Phytopharmaceutical industry in India: An insight towards its growth and sustenance

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Abstract

Advancements in technology coupled with versatility in healthcare approaches led to the rise of a section of herbal medicines called phytopharmaceuticals. The paper presents some factors that affect the scope for rise of phytopharmaceutical industry in India like industrial crops sector and trade, richness of Indian herbal resources, cultivation advantage and government schemes to support development of phytopharmaceuticals. Environmental hazards, loss of biodiversity, plant disease issues, and genetic erosion can occur during the collection and processing of herbs for phytopharmaceuticals. Thus the paper further lists some approaches that can be adopted to sustain the industry e.g. CRISPR technology, DNA barcoding, metabolic engineering, hydroponics, ultra sound assisted/ supercritical fluid based extraction.

Keywords: Phytopharmaceuticals, Industry, Sustainability, Regulation

1. Introduction

The Indian Pharmacopoeia (IP) has monographs segregated into various sections one of them being herbs and herbal products. It is noteworthy that in the 8th edition published in 2018 there was a section on herbs and herbal products but in the 9th edition published in 2022 the IP saw an added section of monographs titled 'Phytopharmaceuticals'. Seven monographs that were in the section 'Herbs and Herbal Products' have been moved into the new section of Phytopharmaceuticals (e.g. Henna). The monograph title bears the suffix 'PPI' e.g. *Lawsonia inermis* PPI for henna. Haridra has been titled as Curcuma longa PPI (1). This upgrading in the official book of standards two years ago, for which the monograph drafting must have commenced much earlier indicates the importance of phytopharmaceuticals (PP) and their immense potential for India.

Herbal medicine is booming as a promising approach healthcare management of the future. Herbs serve as cure for several ailments and have a long established traditional use and a historic background (2). Historical records of China, Egypt and India indicate the medicinal applications of plants as far back as 3000 BC. Ayurveda, Siddha, Arabic Unani Medicine, and Traditional Chinese Medicine, employ herbal therapies (3). With the awareness of adverse effects related to synthetic drugs, many individuals are resorting to herbal remedies (4). Herbal medicinal products encompass a

variety of items, including herbs, herbal materials, herbal preparations, and finished herbal products. These products contain parts of plants, other plant-derived materials, or combinations of these as their active ingredients (5).

A phytopharmaceutical drug is a standardized and purified fraction of an extract of a medicinal plant or its part that contains at least four bioactive or phytochemical compounds (as determined by qualitative and quantitative methods). It can be used internally or externally by humans or animals for the diagnosis, treatment, mitigation, or prevention of any disease or disorder; however, parenteral administration is not included in this definition (e.g. atropine, caffeine, ephedrine, quinine, etc.) (6,7). There is not much difference between PP, nutraceuticals, and functional foods, it is majorly based on the on the preparation, dosage, and other variables, certain plants and their constituents is used in all of the above formulations (8).

2. Market size of phytopharmaceuticals

Plant extracts market referring to the PP market was valued at 33.9 billion USD in 2022 and is predicted to be 94.1 billion USD by 2031 with a projected growth rate of 12% for 2023-2031 (9). The numbers vary slightly based on different surveys but all of them show a rise in the demand for PP. According to FMI's analysis, India's phytochemical market is projected to expand at a CAGR of 6.2% between 2023 and 2033. USA, Germany, UK, Spain China are also on the list towards expansion of their markets (10). The end user the application of PP is so diverse which is the driving their demand. They are used not only in medicines and nutraceuticals but also in foods, beverages, personal care products, nutircosmetics, vegan products.

Some key players in the phytochemical market Include Döhler GmbH – Germany, Naturex -France, Kemin Industries Inc USA, Linnea SA – Switzerland, Sabinsa Corporation – USA, Kothari Phytochemicals & Industries Ltd- India, Indena SpA – Italy, Alkaloids Corporation – India, Arboris LLC -USA , Allied Biotech Corp.- Taiwan, Organic Herb Inc. (OHI) – China and LIPO Foods France (10). Some more Indian companies include Phyto Life Sciences Pvt Ltd: S. G. Phyto Pharma Pvt. Ltd and Blumen. A few others are Bionics Remedies, Wilson Drugs, Navayur Herbal, Indian Herbo Pharma, Alrak Ayurveda, Medlock Healthcare, Gnova, and Biosync Pharma (11).

