

Invited commentary

Globalization of herbal drugs

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Received November 20, 2016; Revised November 28, 2016; Accepted November 30, 2016; Published online December 30, 2016

1. Introduction

Herbal medicines have been widely utilized as effective remedies for the prevention and treatment of multiple health conditions, from centuries by almost every known culture. The first documented records of herbal medicine use date back 5,000 years in China. Similarly, India's Ayurvedic medicine tradition is thought to be more than 5,000 years old and herbal medicines remain an essential component of its practice (Garodia *et al.*, 2007). Today, the populations of certain countries still depend on herbal medicines to address their healthcare needs. In United States of America, the use of herbal medicines continues to grow faster with the first national study of complementary and alternative medicine (Eisenberg *et al.*, 1993, 1998). Additionally, as a general rule, older adult populations are more likely to use both conventional drug therapy and herbal medicines and, thus, the herb-disease and herb-drug interactions increases in older populations (Verma *et al.*, 2013). At present, there is a dearth of research, evaluating the use of herbal medicines, especially clinical trials. The use of plants for remedial purposes predates to the Neanderthal period in human history and forms the beginning of novel medicine (WHO, 1998), which forms 25% of medications recommended globally. India has about 45,000 plant species, out of which, 15,000-20,000 have active principles of proven medicinal values. India ranks second in the world in herbal medicine and there is immense possibility to emerge as a major performer. Natural plant products are professed to be healthier than synthetic medicine. Herbal medicines are now in great demand in the developing world for primary healthcare not because they are economical due to better social suitability, improved compatibility with the human body and minimal side effects (Agrawal *et al.*, 2013). However, current discoveries indicate that conventional herbal products are heterogeneous in nature and may not be safe and impose a number of challenges to qualify control, quality assurance, effectiveness and the regulatory process. Some products found to contain mercury, lead, arsenic, corticosteroids and poisonous organic substances in detrimental quantity. Hence, herbal preparations should also be used with extreme caution on the advice of herbalist who should be well aware with the relevant conventional pharmacology. The manufacturers, researchers and regulatory agencies of the herbal products must adhere to rigorous scientific methodologies, good

manufacturing practices (GMPs) and preclinical testing to gain public trust and to bring quality herbal product into mainstream of today's healthcare system worldwide. Herbal medicines should be purchased from authentic and reputable provider, company or internet site to avoid any disguise. A combination therapy integrating Ayurveda, Unani, Siddha and allopathy whereby the side effects and undesirable reactions could be controlled, can be thought of a modern science. An integrated approach for the cultivation, conservation and preservation of important plant species through plant molecular biology, plant tissue culture, isolation of active constituents and their development into new therapeutics, standardisation and validation of known herbal medicines and other related aspects including pharmacokinetics and metabolomics need to be focussed (Rivera *et al.*, 2013; Pathak and Das, 2013).

2. Herbal drugs and their scope

Medicinal herbs as potential source of therapeutics aids, has attained a significant role in health system all over the world for both humans and animals, not only in the diseased condition but also as potential material for maintaining proper health. Several drugs have entered the international market through study of ethnopharmacology and traditional medicine. Cosmeceuticals are the products which interconnect between the drug and cosmetics (Baumann, 2007; Gottschalck and Breslawec, 2012). Nutraceuticals, *i.e.*, nutrition and pharmaceuticals, have established health benefits and their utilization will keep diseases away and allow humans to sustain an overall good health (Srinivasan, 2005). There is rich biodiversity of medicinal plants worldwide where many species of both medicinal and biopesticides plants are utilized. In India, almost all generations use herbal drugs for their health benefits. These herbal drugs and Indian medicinal plants are also rich sources of beneficial compounds including antioxidant, anti-inflammatory, antiseptic and antimicrobial properties and other components that can be used in functional foods (Eshun and He, 2004).

Herbs are staging a comeback and herbal 'renaissance' is happening all over the globe and the blind dependence on synthetics is over and people are returning to the naturals with the hope of safety and security. Developed countries such as United States, plant drugs constitute as much as 25% of the total drugs, while in fast developing countries such as China and India, the contribution is as much as 80%. Thus, the economic importance of medicinal plants is much more to countries such as India than to rest of the world. Medicinal plants play a vital role for the development of new drugs. The bioactive extract should be standardized on the basis of active compound. The bioactive extract should undergo safety studies. Medicinal plants play a central role not only as traditional medicines but also as trade commodities, meeting the demand of distant

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Email: ukaaz@yahoo.com; **Website:** www.ukaazpublications.com

DOI: 10.21276/ap.2016.5.2.1

markets. India has a very small share of this ever-growing global market. To compete with the growing market, there is urgency to expeditiously utilize and scientifically validate more medicinally useful plants. Medicinal plants are being used for trade purpose and been a source of export and import to benefit the people at global end.

