

Indian Herbal Drug Industry: Present Scope and Future Prospects

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ABSTRACT: Indians have historically been fundamental to the establishment and management of many industries of these biological sources and also protect their relevant information, which was gathered over millennia through trial and error. Because of herbal medicine has many advantages, both industrialized and developing nations are currently concentrating on treatments based on herbal medicine. According to a World Health Organization study report, 80% of the world's population relies on traditional herbal medicine for their primary healthcare needs. Alternative medicine is really becoming more and more popular in industrialized nations because of its effectiveness, safety, and lack of negative side effects. Herbal drug Industry is undergoing a major change with respect to domestic and global requirements. The government ministry's initiatives should be increased in order to promote herbal remedies both domestically and internationally and to facilitate student and scholar exchanges with institutions that offer AYUSH education. Harmonization of international regulatory standards would enable seamless trade in herbal products between exporting and producing nations.

Keyword: AYUSH, Harmonization, Global.

I. INTRODUCTION:

Traditional herbal remedies, which have been utilized to cure sickness within local or regional healing practices, are naturally occurring, plant-derived compounds that require little to no industrial processing. For thousands of years, far before the advent of the allopathic medication system, herbal remedies have been utilized extensively for the good of mankind. Phytomedicines are herbal preparations such as tinctures, tea, poultices, powder, and other forms that were originally made from crude pharmaceuticals. The use of plants for therapeutic purposes predates recorded human history and is credited with inspiring much of contemporary medicine. Most early medications, including

aspirin (derived from willow bark), digitoxin (from foxglove), and morphine, were developed solely via research and studies based on clinical, pharmacological, and chemical analyses of these herbal medicines, which were mostly derived from plants. Ayurveda, Unani, Siddha, and homeopathy (AYUSH) pharmaceuticals are among the herbal exports, which make about 3% of all Indian pharmaceutical exports. 70% of the exports from the herbal industry, which are projected to be valued Rs.10 billion year, are made up of raw materials. 30% of the export consists of finished goods like herbal extracts.

However, India only accounts for 1% of the global herbal export market. AYUSH, one of India's oldest traditional systems of medicine, hasn't been able to take use of the opportunities presented by the rising market. Around 270 million people in India rely on non-timber plant products, medicinal plants, and fragrant plants for their livelihood. As a result, the diversity of accessible natural resources and their sustainable utilization through firm development and industrial procurement significantly influence the economic evolution of these particular areas. Natural plant goods, such as industrial herbal products, formulations, and raw materials, have a substantial influence on a country's foreign exchange profits. Numerous plants, including the opium poppies, plants that contain tropane alkaloids, yams that contain sapogenin, senna, and cinchona, among others, are in high demand in established international markets. India estimates that it exported herbal raw materials and manufactured pharmaceuticals worth \$860 billion to other industrialized nations. Due to the complicated process of medication development, quality control, security, sufficiency, promotion, and administrative requirements, the pharmaceutical sector has shown less interest in producing herbal medicines, and medical professionals have also shown little interest. This situation causes financial hardship for developing and low-income nations.

We have emphasized the advantages and drawbacks of developing and commercializing drugs derived from plants in this study, as well as the range of potential future.

Scope:

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

Preclinical or clinical research, standardization investigations, and the creation of herbal products are the three current hot areas of research on traditional remedies. Standard herbal treatments is being aggressively investigated, developed, and promoted by a range of institutions of higher learning and government and corporate research groups.

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

Laboratory affiliates of the Council for Scientific and Industrial Research are working to create new herbal medicines or formulations. Central Drug has made great progress in this sector. Gugulipid, an anti-hyperlipidemic and anti-atherosclerosis medication, was developed and is sold by the Canadian medication Research Institute (CDRI) under the trade name Guglip® by Cipla Ltd.

- "Arteether," an antimalarial medicine sold by Themis Chemicals Ltd. in Mumbai under the brand name E-Mal. Arteether is a semi-synthetic derivative of artemisinin.
- Saponin-rich "Consap" from *Sapindus mukorossi*, a locally produced spermicidal cream.
- Picroliv, an iridoid glycoside that combines 60% picroside I and kutoside isolated from *Picrorhiza serrata*, has been developed as a hepatoprotective drug.
- A herbal extract from the *B. monnieri* plant that improves memory RRL Jammu commercialized gum resin, an NSAID extracted from *Boswellia serrata*, under the brand name Sallaki® Gufic.

Industry:

AYUSH manufacturing facilities demonstrated statistically Since the previous two decades, medicine output has increased annually. There are traditional kinds of ayurvedic remedies (tablets, medicinal ghee, powder, medicinal oil, decoction, fermented goods, and innovative medicine forms including creams, lotions, capsules, syrups, liniments, ointments, and granules, among others. The Drugs and Cosmetics Act (1940) and its implementing regulations (1945) govern the production process in this industry. The regulatory authorities have established GMP and GLP for the Indian medical system, which organizations participating in the production of conventional and herbal medicines must abide by.

