

# A Review on Challenges and Opportunities in Herbal Medicine

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**Abstract-** *Herbal medicines and their formulations have been used for thousands of years across both developing and developed nations. These remedies represent therapeutic knowledge accumulated over generations through traditional medical systems and practices. In recent years, herbal treatments have gained increasing acceptance worldwide due to their perceived effectiveness, safety profile, and minimal adverse effects. India possesses an extensive and valuable history of traditional herbal practices, especially through its indigenous medical systems such as Ayurveda, Siddha, and Unani, which primarily rely on herbal and herbo-mineral preparations. These formulations may include a single plant or a combination of multiple herbs, which makes standardization and quality control more challenging compared to conventional pharmaceutical drugs. Furthermore, the available scientific evidence regarding the safety and efficacy of many traditional medicines is still inadequate to meet global regulatory requirements. This review aims to highlight the major barriers and concerns related to conservation of medicinal plants, advancements in research and technology, production and quality control, safety and clinical validation of herbal products, as well as the emerging opportunities for herbal medicine at both national and international levels.*

**Keywords:** *Herbal Medicines, Traditional Medicines, Ayurvedha, Siddha, Unani, Medicinal Plants, Herbal Formulations, Safety and Efficacy, Regulatory Challenges, Herbal Drug Development, Quality Control and Standardization.*

## I. INTRODUCTION

Herbal medicine or phytomedicines is related to use different parts of medicinal plants. Herbalism has a deep tradition of its application outside of conventional medicine. In the past decades, it is now becoming mainstream as advancement and developments in analysis and quality control along with advances in clinical research.[1] As per the World Health Organization (WHO), phytomedicine or herbal medicine is the sum total of the knowledge,

skill, and practices based on the theories and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement, or treatment of physical and mental illness.[2] Traditional herbal medicines are naturally occurring, plant-derived substances with minimal or no requirement of industrial processing that has been used to treat illness within local or regional healing practices.[3] Herbal medicines have been widely used for the beneficiary of mankind for the thousands of years much before the development of allopathic drug system. Phytomedicines initially from crude drugs include tinctures, tea, poultices, powder, and other herbal formations. The utilization and application of plants for healing purposes predate human history and lead to the origin of much modern medicine. Research and studies based on clinical, pharmacological, and chemical studies of these herbal medicines, which were derived predominantly from plants, were the only basis of most early medicines such as aspirin (willow bark), digitoxin (from foxglove), morphine (from the opium poppy), quinine (from cinchona bark), and pilocarpine (jaborandi). Herbal medicines still cover up about 70–80% primary healthcare treatment of persons in the developing country of the world. The percentage for primary health-care treatment with herbal medicine is high because of the general belief that herbal drug has no side effect instead of being cheap and easily available. As per the WHO, the use of phytomedicines exceeds to that of conventional medicines by about 3 times.[4]

## II. CLASSIFICATION

Classification of herbal medicines by the WHO on basis of their origin, evolution, and forms of the current use is as follows:

1. Indigenous herbal medicines
2. Herbal medicines in systems
3. Modified herbal medicines
4. Imported products with a herbal medicine base.

#### 1. Indigenous Herbal Medicines:

Indigenous herbal medicines include those which were historically used in local community, tribal community or in region and are very well known due to its long usage by the local or specified population in terms of its composition, treatment and dosage. It must be easily available and can be used freely as well as easily by the local community or in that region.

#### 2. Herbal Medicines in Systems:

Herbal medicines in systems have been in use since many years and are documented with their special theories and concepts, and these are accepted by the countries.

#### 3. Modified Herbal Medicines:

Modified herbal medicines have been achieved by executing modification in shape, form including dose, dosage form, mode of administration or application, herbal medicinal ingredients, methods of preparation, and medical indications.

#### 4. Imported Products with Herbal Medicine:

Imported products with herbal medicine basically cover up all imported herbal medicines including raw materials and products. Imported herbal medicines must be registered and marketed in the countries of its origin.[5] We have different systems of traditional medicine, and philosophy regarding the medicine and practices of each are influenced by the prevailing conditions, environment, and geographic area within which it was evolved. [6,7]