3. Challenges for globalization of herbal drugs

While many benefits from the use of herbs, potential negative outcomes cannot be ignored. Agarwal *et al.* (2013) reported that 20% of Ayurvedic medicines purchased *via* the Internet contained detectable levels of lead, mercury, and arsenic. Many herbal product adulterations have been detected primarily containing drugs like sildenafil, lovastatin, estrogen, alprazolam, indomethacin, and warfarin (Anonymous, 2008). There is an apparent trend of adding analogues to herbs to make them more effective, especially for weight loss and enhanced sexual function (Cohen, 2009). Keep in mind that many medications used today may cause adverse events if not monitored or used correctly.

With the advances of the internet and increased emphasis on a global economy, consumers have much greater access to herbal products from anywhere in the world. Furthermore, industries are using internet sites as a vehicle to increase sales with most companies being less concerned with protecting the public as with making a profit. While many of these sites may claim that their products are safe, effective, standardized, pure, *etc.*, such claims cannot be verified. The international community needs a system for monitoring the legitimacy of internet sites that sell herbs similar to those of internet pharmacies verified by the National Association of Boards of Pharmacy (Agarwal *et al.*, 2013).

The potential for interactions between medications and herbs is one of the significant consequences resulting from the use of several medications, herbal products and supplements. Unfortunately, many consumers of herbal products assume that because these products are “natural”, they are safe (Izzo and Ernst, 2009). In general, herbal products may mimic, increase, or decrease the effects of medications. Examples of herbs that enhance the therapeutic effect of a medication include Ephedra used with amphetamines, valerian or Kava with benzodiazepines (NIH, 2006). This may lead to suprathreshold effects or toxicities, complicating the management of medical conditions and the corresponding medications. Herbs that induce metabolism of medications can lead to decreased medication levels, which may result in decreased efficacy of the medication or therapeutic failure.

Less than 10% of herbal products in the world, market are truly standardized to known active components. For majority of these products in use, very little is known about their active and/or toxic constituents. In many countries including the United States of America, herbal medicines are not subjected to the same regulatory standards as orthodox drugs in terms of efficacy and safety. This raises concern on their safety and implications for their use as medicines. Many plants produce toxic secondary metabolites as natural defence from adverse conditions. In some toxicologically and medicinally relevant plant species like *Digitalis purpurea*, *Hyoscyamus niger*, *Atropa belladonna*, *Physostigma venenosum*, and *Podophyllum peltatum*, these toxic substances are not distinguished from therapeutically active ingredients (Kim *et al.*, 2008; Ifeoma and Oluwakanyinsola, 2013).

4. Opportunities for globalization

During the past decades, public interest in natural therapies has increased greatly in industrialized countries, with expanding use of medicinal plants and herbal medicines. The many and various forms of traditional medicinal products have evolved against widely different ethnological, cultural, climatic, geographical, and even philosophical backgrounds. The evaluation of these products and ensuring their safety and efficacy through registration and regulation presents important challenges. The contributions from governments, institutions, and others would be greatly appreciated in formulating policies on traditional medicinal products and in introducing measures for their registration and regulation, and to facilitate information exchange on these subjects.

One of the most basic problems with the use of herbs is that there is lack of consistent terminology when describing what category herbs fall under. In the United States of America, the 1994 Dietary Supplement Act (DSHEA) provides the regulatory framework for herbal medicines. This Act is considered to be industry friendly and does not apply Good Manufacturing Products (GMP) standards that are required for conventional drug therapy. This law classifies herbal products as dietary supplements; therefore, they are not considered drugs or prescribed substances, allowing the American public greater access to herbal products, but in effect remove the role of herbalists from the practice of medicine and sees them functioning and being regulated more like small businesses (Eddouks and Ghanimi, 2013). Regulations and laws that apply to any and all healthcare providers, which have the safety of consumers in mind, do not apply to those involved in the manufacture and provision of herbal products. The E.U. Directive on Traditional Herbal Medicinal Products replaces most existing member state regulations and creates a unified licensing system for traditional herbal medicine products which came into effect from 30 April 2011.

5. Strategies for development

At present, due to advancement in the chemical knowledge of crude drugs, various methods like botanical, chemical, spectroscopic and biological methods are used for estimating active constituents present in the crude drugs in addition to its physical constants. Plants have been known to relieve various diseases in Ayurveda and Unani. Therefore, the researchers today are emphasizing on evaluation and characterization of various plants and plant constituents against a number of diseases based on their traditional claims of the plants, given in traditional system of medicine (TSM) and the authenticity, quality and purity of herbal drugs are established by reference given in pharmacopoeia (Dixit and Mittal, 2013). The pharmacopoeial standards are mandatory to be adhered for all herbal drug organisation to avoid any side effect due to deviation in the authenticate information (Rao *et al.*, 2012).

