# LEGAL REGIME OF HERBAL MEDICINAL INDUSTRY IN INDIA

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**ABSTRACT**

*Right from the inception, India has a rich heritage of usage of Ayurvedic & Herbal medicines supported by Neutraceuticals. India is called "Botanical Garden of the world" as it is the largest producer of medicinal herbs. Out of more than 25000 plants of medicinal value, only 10 % are used for their medicinal value. Around 1800 species are systematically documented in the codified Indian systems of medicine. These herbal products are preventive, protective, nutritive and curative. [1]These valuable herbs need documentation, patents, and intellectual property rights from time to time and this comes under legal work. Apart from India these Ayurvedic herbal medicines and products must be recognized abroad and more specifically in USA and EU countries. Single drugs like ginger are welcomes in these countries but compound drugs are hard to accept as these may contain heavy metal and carcinogenic compounds. So in order to*

[1] The Pharma Review, August 2010.

*promote the Ayurveda herbal all these hurdles must be handled legally and steps must be taken to clear the way.*[2] *This article through a comparative analysis of the present legal scenario existing in India, and the lacuna apparent in the system tries to bring out the hurdles and the reforms needed for the herbal medicine industry.*

**Keywords:** Botanical Garden, Neutraceuticals, Ayurvedic, Patents.

**Medicinal plants** are those plants that provide medicines - to prevent disease, maintain health or cure sickness. In one or other form, these plants benefit virtually everyone on the Earth. These plants are also related to various other usages, such as for nutrition, toiletry, bodily care, incense and ritual healing.[3]

**Herbal medicine** -- also called botanical medicine or phytomedicine -- refers to using a plant's seeds, berries, roots, leaves, bark, or flowers for medicinal purposes. Herbalism has a long tradition of use outside of conventional medicine. It is becoming more mainstream as improvements in analysis and quality control along with advances in clinical research show the value of herbal medicine in the treating and preventing disease.[4]

## THE IPR FOR MEDICINAL PLANTS AND HERBAL MEDICINE EMERGES IN TWO DIFFERENT BACKGROUNDS

1) Those that are found in nature as wild Medicinal Plants and collected for use, and

2) Those that are developed through plant breeding systems and used as cultivated Medicinal Plants. Plant breeding systems used so far are mostly conventional based on selection and controlled pollination.

[2] Patwardhan Bhushan, *Indian Drugs*, 2000, 37, 213–227.

[3] The Biological Diversity Act (2002).

[4] University of Maryland, Medical Centre http://www.umm.edu/altmed/articles/herbal-medicine-000351.htm (last visited on 25.03.2011)

The **Global Coalition for Bio-Cultural Diversity** established the Working Group for Intellectual Property Rights in 1990 with a mission for uniting the indigenous peoples, scientific organizations and environmental groups to create and implement of a forceful strategies for the use of traditional knowledge and involvement of local people in conservation as alternative people cantered conservation models (Posey and Dutfield, 1996). The group went through a series of discussion, seminars, and workshops with the various associations of indigenous peoples and human rights and finally came to a conclusion that legal instruments used to invoke IPR protection are inadequate for protection of cultural, scientific, intellectual resources and traditional knowledge of indigenous people. The issue in IPR has overgrown and surpassed its name. Therefore, Traditional Resource Rights (TRP) has evolved as a strong arm to define many "Bundles of Rights" related to protection, conservation and compensation for the benefit of indigenous people. So it is important for discussing various facets of legal IPR protection regimes for Herbal Medical Plants and the isolated active ingredients as well as on the methods of developing new varieties and isolation of chemical compounds in relation to TRP that would benefit the country.[5]

