

Ownership and Sustainability Issues of Botanical Medicines

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Abstract

The World Health Organization estimates that more than 70% of the world's population, especially those who reside in the tropics, rely almost exclusively on plants as a primary source of medicines. Over the last decades an awareness has grown of the pharmacological potential of medicinal plants, and a potentially bright future for drugs developed from natural products. At the same time, the use of plants in medical practice contributes to the growing threat to species and ecosystem preservation. This paper expands the narrow view of plants as sources for pharmaceutical development to discuss botanical medicine from an economic and human development perspective. I consider strategies that can ensure that the benefits that accrue from utilization of indigenous plant knowledge become positive forces for human development. Issues of sustainability are discussed vis à vis poverty, protection of ecosystems, and the potential for future use and longterm viability of medicinal species. Issues of ownership also are presented in the context of intellectual property rights, with particular reference to the inadequacy of patent rights to protect indigenous knowledge.

Introduction

Throughout the world, people use many wild species for food, medicine, clothing, shelter, fuel, fiber, income generation and for the fulfillment of cultural needs. There is a growing recognition that biological diversity including medicinal plants is a global asset of tremendous value to the present and future generations. However, pressure from growing populations and the adoption of some modern life styles are threatening the existence of many of these species and the ecosystems that support them. Loss of species caused by human activities continues at an alarming rate. According to the FAO, 5.5 million hectares of resource lands are lost every year due to deforestation, cultivation, over-grazing, burning, erosion, etc. (FAO, 1993).

In forest habitats, whether of high timber value or not, medicinal plants are a major component of annually harvested non-timber forest products (NTFPs). They include herbs, vines, shrubs or trees from which medicine can be extracted from roots, wood, bark, leaves, flowers, fruit or seed. Medicinal plants are the primary source of medicines used by traditional healers. Traditional birth attendants, and many mothers in the home also harvest from wild sources, while maintaining the commonly used, high demand medicinal plants in home gardens. The World Health Organization estimates that as much as 80 percent of the world's population, especially those living in tropical countries rely almost exclusively on herbal products as the main form of medication. Indeed, for millions of Africans, traditional healers, who use botanical medicines predominantly, are their only contact with medicine of any kind particularly in the rural areas where hospitals are rare and doctors are few. The majority of the people depend on treatments given by traditional healers and it is possible that this trend will continue for a long time to come. The increasing scarcity of medicinal plant species represents a trend that should be addressed immediately, otherwise many medicinal plant species that have sus-

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tained rural people for centuries may be lost forever. Thus, policies and procedures that enable medicinal plants to be used sustainably must be developed to check this threat.

The principal objectives of the Convention on Biological Diversity (CBD), which was developed by an inter-governmental negotiating committee, are the conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising from its utilization. The convention recognizes that the key to maintaining biodiversity, including medicinal plants, depends upon using this diversity in a sustainable manner. The CBD also addresses the issue of bearing the burden and sharing of benefits fairly and equitably between developing and developed countries on one hand and indigenous / local communities and end users in modern sectors on the other. Therefore, ownership and sustainability concerns for the medicinal plants used in botanical medicine are adequately covered by the CBD. The CBD was opened for signature at the United Nations Conference on Environment and Development (UNCED 1992) in Rio de Janeiro on 5th June 1992 and it entered into force on 29th December 1993. Currently, there are more than 177 parties (as of March 2005). Parties to the CBD are obliged to contribute to the convention's objectives through the conservation and sustainable use of biological resources that abound within their territory.

Sustainability and ownership issues are very pertinent if plant use in botanical medicine is to be meaningfully integrated, translated and applied to the traditional populations that that use them.

Botanical (Herbal) Medicine

Herbal medicine is part of traditional medicine, in which plants and other natural materials are utilized for preventive and therapeutic purposes. Available records show that over 80% of the registered traditional medicine practitioners make use of leaves, roots and bark of trees of medicinal plants in various forms. Thus, even though there is more involved in traditional medicines than just herbal remedies, medicinal plants may be regarded as the mainstay of traditional medicine practice. The WHO (1991) defined herbal medicine as finished, labeled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant materials, or combinations thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils and any other substances of this nature. Herbal medicines may contain excipients in addition to the active ingredients. Herbal medicines may contain by tradition, natural organic or inorganic ingredients which are not of plant origin. However, medicines containing plant material combined with chemically defined active substances, including chemically defined, isolated constituents of plants are not considered to be herbal medicines. Medicinal plants have also been defined as

any plant which in one or more of its organs contain substances including essential oils that can be used for treatment purposes or which are precursors for the synthesis of useful drugs.