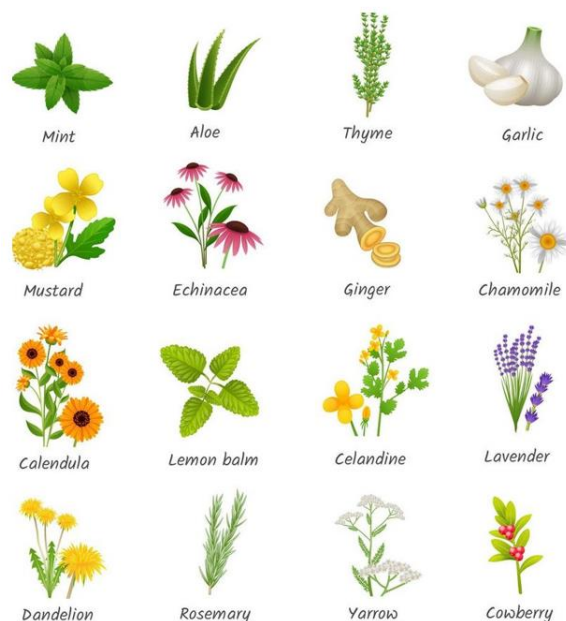


Figure I.1 Different types of Medicinal Plant

### III. IMPORTANCE OF HERBAL MEDICINE

Plant-derived medicinal active constituents have earned a reputation as “people’s drugs” as they are easily available, claimed safe and secure, easy to prepare methods, and are gradually displacing standard restorative treatment frameworks in numerous nations as improvements in quality control and clinical researches way public opinion in their support. Because of the negative effects of contemporary medications, the inability of existing therapies to address chronic conditions, and germ resistance, herbal products have seen a huge resurgence in popularity in recent years. Herbs or herbal products are utilized by a vast number of people for basic healthcare requirements, according to the WHO. Herbs, herbal materials (such as plant parts), herbal preparations, processed and finished herbal products, and active ingredients make up herbal medicine [8]. Traditional herbal remedies are utilized by 80% of the population in numerous Asian and African countries for primary healthcare, but complementary and alternative medicines (CAMs) that mostly consist of herbal items are used by 70–80% of the population in many rich countries. “Kampo” medications are prescribed by 60–70% of allopathic doctors in Japan (largely composed of herbal products). Plant-based medications are

prescribed by over 70% of German doctors. Natural resources contribute to more than 70% of modern pharmaceuticals in India, and several synthetic equivalents have been generated from prototype compounds derived from plants. According to statistics, natural materials are used in more than 60% of cancer treatments on the market or in research. Plants are currently used to make around 80% of antibacterial, immunosuppressive, cardiovascular, and anticancer drugs. Over 70% of the 177 anticancer drugs approved are based on natural or mimetic chemicals [9]. According to the WHO, Regional Office for the Americas, herbal medicine is used by 71% and 40% of the populations in Chile and Colombia, respectively. In Australia, France, and Canada, CAM is predicted to be used by 46%, 49%, and 70% of the populace, respectively. Natural or herbal medicine is used by around 158 million Americans [10]. Plants are always the primary source of medicine or treatment method in several ancient medicinal systems.

#### IV. MARKET SCENARIO

The Indian market for medicinal plants is expected to grow at a CAGR of 38.5% from its 2019 value of Rs. 4.2 billion to Rs. 14 billion in 2026. There is already a worldwide market of almost \$120 billion in botanicals. Primitive farming and quality control practices, a lack of processing, a lack of research and development, a lack of product standardization, and a lack of a legal framework for the trading of medicinal plants all restrict India's contribution to the worldwide export of herbs and herbal products. There has been a steady growth in the export of high-value medicinal plant extracts and plants throughout the years. The value of India's herb exports increased to US\$330.18 million in 2017–18, a 14.22% year-on-year growth. Extracts from medical plants and herbal products with added value had a 12.23% growth in exports to US\$ 456.12 million in 2017–18. The market for herbal or value-added extracts of therapeutic plants is increasing internationally, especially in Europe and other rich nations [11-12]

#### V. FUTURE PROSPECTS OF HERBAL MEDICINE IN INDIA

India lacks medicinal plant cultivation regulations. If farmers formed cooperatives and improved the supply chain, they might cultivate and sell more therapeutic plants. New companies have improved technology. This company uses AI and data analytics for crop profiling, seed analysis for enhanced germination, and other precision farming procedures. Both emerging and developed nations are adopting herbal medicines and other health items. Policymakers, healthcare professionals, and the public worry about their safety, efficacy, quality, availability, preservation, and future development. Herbal and CAM treatments require additional investigation [13]. Herbal medicine may heal individuals and boost the economy, but it requires a lot of study to address these concerns and fulfil public demand. Phytochemical and pharmacological studies of medicinal plants and herbal remedies are being conducted worldwide. Active chemical components are being identified and proven safe and effective [14].