## HERBAL MEDICINAL PLANTS & INTELLECTUAL PROPERTY LAWS

Agriculture has come under the subject of IPR, only after the creation of World Trade Organization (WTO) as a consequence of the General Agreement on Tariffs and Trade (GATT) Uruguay Round agreement. It was thought that Agreement on Agriculture (AoA) is the central focus of WTO negotiations, since agriculture is lifeline of development of most countries in the world. It plays a pivotal role in ensuring food security, providing livelihoods, generating foreign exchange and determining the allocation of natural resources (Murphy, 2003). However, dominant interest within the AoA circles around greater market access and increase in volume of commodity flows. Agreement on Trade- Related Intellectual Property Rights (TRIPs) is the outcome of WTO which has direct impact on farmers' livelihood, food security and economic development of the country. TRIPs provides mechanism for common protection and enforcement

[5] Ghosh, S. P., Medicinal and aromatic plants. *Indian Hortic.*, 1998, 43, 25–27

of IPR such as copyrights, trademarks and patents and also to make rules intended to limit international trade in counterfeit goods. The agreement also recognized that there are no uniform standards in the protection and enforcement of IPR and also no multilateral frame work of principles. There are Various legal protection mechanisms available under the TRIPs for Herbal Medicine Plants that can be harnessed the benefit in India's interest are as follows:

**a) PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHT ACT (2001)**

It allows the registration of three types of plant varieties. These are farmers' variety, extant varieties and new varieties. Although, most of the Herbal Medicine Plants that are in cultivation, are farmers' varieties and an instrument is available now to safe guard these varieties from piracy by registration. However, much benefit cannot be achieved in Herbal Medicine Plants by the farmers because rule states that all the extinct varieties are to be registered within the three years from the date of enforcement of this Act. According to the Act, extant varieties include farmers' varieties also. Only possibility left now is to register the farmers' variety as new variety since provision is available for the farmers also to register new varieties.

**b) PROTECTION THROUGH THE BIOLOGICAL DIVERSITY ACT (2002)**

The key features of this Act are:

1) To regulate access to biological resources of the country with the purpose of securing equitable share of benefits arising out of the use of biological resources and its associated knowledge
2) To conserve and sustainable use of biological resources,
3) To respect and protect knowledge of local communities related to biological resources.
4) To share the benefits with local people as conservers of biological resources and owner of knowledge and information relating to use of biological resources and
5) Conservation and development of areas of importance for biodiversity. Herbal Medicine Plants constitutes a great deal of biological resources and its usages have been recognized by the Act.

Even after developing IP by using the country's Herbal Medicine Plants bio-resources through proper legal permission, one has also to take approval from the National Biodiversity Authority (NBA) for filling an application for any form of IPR. This provision will take care of benefit sharing that will emerge due to utilization of our biological resources.

**c) GEOGRAPHICAL INDICATION OF GOODS (REGISTRATION AND PROTECTION) ACT (1999)**

Geographical Indications is an important protection measure for safeguarding the agricultural goods or for that matter any other goods manufactured at a given location which has the quality related to that geographical location. With the Geographical Indication of Goods (Registration and Protection) Act 1999, the varieties from which the medicines prepared from certain genotypes and at a particular location having a good quality can be protected after registering it under this act with the Controller General of Patents, Designs and Trade Marks. There are few examples existing in medicinal plants that a product is know be its location such as Trinvelly Senna, Java citronella, Neemach Ashwagandha, etc. Many more can be registered in future.

**d) TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (TKDL)**

Since the time immemorial, folk medicines are using herbs in their preparations. This knowledge is disseminated through person to person trough practice without having any written form. Therefore, there is no proper record of these practices. Collection, documentation and validation of various folk medicines, in addition other various traditional knowledge have been initiated by National Institute of Science Communication and Information Resources of Council of Scientific and Industrial Research and also by few other NGOs. This documentation will help in opposing any piracy of patent as experience in case of neem and turmeric.[6]

[6] GoI (Government of India). 1997. All India Coordinated Research Project on Ethnobiology. Ministry of Environment and Forests. Government of India, New Delhi.

