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Journal of Analytical & Pharmaceutical Research

Veterinary Drug Development from Indian Herbal Origin: Challenges and Opportunities

Opinion

Volume 3 Issue 2 - 2016

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Received: September 30, 2016 | **Published:** October 04, 2016

Opinion

Indian forests have played key roles in the lives of people living in both mountains and lowland areas by supplying fresh water and oxygen as well as providing a diversity of valuable forest products for food and medicine. However, medicinal plants diversity and biogeographic position of India is so unique that all known types of agroclimatic and ecologic conditions are there. The classic Indian systems of medicines like Ayurveda, Siddha and Unani make use of only about 2000 plants in various formulations compared to the existing 17000 existing plants. The rural people, who constitute 70 to 75% of the Indian populations live in about 5,76,000 villages located in different agroclimatic conditions, have their own diverse systems of health management and most of the common ailments were/are managed in house by home-remedies which included many species and condiments like pepper, ginger, turmeric, coriander, cumins, tamarind, fenugreek, tulsi, etc. These are indeed community managed systems independent of official or government system and are generally known as local health tradition.

The traditional village physicians of India are using about 4500 to 5000 species of plants for medicinal purpose. In spite of the concerted efforts of government of India, there are huge gaps in scientific knowledge, its proper documentation and validation as there is no systematic, inventory and documentation of the folk remedies of India. Therefore, the scientific fraternity including government of India is concerned about the same and an urgent need to document this fast disappearing precious treasure is being realized. Under All India Coordinated Research Project on Ethnobiology (AICRPE) during the last decade, over 8000 species of wild plants have been recorded which were being used by the tribals and other traditional healers in India. Indians even today believe and practice indigenous traditional knowledge (ITK) for health care system; therefore, introduction of appropriate, simple and low-cost technologies should be encouraged maintaining conservation of biodiversity through small-scale production and preservation of cultural knowledge. One major concern in introducing modern technology for production of traditional medicines is whether the final preparation(s) will be acceptable to the practitioner(s) who has sole faith in extemporaneous preparations and this mental block has to be removed by motivating and educating people.

The demand for plant based-drugs is increasing both in human and veterinary medicine as these are natural products, non-narcotic, have no side-effects, and can be made available easily and at affordable prices and even at times be the only source of health care to the poor. Medicinal plants sector has traditionally occupied an important position in the socio-cultural, spiritual and medicinal arena of rural and tribal lives of India.

The global thrust areas for drugs from medicinal plants are increasing particularly for those disease conditions where modern drugs are either unavailable or unsatisfactory. Worldwide, alternative medicine is becoming popular and herbal medicine has become not only one of the most common forms of alternative therapy but also a complementary and supplementary therapy to allopathic medicines. The international herbal market is approximately $61 billion. Annual sales of herbal medicinal products are approximately $3 billion in Germany and $1.5 billion in the US while the annual turnover of Indian Ayurvedic industry is only $0.8 billion. The Indian market is growing at 15-20% per annum and the world demand is growing at 1% annually, therefore, the size of export market for medicinal plants appears much bigger than the Indian domestic market. As compared to China, which boasts of herbal exports of $ 3billion, Indian exports are highly dismal i.e. only $100 million. Therefore, there is a huge export opportunity for Indian herbal industry.

Major Challenges for Herbal Industry from Global and Indian Perspective are

Regulatory concerns

The regulatory agencies world over are focusing on quality, efficacy, safety and standardization of herbal medicines. The new guidelines from US FDA and EMEA cover the need for documentation in the above areas.

Quality–a major concern: Quality of herbs has become a major concern following reports of heavy metals in Indian herbs. Adulteration of plants is a serious problem. Some of the common adulterants are: botanicals, toxic metals, microorganisms, microbial toxins, pesticides and fumigation agents. In one of the studies on herbal medicinal products from India, 64% of the HMP samples were found to contain significant amounts of

heavy metals. However, this problem is not unique to Ayurvedic medicines from India as in other traditional medicines (Chinese, Middle East and South American) too, similar contamination has been reported which can induce serious harmful effects in patients taking such remedies and could also interfere with the assessment of safety in clinical trials.

Substantiation of clinical efficacy: One of the major issues with HMPs is lack of good quality clinical trials. Even if the animal studies or anecdotal clinical experiences are promising and use of an herb is widespread but such observations cannot predict the results of well-designed randomized, controlled trials. Some of the Indian medicinal plants Phyllanthus amarus, Picrorhiza kurroa, Tinospora cordifolia, Commiphora mukul, Mucuna pruriens, Boswellia serrata have been tested in clinical trials. However, a recent review concluded that evidence-based studies on the efficacy and safety of traditional Indian medicines are limited. As there are few good quality clinical trials on Indian HMPs because of lack of good laboratory, modern instruments and skilled persons. On the contrary, international researchers have made efforts to confirm Indian data in developed countries. Most of the regulatory authorities ask documentation on clinical efficacy of HMPs. Department of AYUSH recommends that manufacturers would be expected to conduct efficacy and safety studies before licenses are granted for Ayurvedic Patent and Proprietary medicines.