3. Prominence of India in the phytopharmacetical industry

India serves to be a promising source of herbal drugs for many reasons such as the abundance in the herbs and herbal products; the herbs used in the traditional system of medicine contain reference in many Pharmacopoeias which guide for acquiring the standard quality of the herbs and their formulations. Some aspects affecting PP industry India are listed below projecting their pros and cons.

3.1. Industrial crops and trade

Plants are used as industrial crops as volatile oils, pharmaceuticals, herbal health products, personal care products, dyes and colorants, semisynthetic derivatives, biopesticides etc. Majority of plants are collected from wild source as against cultivation. The crops with much value and being cultivated are, *Papaver somniferum L, Catharanthus roseus, Aloe* species *, Commiphora wightii, Atropa belladonna L, Strychnosnux-vomica Linn., Solanum* species, *Emblica officinalis, Cassia angustifolia Vahl., Plantago ovata Forsk., Stevia rebaudiana, Coleus forskohlii, Acorus calamus, Ocimum sanctum Linn.* (12). Medicinal plant species are traded in China and India. As per a 2021 annual global trade in. herbal medicines of over $100 billion, China and India account for about $2–5 billion of this trade (13).

Alternative medicine, including Indian Ayurveda, Unani Arabic remedies, and Traditional Chinese Medicine, is beginning to gain popularity in affluent nations and gain more respect in other nations. According to WHO forecasts, the need for medicinal plants will rise to by USD 5 trillion 2050 (14). Research studies on industrialization of medicinal plants would need thorough data on their production, usage, commercialization, and management (15,16). It may be noted that though India is lucrative for the PP industry, there could be a competition from other Asian and Western nations.

3.2. Potential source of raw materials

About 70% of Indian medicinal plants are found in tropical regions, primarily in forests across the Western and Eastern Ghats, the Vindhyas, the Chotta Nagpur Plateau, the Aravalis, and the Himalayas. About 20% of all plant species worldwide (about 45,000 species) are found in the Indian subcontinent. Less than 30% of the medicinal plants with strong medical potential are found in temperate, alpine, or higher elevation environments (17). Less than 20 plant species (approximately 2.5%) are being grown out of the more than 800 plant species used by the herbal business. Over 90 % of medicinal plants in India are harvested from the wild using extremely antiquated and damaging methods which are linked to habitat degradation, overexploitation, changes in land use, threat to genetic diversity and species survival (18). The products from the wild are decreasing in the long run due to the genetic erosion. Measures are necessary to promote trade and homogeneity while simultaneously guaranteeing safety and accuracy (19,20). This scenario of genetic erosion is analogous to India as well.

3.3. Cultivation potential of India

India has an immense potential towards cultivation of medicinal plants with some hurdles as listed in Table 1 (21,22, 23) Key medicinal plants being cultivated are Ashwagandha (*Withania somnifera*), Tulsi (*Ocimum sanctum*), Aloe Vera *(Aloe barbadensis)* and Safed Musli (*Chlorophytum borivilianum*).

Table 1. Advantages and disadvantages of cultivation of medicinal plants in India

Advantages	Disadvantages
15 agro climatic zones that suit a large variety of plants.	Lack of Technical Knowledge on best practices for cultivation and management
Cultivation alleviates pressure on wild populations	Quality threats due to sustitutes and adulterants, affecting product quality.
Biodiversity conservation facilitated	Climatic challenges which affects the product yield
Traditional cultivation methods e.g. with Bhotiya of Himalayas, adapted for commercial use proved economical and preserved indigenous medicinal knowledge	Unregulated supply chain complicates market dynamics and quality assurance

3.4 Government schemes

A new set of laws for “Phytopharmaceutical drugs” was announced by the Indian government in 2013 as an amendment to the Drugs and Cosmetics Rules 1945. These regulations specify and clarify the prerequisites for Indian PP medications. In order to assess and approve the marketing of a plant medication on par with synthetic, chemical moieties, this gazetted notification governs the definition, regulatory regulations, and submission criteria for phytopharmaceutical medications, including scientific data on quality, safety, and efficacy. The Indian Govt. is inclined to support the pharma industry which includes the PP as well. Production Linked Incentive (PLI) scheme and Scheme for promotion of research and innovation in pharma medtech sector (PRIP) support manufacturing and research in the PP industry in India have allocated funds for the same (24,25).