### e) PATENT PROTECTION

Varieties of Herbal Medicine Plants developed using modern plant breeding techniques cannot be patented as such as per the Indian patent law. But the process of developing such varieties can be protected through patents. Similarly, process of extraction of active ingredients, product developments by using Herbal Medicine Plants and usages of Herbal Medicine Plants for new purposes is patentable subject matter in the national law if they meet the standards of novelty, inventive steps and industrial applicability.[7]

## EXISTING PROBLEMS IN THE INDUSTRY

In spite of the developing scenario of support in the form of legislations and other legal frameworks provided to the Herbal Medicine Industry it is strongly felt that India is selectively undermined despite it being used by a majority of the global population and has sizable scientific contributions and also there needs to be proper instruments of check and balance in the industry for its sustainable growth. Some of the problems pertaining to the same have been discussed below:

### a) CRISIS IN INDENTIFICATION

There are no all-India inventories of medicinal plants; there are local and regional inventories, but no national level inventory. The report of the All India Coordinated Research Project on Ethnobiology of the Government of India 1997, only gives the number of species used, but the actual list is not in the public domain. Identification of plants in trade is complicated by the fact that there is no reliable system of matching trade names to botanical names. In the trade, a species is known by its local name, which can change from one market to another or from one region to another. A species which is identified by a particular name by the collectors might be traded under a totally different name. On the other hand, the same trade name may be used for

[7] Biotech Consortium India Ltd. 1996. *Sectoral Study on Indian Medicinal Plants—Status, Perspective and Strategy for Growth*. New Delhi.

more than one species, often representing a set of species belonging to the same genus or including very different species used for similar purposes. For instance, for the trade name *ashok* there are two botanically different species, *Saraca indica* (syn. *Saraca asoka*) and *Polyalthia longifolia*. Similarly, for the trade name *chirayata* the two botanical species are *Andrographis paniculata* and *Swertia chirata*. Another example is the name *safed musli*, which traders assign to a variety of species including *Chlorophytum Borivillianum* and *C. Tuberosum*. Yet establishing the correct botanical identity of traded species is a prerequisite to studying those species in the field. This presents a major problem in identification as soon as the species leaves its natural habitat. The medicinal plants are harvested and traded in their raw form, whether as leaves, fruit, flower, seeds, gum, resin, roots, rhizomes, stems, bark or the whole plant. Since most raw drugs are traded in dried forms, long after their harvest, only the most experienced people in the trade (most often not a botanist, researcher or a forester) are able to recognize the species by their parts used. This is one of the reasons why it is very difficult to study, monitor or regulate the extraction and trade of medicinal plants. Assessment of the species extracted from the wild, and their quantities, is also extremely difficult. Given the above conditions, it is not surprising that data and information regarding medicinal plants is somewhat inadequate.[8]

**b) SUPPLY CHANNELS AND STAKEHOLDERS.**

Given that medicinal plants are sourced from many different biogeographic zones within India, tracing the supply chains of all the species in trade (if it were possible) would produce a most intricate web across the country. There is a long chain between primary collectors and end-users, and the supply channels for each species are different, depending on availability of the individual species and many other factors. The difference between remuneration paid to primary collectors and the market rate of the product is considerable. Thus the supply channel being so long and

[8] Das, B., Padmarao, S. and Kashinatham, A., Taxol content in the storage samples of the needles of Himalayan *Taxus baccata* and their extracts. *Planta Med.*, (1998), 64, 96.

complicated not only makes it difficult to trace the cultivator and primary collector but also increases the price of such herbs unnecessarily.[9]

**FATE OF COLLECTORS**

Collectors are usually Tribals and the rural poor, who are most dependent on the forests for their basic needs like fuel and fodder. Most often, those who go into the forests for fuel wood and fodder collection also collect seasonal medicinal herbs except for a few species. Collection from wild or 'wildcrafting' is a labour intensive activity, often involving entire families. Studies show that women and children form the major chunk of the rural poor most actively involved in herb collection from the wild. Payment to the collectors seems to be based upon the prevalent daily wage rate (or a slightly higher amount) in the area, for whatever quantity and number of species of medicinal plants are collected. The agent who engages the collectors, based on the perceived availability of the species and current wage rate, fixes the price for different species, which at the end of the day generally totals to a day's wages. This rate has usually no correlation with the final rate of the raw material paid by the consumer. The connection between rural poverty and the potential for generating livelihood security through collection and growth of medicinal plants has to be understood in order to be able to formulate strategies for the conservation and sustainable use of medicinal plants.[10]