Traditional and herbal medicines: Ayurveda business people are promoting awareness of the effectiveness and capabilities of conventional medical systems, dissatisfaction with allopathy, synchronized negative consequences, government assistance, and growing R&D projects, etc. Interest in implementing traditional health care services has increased in response to the WHO's Beijing declaration on herbal products. Ayurveda and other nutrition sectors have grown as a result of government assistance, expanding e-commerce, and rising demand to meet the needs of the global population. The clinical practitioner prefers herbal formulations for the treatment of such disorders due to the rising incidence and prevalence of chronic diseases including arthritis, cardiac issues, allergies, and others as well as the minimal side effects and ineffectiveness of contemporary allopathic medications.

Clinical trials and ethics with herbal drug:

The numerous chemical components (phyto-constituents) found in herbal medicines have been used for centuries and are known for their pharmacological effects on the body. The widespread acceptance and usage of herbal medicines worldwide suggests their effectiveness and safety. However, the majority of herbal medications lack adequate pharmacokinetic, pharmacological, and clinical evidence, which adds to the uncertainty around their safety and efficacy.

There are several challenges in herbal medication research that must be overcome. Before doing large phase III trials on an investigational new drug, there are a number of challenges to overcome, including those related to finances, ethics, product standardization (quality control), research design, and regulatory requirements. In

2005, the WHO issued operational guidelines for regulatory standards for clinical trials including herbal products.

The patient's involvement is largely responsible for the effectiveness of conventional herbal therapies. When providing psychological support to patients in addition to physical therapies, traditional medicine makes considerable use of placebo effects to help them on certain elements that contribute to the efficacy of any therapy. Treatments with herbal medicine are challenging because they combine active substances and have specific administration requirements

As a result, the success of the herbal treatment depends on the patient's willingness and motivation to stick with the therapy. However, these factors can be minimized by utilizing blinding and randomization. Another difficulty in conducting randomised clinical trials of herbal medicines is choosing the controls. As closely as feasible to the intervention group is chosen as the control group because comparator comparability is necessary for the study to provide proof of a specific effect of the herbal medication.

Education and Practice:

Since the previous two decades, there has been a noticeable increase in AYUSH training institutes, which is complicated by the fact that the CCIM (Central Council of Indian Medicine) regulates education and training in the traditional health care system.

In 2013, there were over 500 AYUSH undergrad campuses in India with a capacity to enroll more than 25,000 students. Some of India's top traditional medicine educational institutions include the 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), and All India Institute of Ayurveda.

Numerous organizations provide a range of programmes, including diploma courses, bachelor's degrees, PG degrees, PhDs, MDs, and MSs in the various sectors of the traditional healthcare system.

DNA barcoding in herbal industry:

Today, more people are turning to plant-based traditional remedies, and it is predicted that 80% of the world's population would use herbal products for wellness and healthcare. Consumer safety is ensured by the successful application of the DNA barcoding technology to identify medicinal plants and herbal items. It is clear from

the thorough and rigorous review of the literature that no one has yet developed an effective barcode for every category of plant. The defect in DNA template quality, primer affinity, the impact of PCR in herbal products, and additive contamination of DNA samples are the limitations of DNA barcoding.

Additionally, throughout the production process, which includes intensive heat treatment, irradiation, UV exposure, and extractive distillation, the availability of DNA might be lost or damaged. Processed foods do not contain any DNA at all, making them unsuitable for DNA barcoding.

Prospect: Regulation policies' effects on the use and safety of herbal medicines:

The Drug and Cosmetic statute of 1940 and the Drug and Cosmetic Rule, which were revised in 1959, allowed conventional and alternative medicines into India in 1940. The government also incorporated the traditional Indian medical system in the statute. The first committee was acknowledged in 1962 because numerous experts' panels for distinct ISMs were periodically acknowledged. Unani, Ayurveda, and Siddha were first included as independent chapters under Act 13 of 1964 in 1969. These chapters were updated with minor substitutes in 1983, 1987, 1994, and 2002.

Under the 1945 Drug and Cosmetic Rule, numerous instructions for the assessment and examination of ISM pharmaceuticals were provided in 2006 and 2008. The Central Council of Indian Medicine (CCIM), which was created in 1970, is in charge of creating and putting into practice a number of ISM rules, including curriculum and syllabus (for Unani, Siddha, and Ayurveda). In 2012, CCIM included the Sowa Rigpa medical system under its umbrella. The Department 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 2013. The Department of Indian Medicine and Homoeopathy (ISM & H) was founded with the aim of establishing the ISM. But in 2014, a separate AYUSH ministry was created.

Limitation on commercialization:

The biggest challenge for the Indian herbal industry is getting exporting nations to follow regulations on herbal ingredients. The main obstacles for Indian manufacturers and exporters

are individualised regional GMP standards and various registration procedures.

