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Integration of Botanicals in Contemporary Medicine: Road Blocks, Checkpoints and Go-ahead Signals

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ABSTRACT

The use of botanicals for maintaining good health and preventing diseases is undisputed. The claimed health benefits of natural health products and herbal medicines are based on traditional claims, positive results obtained in preclinical studies and early phase clinical trials that are not backed by safety and efficacy evidences approved by regulatory agencies. Although, the popularity of botanicals is growing, health care practitioners of modern medicine seldom recommend their use because of ill equipped database of their safety and potency. This review discusses problems that preclude botanicals from integrating into the mainstream contemporary therapeutics and cues that provide impetus for their realisation.

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1. Introduction

The use of plants for therapeutic purposes can be traced back to the Neanderthal period and since then their use for remedial purposes has been growing¹. Animals have also been consuming plants for their healing properties and such serendipitous occurrences have provided leads for identifying plants with medicinal potentials^{2–5}. Many of the drugs in modern therapeutics are natural products or have been derived from them (plants, microbes, marine organisms/plants, insects, microbes, animals)^{6–9}. Data collected over the years from drug manufacturing community has indicated that about 50% of drugs available in the last several decades had natural origin and around 27 anticancer drugs including actinomycin D, paclitaxel, vincristine, topotecan,

dexamethasone, etoposide, tamoxifen etc developed during the period 1940–2010, were from natural sources^{8–10}.

The search for medicinally relevant compounds from natural sources is relatively easy because they have a history of use in prevention and/or treatment of diseases. Thus, drug discovery from herbal sources is experience driven and on the contrary, the search of a clinically useful compound ‘de novo’ with no source leads is a ‘shot in the dark’. Drug development from plants is carried out in three elaborate steps namely: pre-drug stage; quasi drug stage and full drug stage¹¹. Pre-drug stage is the first stage of drug development and involves the information driven selection of herbs or plants, based on results obtained in animal studies, experience obtained by their indigenous use and through self-medication. Thus, fruits, vegetables, spices, and traditional medicinal plants

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are obvious targets for this approach. Once cleared through the pre-drug stage, the plant enters the quasi drug stage which involves the preparation of extracts, screening of phytochemicals, structure and composition elucidation, bioactivity evaluation and identification of possible lead compounds using modern techniques¹². Once the lead compound is identified, it is structurally modified if needed. It is then evaluated in animal models, in-vitro studies and clinical trials and upon approval; it enters as a marketed drug. All these comprise the full drug stage. Although, modern, scientific and high throughput technologies are available for the drug discovery process, however, unless these take care of the ADMET profile (i.e., absorption, distribution, metabolism, excretion, and toxicity) they may not be able to successfully produce a good medicinal product.

The drug development process is growing at an enormous pace and it is undeniable that chemically synthesized drugs have revolutionised the field of medicine. Despite, the well established system of modern conventional medicine, plants still continue to provide benefits for medicinal purposes to about 80% of the world population, largely in developing countries^{13,14}. Over 70-95% of the population in Africa, Asia, Latin America and Middle East use some form of traditional medicine as their first line of treatment¹⁵. Majority of the hospitals in China have well established units rendering treatment through traditional healing systems^{16,17}. In China, traditional Chinese medicine (TCM) was very widely used for controlling severe acute respiratory distress syndrome and in Africa, traditional herbal medicine was used to alleviate symptoms associated with human immune deficiency virus (HIV) infection^{18,19}. Plant based remedies are the primary form of healthcare amongst the unprivileged sections of populations because of poverty and limited access to modern medicine.

Complementary and alternative medicine (CAM) therapies is divided into two broad categories namely drug based CAM therapies and non-drug based CAM therapies²⁰. Plants constitute about 80% of the drug based CAM therapies. There has been a change of perception among the general public and adoption of alternative remedies has increased even in the developed nations^{13,21}. Particularly, herbal medicine is drawing attention and has given a boost to the phytopharmaceutical market in international trade. Global giants in pharmaceutical manufacturing have been aggressively investing in herbal medicine^{17,19}. Chinese herbal medicine registered an increase of 20 percent in sales in 2012 from the previous year; reaching to about US\$83 billion²². The international market for herbal supplements and remedies is expected to reach US\$115 billion by 2020, with Europe being the largest and Asia-Pacific being the fastest growing market²³. Worldwide, about 35000 plant species are being used for medicinal purposes²⁴. The Indian herbal industry uses about 960 plant species and among these about 178 have huge consumption surpassing hundred metric tonnes²⁵. Among the European countries, Germany and France have the largest sales of herbal medicines¹⁷. The use of herbal supplements is also very popular in United States of America (USA) and their eminence for purported health benefits is on a continuous rise²⁶.

Modern medicine targets the disease usually by employing a single agent (monotherapy). Traditional healing systems like

ayurveda employ different approaches like medicinal herbs, yoga, dietary control, meditation, prayers etc for restoring balance in the body and alleviation of diseases. Traditional systems of medicine are based on the holistic treatment of the patient which also takes into consideration behavioral, physiological, psychological effects of drugs on the mind-body complex. Ayurvedic medicinal preparations contain combination of medicinal plants, minerals, metals etc. Polyherbal formulations are recommended as they provide synergism of positive effects and antagonism of negative effects and drug associated side effects^{27,28}. The use of multiple herbs in combination with other ingredients and modalities serves well to provide symptomatic relief alongside targeting the disease at the tissue level. The modern chemotherapeutic approaches which are largely 'molecule driven' have taken an edge over traditional healing systems because plant based preparations and other complementary modalities are slow to act and provide relief gradually, in comparison to the drugs used in modern medicine^{28,29}. However, the ill effects emanating from the use of these drugs has provided grounds for renewed interest in traditional therapies^{30,31}.

Fig. 1 and Table 1

The increase in adoption of herbal remedies may be ascribed to: a general preference of natural therapies and aversion for other interventions like surgery, allopathic medicines etc; inclination towards self-medication based upon experience; affordable cost of herbal medicines and ease of availability; side effects associated with conventional medicines (especially in cases of chronic problems) and growing promotion of herbal medicines^{13,32}. Herbal remedies are generally used and/or recommended for maintaining good health, alleviation of chronic problems and rarely for acute and/or life-threatening problems^{33,34}. People begin using alternative forms of treatment, including herbal medicine when conventional medicine is ineffective or for pain palliation in case of long standing problems like cancer, arthritis etc¹⁷. The use of natural dietary supplements among the general population is also very popular in an attempt to prevent cancer^{35,36}. The use of dietary supplements (containing natural products) among cancer patients in USA has become very popular and many patients begin using new dietary supplements with natural ingredients after being given a cancer diagnosis³⁷. Botanicals when sold commercially are often referred to as 'Natural Health Products (NHPs) or Herbal Medicinal Products (HMPs). They are available as single isolated/enriched compounds or as complex mixtures of several biologically active compounds and they may be obtained from single herb or combination of herbs (polyherb formulations). They are prepared in a variety of ways and can be taken in the form of decoction, tinctures, essential oils, teas, syrup, ointments, salves, and tablets/capsules that contain powdered form of the whole plant/plant part or dried extract¹⁷.

Although, the adoption of herbal medicine/botanicals in preventing and/or curing diseases through self-medication instigated by promotion in popular media has seen a surge³⁸, however, its acceptance among health care practitioners is not very encouraging³⁹⁻⁴¹. Strange as it may appear, but many professional health practitioners admitted to having little knowledge regarding herb supplements, which discourages their prospective clinical trials and use. It was revealed in a

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