Thus legal and administrative structure pertaining to medicinal plants can also play an important role in ensuring a fair share for the primary collectors/growers.[11]

**SUSTAINABLE MANAGEMENT OF MEDICAL PLANTS**

The scale of consumption of raw material, particularly by unlicensed units, is very difficult to assess—as is both the quality and source of that raw material. But it is reported that some species

[9] Kamboj, V.P. 2000. Herbal medicine. *Current Science*: Vol. 78 (1), pp. 35–39.

[10] Medicinal Plants of India: Guidelines for National Policy and Conservation Programmes. FRLHT, Bangalore

[11] Ibid.

have already become extinct through overharvesting, and other species are endangered. Hence the need to develop and maintain a sustainable supply from known sources presents a major challenge.[12]

It is clear that in order to move towards a system of sustainable management of medicinal plants, a number of aspects need to be addressed. Some of these are summarized below.

1. Better information on the current status and potential production of medicinal plants, both those that are cultivated and those that are collected from the wild, is required as a baseline from which to estimate trends in production.

2. Regulatory mechanisms that control the extent and nature of extraction can ensure that plants are sustainably harvested, while government support prices (or other incentives) can help ensure a fair share for the primary collector/ cultivator.

3. There is a need to not only impart scientific training to harvesters but also to educate them about the short-term and long-term advantages of following harvest practices that do not damage the plants in the long run.

4. Support to small and marginal farmers to undertake cultivation of low-risk medicinal plants cannot only help bring marginal lands under cultivation but also increase production as well as improve returns to these farmers. This will, at least in some cases, reduce pressure on forest areas to meet income needs of the dependent communities.

## INSTITUTIONAL INTERVENTION IN MEDICAL PLANT SECTOR

Central Government Organizations dealing with medicinal plants:[13]

[12] Singh, S. K., Proceedings of Global Promotion of Tradition Medicine in View of Institute – Industry Relationship, 2002, Faculty of Ayurveda, Banaras Hindu University, pp. 112–115.

[13] Planning Commission 2000, *Report of task force on conservation and sustainable use of medicinal plants.* Planning Commission, New Delhi.

There are numerous central government departments and ministries with some responsibility for medicinal plants but mere intervention and policy making is not enough unless they are implemented and followed on a periodic basis.

1) Department of Preparation of list of medicinal plants in Indian Systems of Medicine
2) Preparation of list of medicinal plants in ISM. Indian Systems of Medicine Documentation of local health traditions and Indian system of medicine and homeopathy.

**1. Department of Biotechnology Tissue culture and preservation of medicinal plants.**

| **Ministry/Department** | **Subject/Area of Work** |
|---|---|
| Department of Indian Systems of Medicine | Preparation of list of medicinal plants in ISM. Documentation of local health traditions and Indian system of medicine and homeopathy. Encouragement to *ex situ* cultivation. Development of agro technologies. |
| Department of Biotechnology | Tissue culture and preservation of medicinal plants. |
| Department of Science and Technology | Bio-technologies, agro-technologies, CSIR Germplasm preservations, etc. |
| Ministry of Agriculture | *Ex situ* propagation of medicinal plants. Development of agro-technologies. Tissue culture and preservation of medicinal plants. |

| | |
|---|---|
| Ministry of Environment and Forests | Conservation of medicinal plants. Identification and notification of threatened species and advice to the Ministry of Commerce to regulate their export. Documentation of ethno-botanical use of medicinal plants. Studies on ethno-biology, survey and identification of plants including medicinal plants by Botanical Survey of India. |
| Ministry of Commerce | Regulation of export of medicinal plants, plant products or their derivatives as per the advice of MoEF. |
| State Governments | Collection of medicinal plants from the wild. *Ex situ* cultivation of priority species. |

Beside from a recent Planning Commission initiative (Planning Commission 2000), there appears to be little recognition of the importance and potential of medicinal plants both in commerce and in terms of the livelihoods of forest-dependent people.