Thus with its rich heritage of traditional medicine, vast biodiversity, plenty of forest area and cultivable land, availability and accessibility of labour and technology, skilled workforce, government support, the PP industry in India is gaining importance.

4. Sustainability of phytopharmaceuticals industry

Sustainability is defined as the ability to maintain or improve the state and availability of desired resources over a long period of time. Sustainability usually has three dimensions (or pillars): social, environmental, economic. However, the environmental dimension is mostly emphasized. This includes addressing key environmental problems, including climate change and biodiversity loss (26).

Sustainable practices in PP are crucial for ensuring the long-term availability of medicinal plants and minimising environmental impact. Here are some key strategies:

- Developing sustainable supply chains to ensure a constant supply of medicinal plants and replenishing of resources (27).
- Adopting green chemistry and green technology to reduce the carbon footprint.
- Regulation, Government policies and Community involvement to ensure prevention of overharvesting and unscrupulous trading and overexploitation.

4.1. Supply chain of raw materials

This includes ensuring a constant supply of raw materials i.e. herbs. This can be achieved in several ways like, practising sustainable harvesting techniques both from the wild and cultivated sources, adopting conservation methods: in situ and ex situ, like seed banking, gene banking and cryopreservation, promoting cultivation of medicinal plants and adopting good agricultural practices (GAP), creating alternate sources of medicinal plants from techniques like vertical farming, hydrophonics, aerophonics, tissue culture, biotechnology, and investing in research and development activities to explore latest developments in the field (28-30).

- CRISPR/Cas9 Gene Editing facilitates enhancement of the traits of medicinal plants, like diseases and pests resistance thus aiding higher yields and reduced need for chemical inputs.
- Metabolic Engineering: helps modify the metabolic pathways of plants to raise the production of desired phytochemicals, making the extraction more yielding.
- DNA Barcoding helps to use genetic markers to accurately identify and catalogue medicinal plant species, thus suitable for monitoring and protecting biodiversity.
- Tissue Culture, Hydroponics, and Biotechnology when integrated into the cultivation of medicinal plants is transforming traditional practices and enhancing sustainability. These modern techniques address challenges such as overharvesting, climate change, and the need for consistent quality in medicinal plant production (31).

4.2. Reduction of carbon footprint and water foot print

This includes implementation and adoption of various strategies like choosing eco-friendly materials e.g. the packages that are employed in the PP industry (31). Optimizing manufacturing processes by eco-friendly extraction methods like:

- **Supercritical fluid extraction (SFE):** Using supercritical CO2 as a solvent to extract phytochemicals, which is more environmentally friendly compared to traditional solvent extraction methods.
- **Ultrasound assisted extraction (UAE):** Utilizing ultrasonic waves to enhance the extraction efficiency of bioactive compounds, reducing the need for harsh chemicals.

Optimizing waste management wastes segregation and disposal to prevent pollution, ensuring recycling and replenishing water resources to ensure water conservation and use of using renewable energy sources.

5. Conclusion

Phytopharmaceuticals are employed in pharmaceutical products, foods, beverages, cosmetics, nutraceuticals, wellness products, teas, etc. India has an advantage due it geographical, technological, human resource features, ecological factors. Not only forest based but also the availability of a marine ecosystem provides diverse vast and versatile drugs. But if the natural resources are being exploited unhindered, right from the source of phytopharmceuticals, to its processing and delivery as a finished pharmaceutical product, the depletion of soil, loss of biodiversity, reduced yields may occur. Thus though India has immense potential in the phytopharma industry, measures have to be taken to ensure that there is continued growth and progress by ensuring the environment is not adversely affected due to the reliance on plants for medicines and employment of organic solvents for isolation and extracting the phytoactives. Sustainability practices not only help in conserving medicinal plants but also ensure that the benefits of phytopharmaceuticals can be enjoyed by future generations.

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