Sustainable Use of Medicinal Plants

Sustainable use as outlined in Articles 2, 5 and 10 of the CBD means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of the resource. The central idea of sustainability is that of ensuring that whatever action is taken, and however useful it might look at the time, its long-term effects must be assessed and if they are negative in the long run, they must be abandoned. Conversely, action that will have long-term beneficial effects should not be ignored in favour of short-term profitability. The convention recognizes the need to maintain the potentials of medicinal plants to meet the needs and aspirations of present and future generation. Therefore there is an existing framework that can be adopted by all the nations for the conservation of medicinal plants.

Use of a species is likely to be sustainable if:

- It is compatible with maintaining the ecosystem in which the species is found;
- It does not reduce the future use potential and impair the long term viability of the species; and
- It does not reduce its future usefulness to humans.

The current mode of use of medicinal plants in botanical medicine at the grassroots level is a far cry from these requirements and there is no indication that it will get better soon. The major concerns especially in Nigeria and other parts of the sub-Sahara Africa are as follows.

Major Concerns

Poverty

Poverty and herbal medicine are inter-related. Rural poverty is both a cause and consequence of over-exploitation of natural resources and the resultant degradation of the environment. The poor are the ones that are usually prone to diseases. Most of our herbal practitioners live in the countryside where the standard of living is generally very poor. Generally, the rural communities depend entirely on forest resources for their sustenance in terms of food security, income, domestic energy and primary health care. In some communities, up to 80% of household materials, e.g. food, utensils, shelter, furniture, etc. are derived from forest plants. Provision of appropriate information concerning sustainable means of harvesting and alternative ways of earning a living is extremely important for sustainability.

The mode of use of medicinal plants

The mode of herbal practice varies from country to country and from one community to the other. Practically every practitioner prepares his own remedies without reference to any universal protocol or formulated standards. The medicaments being produced are largely unstandardized in quantity and uncontrolled in quality. This situation makes control and regulation of botanical medicines very difficult. Those of them who overharvest when collecting plants from the field are usually not aware of the harm being done. In some places, herbalists and other users boil their plant medicines using precious fuel wood collected from the same forest and by this practice add more insult to ecological injury. It is absolutely necessary to design alternative ways to harvest medicinal plants without endangering them.

Accredited formal training institutions are virtually non-existent. There is hardly any proper documentation of the diseases treated or the medicines being used. Due to high level of poverty, traditional healers employ low levels of technology in the preparation of their products. This type of approach makes regulation and control very difficult. Indeed, herbal medicine practice today is an environmental and health emergency.

Loss of medicinal plant species and damage to ecosystem

The activity that consumes the highest number of species in sub-Saharan Africa today is herbal medicine. Most medicinal plants are harvested with little or no regard to the future. This is damaging both species and ecosystems. The damage is especially serious, when bark, roots, seeds, or flowers are removed, since these parts of the plant are essential for their reproduction. The emergence of commercial medicinal plant gatherers in response to urban demand for medicines is an even greater danger. Considering the population of herbal users and the frequency of usage, significant volumes of plant materials are used. Several indigenous species have already been lost because of indiscriminate exploitation, and many more medicinal plants face extinction or severe genetic loss.

Presently, there is little or no evidence of large-scale cultivation of plants. Obviously, herbal medical practitioners lack the means or know-how for large-scale cultivation of medicinal plants. However, they can manage backyard gardens in their traditional localities. Sustainable forest management strategies should be developed which include those that permit local communities to use resources appropriately. When local communities see themselves as being involved and actually benefiting from combined efforts to conserve medicinal plants, they can be mobilized for *in-situ* and *ex-situ* conservation. Some key species that have been identified to be central to health care delivery in communities may be used in this manner. Sus-

tainable use strategies may be developed for such medicinal plants for preventive and curative medicines in commercial quantities and in this way the economic status of the rural communities may be enhanced through proper management.

Lack of Standardization

Standardization of herbal medicines is the process of establishing quality and identity profiles as well as unshared, unique features that can be used for the purpose of safety monitoring and overall quality assurance of herbal medicines. Lack of standardization has hindered the regulation and control of herbal medicine despite its existence over many centuries and its expansive use in most countries in the last decade. There is hardly any evidence of adequate control measures to ensure reproducibility and repeatability in terms of quality, safety, dosing and toxicity at all stages of herbal medicine production. This situation makes people feel very reluctant to accept the use of botanical medicines even where there is proof of efficacy. The process of collection, drying, extraction, formulation, and packaging must be standardized so that the materials in use may be classified, quantified and volumes estimated at any given time. We need standardization in order to define precisely the direction of use of medicinal plants and therefore their conservation. A set of such standards should be compiled in the form a monograph for each herbal medicine. Provision of a monograph in an Herbal Pharmacopoeia is evidence of standardization, for that particular herbal medicine. Such sets of standards carry with them, an assurance of quality for monitoring safety, efficacy and reproducibility, which become the most essential parameters in their evaluation and any national drug regulatory requirements for a dossier. Such standards are complied with through all the stages of production of such herbal medicine (Elujoba 1999). Recently, many international authorities and agencies including the World Health Organization have started creating a new mechanism to induce quality control and standardization of herbal medicine.