Non standardized procedures of extraction may lead to the degradation of the phytochemical present in the plants and may lead to the variations, thus leading to the lack of reproducibility. Efforts should be made to produce batches with quality as consistent as possible and to develop and follow the best extraction processes (Pandey and Tripathi, 2014). The pharmacist is in an ideal person to advise/monitor the use of herbs, especially in older adults.

The most important strategy for the safe use of herbs is to integrate evidence-based medicine knowledge into the Western medicine healthcare curriculum. Patients should also be careful when claims are made for a particular herb and should only purchase herbs from a reputable provider (Eddouks and Ghanimi, 2013).

The growth of the pharmaceutical industry and the unceasing development of new and more effective synthetic and biological medicinal products have not diminished the importance of medicinal plants globally. On the other hand, growth of population and increasing interest in the industrialization have greatly expanded the demand for herbal drugs. The regulations for the assessment of the quality, safety and efficacy of herbal drug including WHO monograph support the preparation of model guidelines and will be helpful in strengthening recognition of herbal drugs globally in healthcare. The studies based on the traditional claims for scientific validation, pharmacokinetics and metabolomics will provide an answer to the western world for acceptance of herbal drugs globally.

6. Conclusion

The studies based on the traditional claims for scientific validation, pharmacokinetics and metabolomics will provide an answer to the western world for acceptance of herbal drugs globally and Annals of Phytomedicine is doing well in this field as an ultimate source of information. The phytomedicine is gaining wider acceptance and importance due to the biomolecules that are synthesized in the living cells. Phytomedicine is truly a multidisciplinary area and encompassing several disciplines. It is established that a large number of Journals devoted to this branche of science, but only few of them publish articles from multidisciplinary areas. It is fortunate to see that Annals of Phytomedicine is catering to the needs of natural sciences. A Journal's standard is gauged by the quality of the papers published in it and widely indexed in various indexing bodies and inclusion under Thomson Reuters journal list , U.S.A, within short span of time. No doubt, it is a challenging job to run such a journal successfully. I am very happy to note that Annals of Phytomedicine : An International Journal is already on its way towards accomplishing its mission and reaching to its zenith.

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Professor S. H. Ansari is one of the well known leading research scientist. He obtained his B.Pharm. in 1979 from University of Delhi, M. Pharm. in 1981 from Punjab University, Chandigarh and Ph.D. in Pharmacognosy and Phytochemistry in 1997 from Jamia Hamdard. He was conferred Doctor of Science (D.Sc.) in 2002 by International University of Contemporary Studies., Washington (D.C.), U.S.A. Professor Ansari is having teaching and research experience of more than 36 years. He has served in Jamia Hamdard, in different capacities as Head, Department of Pharmacognosy and Phytochemistry; Dean, Faculty of Pharmacy; Dean, Students' Welfare; Director, Directorate of Open and Distance learning (DODL) and as **Vice Chancellor** as well. Presently, he is working as Professor and Head, Department of Pharmacognosy and Phytochemistry at Faculty of Pharmacy, Jamia Hamdard, New Delhi-110062, India.

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He has received research grants to the tune of more than Rs. 5 crores from UGC/ICMR/AYUSH/AICTE/DRDO/DST/industries, etc. He has successfully completed 15 major research projects. He has also successfully transferred technologies as outcome of funded project to industry. He is also consultant of many Pharmaceutical industries. He was instrumental to implement the scheme of FIST of Department of Science and Technology (DST) and Special Assistance Programme (SAP) of UGC and the Department got facelift with state of art facilities. He is supervising scientific research of the post-graduation and the doctoral level. He has supervised 26 M. Pharm. students and 20 Ph.D. scholars. He has written several textbooks and has contributed several chapters in books on Indigenous drugs and Herbal formulations of Indian and International Publisher. A widely travelled person, he has presented his research work in more than 75 conferences, held in India and abroad. He has delivered more than 100 invited lectures across the globe (Austria, Hungary, Thailand, Australia, Bahrain, Saudi Arabia, Iran, Malaysia, Singapore and Srilanka). He has also organized staff Development Programs, Refresher courses, National Seminars from time to time for faculty development. He has a list of more than 175 manuscripts in journals of repute. He is reviewer to a large number of international and national Journals of repute. He is Chief - in - Editor and on the editorial boards of Journals of repute.

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