#### VI. CHALLENGES

##### FACING IN HERBAL DRUG DEVELOPMENT AND THEIR PROMOTION

Due to their natural origins and lower side effects or unhappiness with the results of synthetic pharmaceuticals, herbal medicines, and their preparations have been widely utilized in developing and developed countries for thousands of years. Oriental herba medicine has several distinct qualities. All herbal remedies, whether presented as single herbs or as a combination of plants, are referred to as medicine preparations [15]. Medicinal ingredients are used in traditional remedies. Plants, minerals, organic matter, and so on are all examples of organic matter. Herbal remedies are mostly those that are used in traditional medicine which primarily treats patients with medicinal plant mixtures [16]. These medications are made of eco-friendly procedures, renewable raw material resources will be available, bringing economic benefits. The people who grow these basic materials should profit [17]. Due to the availability of thousands of medicinal plants in

various bioclimatic zones, India is regarded as the "Emporium of Medicinal Plants" [18]. Both in modern medicine and in traditional medicine, medicinal plants continue to deliver essential therapeutic substances. The examination of the efficacy of plant-based pharmaceuticals used in traditional medicine is being focused on since they are inexpensive, have few side effects, and as reported by the WHO approximately 80% of the population of the world generally depends on herbal medicines [19].

#### VII. FORMULATION DEVELOPMENT

The advancement of herbal medicine within the scaffold of evidence-based medicine is comparatively the latest. Applying the techniques of western-based pharmaceuticals to herbal medicines shows the research workers a multifaceted set of challenges. On the other hand, it is important that research plans in herbal drugs and conduct be systematically and strong, whereas on the view of medical philosophies and practices that escorts the use of conventional herbal medicines [20].

#### VIII. STABILITY OF HERBAL DRUG

Stability testing aids in the establishment of storage conditions for a drug product's Quality-Safety-Environment (QSE) to be maintained during its shelf life. However, confirming QSE for an herbal product under the effect of diverse storage circumstances is far more difficult than it is for a synthetic drug product. There are some hurdles that make the stability testing of herbal drugs difficult, are chemical complexity, variety in biochemical properties of raw material, choice of marker(s) for stability testing, and influence of enzymes present in herbal products [21].

#### IX. INSUFFICIENT PHARMACOKINETIC INFORMATION ON HERBAL DRUGS

The amount of a drug that reached systemic circulation and the location of action are tied to the dose, the route of administration, and the pharmacokinetic properties of drugs. Data on the dose and administration route utilized to achieve therapeutic results without adverse reactions are

included in preclinical and clinical studies that were conducted to determine a new drug's approval rating. Furthermore, the pharmacokinetic data collected in the above studies, combined with the assessment of the drug's long-term safety and efficacy (benefit-risk ratio), reveal a few factors, including disease states, age, genetic polymorphisms, and poly pharmacy, that may alter the drug's pharmacokinetics and thus influence its responses. However, the use of a medicinal plant concurrently with medicine may result in a lack of therapeutic benefit or unforeseen negative side effects [22].

#### X. EFFICACY, BIOAVAILABILITY, SAFETY, AND TOXICITY OF HERBAL PRODUCTS REGULATION

Herbal medications are regulated and registered differently in different countries. Herbal medications are classified into prescription and non-prescription medicines in the countries where they are controlled. Other than medicinal use, herbal products can also be grouped in various ways. Furthermore, the regulatory status of a few herbal drugs may vary from country to country. The concerned competent providers and distributors of specific chemicals are normally included in the national regulatory framework as a result; the regulatory status of these products dictates who has access to them and how they are distributed.

#### XI. QUALITY ASSURANCE AND CONTROL

Every country that regulates herbal medicines should have quality control and quality assurance in place, such as national quality specifications and standards for herbal products, GMP for herbal drugs labeling, manufacturing license, imports, and merchandise.

#### XII. PHARMACOPOEIAS

Quality specifications and standards for various types of herbal materials, such as volatile oils and powdered herbal products, are defined by national and regional Pharmacopoeias. Herbal materials are used and included in such Pharmacopoeias are dependent on the items' local availability.

### XIII. ACTION REQUIRED

Herbal medicines, like other human medications, should be controlled by a drug regulatory procedure to make sure that they meet the necessary criteria of safety, efficacy, and quality [23,24,25].