Regulatory Requirements by Country:

Domestic producers are not required to give any safety and effectiveness data while producing traditional herbal medicines under the traditional medical systems of Ayurveda, Siddha, and Unani in India, as per the Drug and Cosmetic Act, 1940 (DCA). The marketing position of herbal medicines as supplements rather than herbal remedies prevents them from receiving the required recognition, according to the Indian industrial perspective. Additionally, Indian domestic herbal standards differ from those of the majority of exporting nations. The cost of production increases due to variations in pharmacopoeial regulations, which include differing acceptable limits for pesticides, heavy metals, and microbiological contamination for herbal medicines depending on the country and domestic level. This also makes the export process more dangerous.

Limited Market:

Marketing of Indian herbal medicines abroad through trade fair and display arrangements . To advance Ayush education on a worldwide scale, the Indian government has launched a foreign exhibition and exchange programme for academics as well as temporary technical and academic support to overseas institutions and colleges . The University of Mississippi's Centre for Natural Product Research and the Indo-US Collaborative Organization were both founded to advance scientific validation and transmission of ASU medicine-based information, which will ultimately aid in the global acceptance of India-based herbal medicines.

Standardizations of raw materials issues:

One of the dubious parts of Indian Herbal Industrial manufacturer's concern is the authenticity and standardization of raw materials and developed herbal goods. The Department of Ayush has provided information on the usage of roughly 600 medicinal plants and 50 animal-derived ingredients in these formulations. Due to the fact that most

Indian firms are small to medium sized businesses, a survey also found that just 10% of the herbal industry has its own research and development facilities. They predominantly used old chemical and phytochemical standardisation methods for both formulation and raw materials due to a lack of equipment and human resource facilities.

Present Scenario of herbal industry:

With approximately 1.5 million users of the traditional medical system, India has roughly 25,000 efficient plant-based remedies. In India, there are 7800 production facilities for pharmaceuticals, and they use roughly 2000 tonnes of herbs annually. The global market for herbal or phytomedicines is still growing quickly. In many national health-care contexts, many individuals are now turning to herbal medications for the treatment of a variety of health issues. Both in industrialized and emerging nations, public interest in natural medicines has increased over the past few decades. In poor nations like Africa, up to 90% of the population still relies on traditional doctors and herbal remedies for their basic care, as does up to 70% of the population in India.

Market value of herbal drug:

The health advantages of plant-based medicines have had an influence on people all around the world, and they are also frequently more affordable than contemporary synthetic remedies in many nations. The global market for herbal medicines has grown due to market-driven phenomena such as increased consumer education, FDA regulations for current Good Manufacturing Practices (GMP), the expensive cost of modern pharmaceuticals, and few or no bad effects. China and India are the two countries that generate the most herbal medicinal plants worldwide. In Europe, France produces the majority of herbal medications, followed by Germany.

The global COVID-19 pandemic has been unprecedented and staggering with herbal medicine witnessing higher than anticipated demand across all region compared to pre pandemic levels .Based on our analysis, the global market exhibited a growth of 8.46% in 2020 as compared to 2019.

Sr.no	Name of industry	Location	Year of establishment
1.	Dabur India Ltd.	Ghaziabad	1884

2.	Patanjali Ayurved	Haridwar	2006
3.	Charak Pharma Pvy Ltd	Mumbai	1946
4.	Vicco Laboratories	Mumbai	1952
5.	Himalaya Drug Company	Bangalore	1930
6.	Aarya Vaidya Shala	Kerala	1902

II. CONCLUSION:

The market for herbal medicine, which is currently worth billions of dollars, is quite small in comparison to that of contemporary healthcare. This research examines the breadth and potential of herbal medications as well as the challenges and barriers that producers of herbal pharmaceuticals are currently dealing with. Due to their high efficacy, safety, and synergistic impact, herbal medicines are now more widely used than ever before. Because it has an impact on the quality and effectiveness of the treatment, the formulation stability of herbal medications is a critical issue. Innovative approaches to reducing medication instability, such as the use of suspension, biodegradable cellulose, therapeutic proteins, nanoparticles, and emulsifiers, can be very helpful. Preventing drug degradation brought on by environmental variables is a major issue when it comes to medicine stability. To maintain medication stability, certain procedures, including packing and container standards, must be followed. Pharmacokinetics and ADME studies are essential to guaranteeing the effectiveness, toxicity, and safety profile of herbal medicines since the side effects and toxicity of herbal remedies have been well-documented, including kidney injury, the development of stones, acute neuropathy, and neonatal mortality.

The government's business and market growth plan should be understood by herbal businesses, producers, and business owners who should also

promote high-quality, secure drugs that are regularly updated. The market for herbal medicine, which is currently worth billions of dollars, is quite small in comparison to that of contemporary healthcare. This is because there is a knowledge gap, there are technological and regulatory obstacles, there is a lack of research motivation, there are pharmaceutical firms, and the industry is not very involved in the market.

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