## SUMMARY OF RESPONSIBILITIES HANDLED BY DIFFERENT WINGS OF THE MINISTRY OF ENVIRONMENT AND FORESTS REGARDING MEDICINAL PLANTS

| ***Divisions of MoEF*** | ***Areas of responsibility*** |
|---|---|
| Wildlife Division | CITES18 to regulate export of trade in threatened and endangered species of plants and animals including medicinal plants. Conservation Strategy Division represented in the committee for |

| | |
|---|---|
| | negative list. |
| Research and Education Division | All India Coordinated Project on Conservation of Endangered Plant Species—Seed Biology and Tissue Culture Programme. All India Coordinated Project on Ethno-biology, etc. |
| International Cooperation Division | Co-ordination of Global Environment Facility and UNDP programmes. Projects on medicinal plants funded to NGOs. |
| Botanical Survey of India | Preparation of Red Data Book on threatened and endangered species of all Indian plants including Medicinal plants. |

## STATE LEVEL ORGANISATIONS

The status accorded to medicinal plants in the state policies differs from one state to another. But one aspect is common; none of the states has incorporated 'medicinal plants' in a manner that reflects their enormous socio-economic-ecological significance. There is no consolidated, central level policy study available comparing the legal status of medicinal plants across the states. TRAFFIC-India is currently engaged in a study that tries to address this gap. However, states

like Madhya Pradesh and Himachal Pradesh have shown some initiative in according the deserved status to medicinal plants in their policy framework.[14]

## CONCLUSION

As the legal instruments available to invoke Intellectual Property Rights (IPR) are inadequate to protect the vast intellectual resources available in the country with the indigenous people, we need to be agile and alert in watching the IPR infringement by others and claiming the benefit sharing in proportion to the commercialization of our potentials as well as intellectual resources of Medicinal Plants. The IPR system and the misappropriation of potentials without prior knowledge and consent of the indigenous tribal community are bound to evoke feelings of anger, frustration, of being cheated and helplessness of knowing nothing about IPR and piracy. Even now, for indigenous tribal community, life is a common property that cannot be owned, commercialized and monopolized by an individual or a group and majority of Indians are unaware of IPR intricacies of how the system operates. We are now in the process of learning the new world order of IPR and have to tight our nuts and bolts to develop efficient safeguarding strategies by developing capacity building of the people through networking with various groups who own the intellectual resources in their interest in particular and nation as a whole.

## RECOMMENDATIONS & SUGGESTIONS

During the course of our research, various problems were identified with and several legal obstacles have been observed and also the relevance of this industry was well understood and thus the Authors come up with certain Recommendations and Suggestions which are as follows:

1. It is important to try to capture the salient features of the medicinal plants trade in India and the related aspects of conservation and use in order to explore possibilities of private sector intervention, which can address the twin objective of sustainability of the resource as well as a better stake for the collectors/ growers.

[14] Mulliken, T. n.d. *New support for medicinal plants*. TRAFFIC International

2. Transit permit (issued by the Forest Department) should be made mandatory for transportation of commercial quantities of the fruits so that it ensures a fair share for the primary collectors/growers. This will act as automatic regulation on when the fruit was harvested. The Forest Department personnel, should be already oriented about the importance of proper time/method of harvesting, accordingly they should refuse to issue transit permits before the right time.

3. The legal and administrative structure pertaining to medicinal plants can play an important role in sustainable management through proper check while granting licenses, etc.

4. The State level intervention should be more active and policies on Medicinal Plants should be important criteria in their policy framework.

5. India, should be developing viable policies that effectively promote bio-prospecting and sustainable development while protecting the rights and the cultures of local communities.

6. Establishment or designation of scientific authorities to conduct non-detrimental studies for listed species, and management authorities to issue permits and certificates is important.

7. Legal instruments should be implemented to address biological diversity conservation and the sustainable use of its components comprehensively.

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