### XIV. CHALLENGES: IN CLINICAL TRIALS AND ETHICS WITH HERBAL DRUGS

Herbal medications contain various chemical constituents (Phyto constituents) that have been utilized for ages and are recognized for their pharmacological effects on the body. Herbal medications are widely accepted and used over the world, implying their safety and efficacy. However, most herbal medicinal products have insufficient pharmacokinetic, pharmacological, and clinical data, which contributes to the lack of guarantee of safety and efficacy. The problem of herbal drug regulation is exacerbated by the large gap in satisfying statutory criteria for research on herbal medications [26]. There is not enough scientific evidence to assess herbal medications' safety and efficacy. The trial drug's quality must be checked for batch-to-batch consistency of the active ingredients. It is tough to create active and control groups that are similar in color, smell, and taste to the herbal medication, which can't be replicated when made a placebo. These difficulties can be mitigated or eliminated by using the most up-to-date clinical research procedures and protocols. Because quality control of herbal medicines is complex and demanding, relevant and adequate standards for the assessment of safety and efficacy for various categories of herbal medicines should be defined to save money and time. Furthermore, attempts should be made to include conventional medicine in national medical practices [27]. The clinical research can begin only after collecting necessary preclinical data on the intervention and receiving proper clearance from the relevant Health Authority Ethics Committee for the study's design and objectives [28]. The different hurdles and regulatory rules highlighted for herbal medication clinical trials will be important for many sectors to consider before proceeding with a clinical study of their product.

Herbal drug research is fraught with difficulties that must be overcome. Before registering an investigational new medicine for performing big phase III studies, they include difficulties such as financial, ethical, product standardization (quality control), study design, and regulatory requirements. The WHO established operational recommendations in 2005 covering regulatory criteria for herbal product clinical studies [29].

The success of traditional herbal treatments is primarily determined by the patient's participation [30]. Traditional medicine makes extensive use of placebo effects in offering psychological support to patients in addition to physical therapies to optimize them on specific actors that contribute to the effectiveness of any therapy. Herbal medicine treatments are complicated, involving a combination of active ingredients as well as administration guidelines [31]. As a result, the patient's willingness, and drive to continue the therapy determines the efficacy of the herbal treatment. However, using blinding and (randomization) these variables can be reduced.

The selection of controls is another challenge in randomized clinical trials of herbal medications. Controls are chosen to be like the intervention group as possible, as comparator comparability is required if the study is to give evidence of a particular impact of the herbal medication. The parameters such as color, odor, length, frequency of intake, the believability of the therapy to the patient, and physical circumstances in which treatments are provided should all be regulated [32]. Selecting a matching control for many crude drugs, for example, ginger having a distinct odor, is a difficult challenge. In this part, we will be focusing on the problems of herbal medicine clinical research as well as herbal medicine regulatory concerns.

### XV. QUALITY CONTROL-RELATED ISSUES

Several suggestions for quality monitoring and cultivation of raw materials for herbal formulations were made during a WHO conference in 2000. The development of a good agricultural and collection Practices (GACP) subcommittee to facilitate the

availability of high-quality herbal medicines on the market by providing training and support to small producers and farmers was one of the proposals. Incentives for cultivators of herbal Phyto-constituents might be offered to encourage GACP implementation. These services include offering technical and logistical assistance in identifying optimal agricultural production areas, delivering seeds and seedlings, selecting fertilizers and pesticides, and providing or providing advice on harvesting an (primary processing gear.

Quality control maintains the quality of goods by adhering to well. Structured and defined requirements. Official pharmacopoeias monographs, handbooks, and other sources of standard parameter information are available. Various analytical techniques may be employed to find out the quality of herbal materials. The validity, precision, accuracy, and resilience of the approach must all be considered while selecting analytical methods. It is now feasible to identify and quantify the test chemical using advanced methods such as gas chromatography (GC), high-performance liquid chromatography (HPLC), and gas chromatography-mass spectrometry (GC-MS).

#### XVI. ADMINISTRATIVE ISSUES

This creates significant difficulties in defining the idea of national regulation of herbal materials, while also confounding patients and customers. Since 1994, natural products are regulated in the US under the Dietary Supplement Health and Education Act (DSHEA). A nutritional supplement is defined as an edible material that has a "dietary element" and is meant to augment the diet. Herbs, minerals, vitamins, and other botanicals are among the nutritional constituents of these products. Further toxicity studies are typically not necessary under the DSHEA for the herbs available in the market before 1994(NIH Office of Dietary Supplements, 2011). in this case, the FDA is responsible for proving that an herbal therapeutic product or "dietary component" is harmful or unfit for human consumption. In Manu developing countries like India, another key difficulty is the exchange of regulatory information on herbal

medications between regulatory agencies and safety monitoring or pharmacovigilance centers.

