverse medication responses to herbal remedies, is critical. To successfully monitor the safety of medicinal herbs, botanists, phytochemists, pharmacologists, and other significant players will need to work together.[73]

Challenges related to clinical research of herbal medicines

Studying herbal drugs poses numerous challenges that need to be addressed before documenting a novel drug for carrying large phase III trials, which includes issues related to the economic, moral, quality control, study plan and the regulatory necessities. In 2005, an operational strategies was issued by WHO regarding regulatory necessities which support scientific trials of herbal products.[60]

In randomized clinical trials (RCT), blinding is the best method that reduces bias and eliminates placebo effects. This process is usually conducted in a double-blind manner i.e., neither the analyst nor the patient is aware of the therapy allocation. However in herbal preparations, it is hard to uphold double-blind, as this curative process entails a multifaceted therapy approach including lifestyle, listening, counseling, explaining, and nutritional recommendations as well as suggesting herbal remedies. Therefore, single blinding can be used in which only the analyst but not the patient are aware of the therapy allotment.[74] Other factors that may affect the outcome clinical research and should be considered are:-

- The selection of controls: Because comparator comparability is essential if the study is meant to offer evidence of a specific impact of the herbal medication, controls are chosen to be as similar to the intervention group as feasible. Selecting a matching control for some natural substances, like as ginger, that has a unique odour, might be difficult.
- Calculation of sample size is essential in order to conduct a clinical study.
- It has been recognized that occupational harmonization is necessary. This is particularly true in herbal product studies, where the therapist plays an important role.[75]

REGULATION

In China, India, and Korea, traditional system of medicines are approved in national health scheme, which include endorsement for clinical trial and for marketing. This system of medication is also getting same reputation as modern pharmaceuticals. For the approval, the data required for the application of drug registration include overall product data, medicinal data, pharmacological/toxicological data, and experimental data and became compulsory not only for producers but also for marketers which is certified by local drug regulatory authorities.[47]

Both the producers and the governing bodies are equally responsible for the quality assurance of herbal drugs.[76] Governing bodies created strategies on various facets of quality pledge, dossiers, data assessment and evaluation of post marketing compliance of merchandises with the stipulations set out by the manufacturers as well as compliance with GMP.

***Infrastructure related issue*:** Absence of well-trained personal, advanced appliances, employment of latest techniques and capability to manufacturing instrument locally are some serious issues.

***IPR and biopiracy*:** Biopiracy is a major issue in traditional health-care advertising. As a result, the credibility of traditional information is critical for our prospects. According to an inquiry, 90 therapeutic herbs have been registered in the US patent and trade mark official directory, with Indian herbal plants accounting for 80% of the references, including Kumari, Mustaka, garjara, atasi, jambira, kharbuja, and tamraoarna.

***Irrational use*:** Herbal medicines have no side effects or interactions, which is not the case. As a result, irrational preparation of these medications poses a number of problems, delaying the marketing of herbal goods.

Other difficulties include unethical herbal drug training, a shortage of qualified practitioners, the disclosure of changeable and confusing data, a lack of financing, a lack of motivated marketing and labelling, a lack of understanding of herbal medications, and the embracing of international advertising of such items. A key worry is the lack of biodiversity protection and the preservation of traditional herbal remedies.[77]

CONCLUSION

Medicinal herbs have played an essential role in human health care systems all over the globe, not only in sick situations, but also as a possible material for maintaining adequate health. It is obvious that the herbal sector has the potential to make significant contributions to the global economy. With the growing usage of herbal products, future global labeling practices should appropriately address quality concerns. Standardization of techniques and quality control data on safety and efficacy are necessary for an understanding of herbal medicine use. The lack of knowledge on the social and economic advantages that may be obtained from the industrial usage of medical plants has been a serious obstacle to the establishment of medicinal plant-based enterprises in underdeveloped nations. Herbal medicines are undergoing extensive investigation in order to be incorporated into new drug delivery methods. The implementation of these novel approaches to traditional medicines will result in increased bioavailability, decreased toxicity, sustained release action, and protection from GI degradation, which cannot be achieved using conventional drug delivery systems because of the large molecular size, poor solubility, and degradation of herbal medicines in GI media. Constituents such as flavonoids, tannins, and terpenoids have shown improved bioactivity and focused effect at low therapeutic doses when integrated into new methods. As a result, the integration of herbal medicines into new delivery systems is also being used on a large scale.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; **WHO:** World health organization; **HIV:** Human Immunodeficiency Virus; **AYUSH:** Ayurveda, Yoga, Unani, Siddha and Homeopathy; **ISM:** Institute for supply management; **ITM:** Indian Traditional Medicine; **NRCH:** Nationwide Reproductive and Child Health; **JSY:** Janani Suraksha Yojana; **ICDS:** Integrated Child Development Services; **NRHM:** National Rural Health Mission; **CRISM:** Center for Research on Indian Systems of Medicine; **CSIR:** Council for Scientific and Industrial Research; **CDRI:** Central Drug Research Institute; **RRL:** Jammu Road Research Laboratory Jammu; **NSAID:** Non-steroidal anti-inflammatory drugs; **NBRI:** National Botanical Research Institute; **CIMAP:** Central Institute of Medicinal and Aromatic Plants; **ICMR:** Indian Council of Medical Research; **GMP:** Good manufacturing practice; **GLP:** Good laboratory practice; **CCIM:** Central Council of Indian Medicine; **R&D:** Research and development; **CAGR:** Compound annual growth rate; **DSHEA:** The Dietary Supplement Health and Education Act; **MAO:** Monoamine oxidase; **GABA:** Gama amino butyric acid; **GACP:** Good agricultural, and good collection practices; **U.S. FDA:** United States Food and Drug Administration; **ASUDTAB:**

Ayurveda, Siddha and Unani Technical Advisory Board; **ASU drugs:** Ayurveda, Siddha, and Unani Drugs; **ASUDCC:** Ayurveda, Siddha, and Unani Drugs Consultative Committee; **CCRAS:** Central Council for Research in Ayurvedic Sciences; **CCRUM:** Central Council for Research in Unani Medicine; **RCT:** Randomized clinical trials.

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GRAPHICAL ABSTRACT

SUMMARY

In this environment, when traditional medicine and knowledge are on the point of extinction, it is imperative that we act forcefully and diligently to conserve and preserve our history. The regulatory organisations are now responsible for monitoring the regulated and quality flow of herbal products and facilitating their development to clinical trial stages. If governing bodies collaborate closely with academia, R&D institutions, scientific centers and laboratories, healthcare, industry, and pharmacy colleges, the aim will not be far away.

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