Safety issues: Adverse reactions and drug interactions: Herbal medicines are generally considered comparably safer than synthetic drugs. However, recent reports challenge such assumption. Ephedra marketed as a dietary aid in USA, led to at least a dozen deaths, heart attacks and strokes. Other well-known safety issues have been hepatotoxicity of kava and renal effects of aristolochic acid. Besides, drug interactions of herbal drugs are of a serious concern. Serious adverse effects have been reported when the addition of St. John's wart caused serum levels of cyclosporine and antiretroviral agents to fall to sub therapeutic levels. Garlic is reported to increase clotting time in patients taking warfarin. So there is urgent need to establish regulatory mechanisms to control the safety and quality of products.

Standardization of herbal drugs: For safe and effective use of herbal drugs, consistency in composition and biologic activity are essential. However, herbal drugs frequently fail to meet this standard, because there are problems of:

a. Difficulties in identification of plants,

b. Genetic variability,

c. Variations in growing conditions,

d. Diversity in harvesting procedures,

e. Processing of extracts,

f. Lack of information about active pharmacologic principles

So we must focus attention on quality during the whole process chain from accessing raw materials to finished products – to meet global expectations.

Consumer perceptions

HMPs have become popular because of perceived safety and economy and inability of allopathy to cure everything. However, recent reports of contamination and potential for adverse reactions, have tempered the enthusiasm of consumers for these "natural" cures, resulting in decline of sales of herbal products in the United States. The consumers now want more authentic information on quality, safety and efficacy of HMPs.

Competition

Amongst the countries with herbal resources, China is a major competition. The discovery of artemisinins as a new class of anti-malarial drugs from Chinese plant artemisia, has brought Traditional Chinese Medicine (TCM) practices and Chinese HMPs made attractive for research. A random search of MedLine showed that number of publications on TCM was three times greater than the number of publications on Ayurveda. Some of the therapeutic areas of TCM clinical trials are: neurology, oncology, cardiology, diabetic complications, rheumatoid arthritis and the clinical trials are conducted according to scientific and ethical principles of modern clinical research. Chinese government highly values the development of TCM and has established a modern TCM innovation system and supporting the development of a number of new TCM products and key technologies, and encouraging creation of a competitive modern TCM industry.

Some of the minor challenges which affect development of drugs

Increasing rarity: The continuous exploitation of several medicinal plant species from the wild fauna and substantial loss of their habitats during last two decades has resulted in population decline of many high valuable medicinal plant species over the years. Other potential causes of rarity in medicinal plant species are habitat specificity, narrow range of distribution, land use disturbances, introduction of non-natives, habitat alteration, climatic changes, heavy livestock grazing, and explosion of human population, fragmentation and degradation of population, population bottleneck and genetic drift.

Cultivation of medicinal plants: Information on propagation of medicinal plants is available for less than 10% and agrotechnology is available only for 1% of the total known plants globally, therefore, developing agro-technology should be one of the thrust areas for research. In order to meet the escalating demand of medicinal plants, farming of these plant species is imperative and apart from meeting the present demand, farming should be focused on conservation of wild genetic diversity, production of uniform material, better species identification, improved quality control and increased prospects for genetic improvements. The planting material and the technology of propagation, therefore, should be of good quality, rich in active ingredients, pest and disease resistant and environmental tolerant.

Bio-prospecting and bio-piracy: The former remote green forests have now become part of a dynamic, profit-seeking economy and demanding pluralistic politics worldwide. Medicinal plants are the local heritage with global importance. Bio-prospecting,

at present, occurs in an environment of suspicions and growing tensions between the bio-piracy and rights of sharing benefits between the developing and developed countries. Different ways and systems for awarding patents on the medicinal plants in India, United States, Europe, Canada and other countries have widened the confusion. In many countries, the plants and inventions directed to the plants and the plant products (seeds, flowers, gums, and resins) are not eligible for filing a patent. In United States, however, any living organism derived by human invention, such as by breeding or by laboratory-based manipulation, can be filed for awarding patent.

Therefore, based on global opportunities for HMPs and global regulatory guidelines for botanicals and even dietary supplements and ensure supply of safe and effective HMPs for human and veterinary medicine, quality, efficacy, safety, and standardization has to be ensured by Indian Pharma sector. The international regulatory authorities expect the data generated should meet the standards of GPs (Good Practices), good agricultural practices, good laboratory practices (GLP), good clinical practices (GCP) and good manufacturing practices (GMP). These guidelines will make licensing difficult for herbal medicinal preparations (HMPs). WHO has also recommended that it important for governments to establish regulatory mechanisms to control the safety and quality of products and traditional medicines practice. Therefore, future of development of quality veterinary drugs depends on how the Industry prepares itself to face the challenges of the regulatory concerns, consumer perceptions, and ever increasing global competitions.

Citation: Sankar P (2016) Veterinary Drug Development from Indian Herbal Origin: Challenges and Opportunities. J Anal Pharm Res 3(2): 00052. DOI: 10.15406/japlr.2016.03.00052