#### XVII. PHARMACOVIGILANCE

The enormous worldwide usage of herbal items and pharmaceuticals is a past instance for them to be incorporated into pharmacovigilance systems. In respect of population experience, it is vital to identify the hazards involved with the usage of herbal medicine and the safety of the herbal materials that have become a major public health concern in this respect. The requirement for pharmacovigilance for the interaction between drugs and herbal products is critical for identifying and assessing hazards associated with the use of herbal items (safety efficacy, and superiority), which are not usually rigorously researched and are frequently not subject to regulatory approval. Herbal product pharmacovigilance centers are mandated to examine and gather information about the safety and efficacy of herbal medicines by analyzing the side effects of drugs. There is no question that the recent increase in poisoning incidents of the use of herbal drugs in many parts of the world necessitates the need for extensive toxicity evaluation as well as pharmacovigilance on herbal medicines to encourage their appropriate application and safeguard human wellness.

#### XVIII. IPR AND BIOPIRACY

Biopiracy is a major hindrance to the spread of herbal traditional medicine. Conservation of traditional knowledge is so critical for out development.

#### XIX. IRRATIONAL USE

Herbal products are commonly considered to have no side effects or interactions; however, this is not the case. As a result, irrational use of these medications can lead to a variety of issues that might stymie their development. In this situation, when traditional medicine and knowledge are on the verge of extinction, it is imperative that we move wifly and decisively to conserve and preserve our history.

Regulatory agencies now have the responsibility of monitoring the regulated and quality flow of herbal products and facilitating their development to clinical trial phases. If regulatory agencies collaborate closely with academic institutions, research institutes, research clinics and centers, hospitals, industry, and pharmacy colleges, the aim will be achieved sooner rather than later.[33]

#### XX. CHALLENGES IN MARKETING AND COMMERCIALIZATION OF HERBAL DRUGS SOURCES OF REPORT

In general, the Council for International Organizations of Medical Sciences Working Group Recommends that the quality of report takes precedence over its source. As a result, the worth of a report is judged by how well it is written, documented, received, recorded, followed on, clarified, and evaluated, not by who wrote it [34]. However, because the source of a report can affect the information's quality and value, it is an important factor to consider while studying it. The nature, scope and even feasibility of any follow-up will be influenced by the source. The most common sources of information about adverse events and drug responses are clinical trials and spontaneous reports (voluntary and unsolicited communications on marketed medicinal products). In terms of both amount and type, the latter frequently outnumber the former during a product's life, especially in severe reports.

Herbal medicine providers should be included in national reporting systems for prescribing and dispensing medicines, as well traditional, complementary, and alternative medicines. Some countries exclude herbal medicine providers who are not doctors, dentists, pharmacists, or nurses from reporting systems.

#### XXI. REPORTS FROM HEALTHCARE PROFESSIONALS

In the post-marketing safety monitoring scenario, adverse drug reaction reporting systems rely mostly on voluntary reporting by health-care professionals, particularly those who are intimately connected to the

patient/care consumer (e., the patient's primary health care provide or specialist). Many herbal remedies account for a significant portion of non-prescription drugs, and many of them are hurried into this category after completing post-marketing safety testing as prescription drugs. Community pharmacists and nurses can help ensure the safety of these products by working closely with patients and their doctors [35].

#### XXII. REPORTS FROM CONSUMERS

Consumer participation in the use of herbal treatments and herbal products in health care, as well as their concerns about possible adverse effects, should be commended. Consumer complaints of adverse reactions should be taken carefully as a source of information that can help detect signals for unknown herbal medicine effects. Consumer reports may be the only source of information about nonprescription pharmaceuticals, which are frequently taken without consulting a doctor. When it comes to herbal remedies in the non-prescription medical setting, consumer reporting is critical [36]. Consumer reporting, in some form or another, is critical if enough risk information is to be acquired. At present, only a few national regulatory organizations specifically require the collection of direct consumer reports.

#### XXIII. MANUFACTURERS

Manufacturers of herbal medicines may be able to provide information about the side effects associated with their products. As part of its regulatory framework, manufacturers in some countries are obligated to disclose bad incidents. Consumers can make complaints directly with companies or their agents. A customer may call a company for a variety of reasons other than fear of a negative outcome. Among these are legal difficulties and, most typically, requests for further information about the goods. Several industry programs that solicit information on adverse responses are another source of consumer complaints, such incidents are not considered spontaneous reports.

#### XXIV. REPORTS FROM OTHER SOURCES

As a side effect of herbal medicines, toxicity to the following substances has been observed.

- In nations with limited resources and no pharmacovigilance center a poison center could play an important role in pharmacovigilance and safety monitoring of natural medicines.
- Drug information centers can also operate as the first point of contact for clinical information. National pharmacovigilance centers and comparable organizations should be able to communicate effectively.
- Consumer advocacy organizations get complaints about any product on the market and may be able to acquire relevant information on herbal treatments.

#### XXV. HERBAL PRODUCTS TARGETED FOR SAFETY MONITORING

To acquire a complete picture of herbal items, it's helpful to conceive of them in terms of the following categories:

Herbal medicines can be classified into two categories, one for use in the prescription medicines category and one for non-prescription medicines.

#### XXVI. REPORTING OF SUSPECTED ADVERSE ACTIONS

Even though these guidelines utilize the phrase "national pharmacovigilance center" it is well known that in some countries, the national pharmacovigilance system is made up of a network of national and regional centers. In accordance with the unique national reporting system, reports should be sent to the appropriate center.

The following individuals should submit reports.

- Any findings should be reported to the national pharmacovigilance center by physicians, pharmacists, and nurses who prescribe herbal drugs.
- In most cases, patients/consumers should tell their doctors or herbal medicine providers. They may also report directly to the national

pharmacovigilance center, consumer advocacy groups, or manufacturers.

- Manufacturers should directly notify their country's pharmacovigilance center or regulatory authorities.

#### XXVII. OPPORTUNITIES

Globalization: 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.[37] 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.[38] 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.[39]

Herbal treatments have also been extensively adopted in many industrialized nations, and are now gaining extreme importance in European Union, Australia, North America and in United Kingdoms.

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 identify their problem properly.
- Self-medication [40]

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.

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. 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 budget allotted for such ministry also increases gradually over the years. In 2017-18 the budget allotted was 1428.7 crores, which was more than double than that in 2013-14. 120) The various objectives of AYUSH include

- 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, Punarnava 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 stabilization 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 programmes 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.[41]

Opportunities in field of Research, industry, education and practice:

The current time hot of research 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, organizations, 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),
- Antimalarial drug “arteether” a semisynthetic derivative of artemisinin, marketed under

trade name E-Mal by Themis Chemicals Ltd., Mumbai.

- Saponins rich local spermicidal cream “Consap” from *Sapindus mukorossi*.
- Hepatoprotective agent Picroliv an iridoid glycoside was developed, which is a mixture of 60% picroside 1 and kutoside isolated from *Picrorhiza serrate*.
- Memory enhancer herbal preparation of plant *B. monnieri*.
- Gum resin, a NSAID isolated from *Roswellia 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. 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. 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. 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,

#### 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.

#### 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 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.

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.

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.[42] 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. 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. Similarly in Meghalaya, traditional remedies play an important role in the prevention/management of common diseases. A study demonstrated the potency of Ayurvedic multimodal in osteoarthritis management; and suggested an alternative of NSAIDs in such treatment. 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 prefers herbal formulations for the treatment of such diseases and also due to least side effects and lack of effectiveness of modern allopathic drugs.[45] 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, garcena 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.[46]

#### XXVIII. CONCLUSION

Herbal medicine continues to play a vital role in global healthcare and offers promising opportunities for the development of safe, effective, and affordable

therapeutic agents. Its wide cultural acceptance, rich biodiversity, and potential for novel drug discovery make it an important field for future research and commercialization. However, the full benefits of herbal medicine remain limited by major challenges such as lack of scientific standardization, inconsistent quality control, regulatory gaps, and insufficient clinical evidence. Addressing these issues through advanced analytical techniques, rigorous clinical trials, standardized manufacturing practices, and strong regulatory frameworks is essential to improve safety and efficacy. Collaborative efforts between researchers, clinicians, industry, and policy makers will enable herbal medicines to evolve from traditional remedies into scientifically validated, globally accepted therapeutic options. Ultimately, overcoming current challenges will unlock vast opportunities for integrating herbal medicine into modern healthcare systems and contributing to innovative drug development.

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