Research and Development

In order to improve on the general acceptability and sustainable use of botanical medicines and provide some scientific validity, much research and development (R&D) work is needed to standardize the nomenclature, collection, extraction, processing, formulation procedures, quality, safety, dosage, indications, contra-indications, etc. The major drawback in R&D is low funding. R&D funds hardely exceed one percent of the GDP in developing countries. However, 2-4% of GDP is directed to R&D in industrialized countries. R&D can generate appropriate knowledge and add value to our medicinal plant resources locally and build technical capacity for improving the resources. Therefore botanical medicine should become

an important component of national economic development strategy.

Education and Training

It is absolutely essential to focus on the development of the right caliber of manpower for botanical medicine at all levels. A formal training programme should be designed to replace the hereditary mode of knowledge transfer. Such training may be organized through relevant government institutions or non-government organizations. It is necessary to organize a forum for exchange of information and to dialogue with traditional medical practitioners on a routine basis. This may be in the form of workshops, seminars or courses to educate the traditional healers on some important aspects of their practice.

Information Databank

Most of the knowledge on uses of medicinal plants is held by the traditional societies whose very existence is also under threat. Health traditions in Sub-Saharan Africa are being lost because they are oral and largely undocumented. Proper and careful scientific documentation will ensure successful exploitation and conservation of the medicinal plants. Adequate pharmacopoeia information should be developed to replace the traditional method of knowledge transfer. There should be monographs of each medicinal plant that should be upgraded periodically. There is need to strengthen the information network on medicinal plants for their conservation. There is need for national databases on medicinal plants and for these to link up with other international efforts (Thomas 2003). This may be developed through bio-geographic/socio-economic surveys and adoption of existing databases on medicinal plants so as to provide baseline information that is required to understand the values of medicinal plants to local communities.

Biotechnology

There is the need to strengthen indigenous capacity in biotechnology for medicinal plant conservation. Biotechnology (genetic engineering and related technologies) and cell culture techniques are widely employed in the improvement of plants and animals, and to make or modify products. Clonal micro-propagation of plants through tissue culture, protoplast fusion, embryo transfer and cryopreservation techniques contribute to genetic improvement of the plants and to conservation of valuable germ plasm. Application of recombinant DNA technologies can lead to development of transgenic plants with improved characteristics. Genetic engineering techniques can be used for identification of unique population using DNA fingerprints and valuable species with useful traits (e.g. insecticide properties) or genetically improved varieties may be preserved through established germ plasm banks. Gene-banks can easily and economically store large amount of seeds of different species and include intraspecies variability. Gene-banks are therefore necessary for conserving sufficient diversity of plants and their relatives to ensure that all their potentials are preserved for use in the future.

Ownership Issues

Ethical and economical issues are very important components in the management aspects of herbal medicine development. Issues of equity in the distribution of benefits from the use of medicinal plants and traditional crop varieties have underlain international debates over biodiversity for more than a decade (Elisabetsky 1991).

Unimproved genetic and biochemical resources are generally regarded as the common heritage of humankind (ownerless), freely accessible by anyone. However, developing countries are seriously worried about the system that labels their resources as "open access" but then establishes private ownership (property rights) for improved products based on these resources. They consider it unfair that individuals and companies based in the genepoor developed countries obtain resources free-of charge from the gene-rich developing countries, then patent the genes and chemicals and sell the patented products back to the country where they originated. Therefore, they often argue that intellectual property rights (IPR) should be modified in order to internalize the cost of biodiversity loss and management and to ensure that the source countries as custodians, receive more of the economic returns from its development. As a supplement to these property rights, formal and informal contracts have to be included to ensure just compensation for traditional medical knowledge (Laird 2002).

Article 8 (j) of the CBD provides that subject to national legislation, the "knowledge, innovations and practices", in other words, knowledge and technologies of indigenous and local communities shall be respected, preserved and maintained. Access to this knowledge and technologies shall be obtained with the prior informed consent and involvement of the communities. The conference of the parties to the CBD held in Bratislava, May 1998, ruled, "National law could legally recognize Community Intellectual Rights". The convention notes that countries should encourage the "equitable sharing of the benefits arising from the utilization of the knowledge, innovations and practices of indigenous and local communities". Therefore, if extending intellectual property rights to unimproved genetic resources fails to capture benefits from the use of medicinal plant resources, contract agreements, and access restrictions and the promotion of value-added industries would.

Basically, the arguments are as follows:

Intellectual Property Rights (IPR)

Intellectual property consists of legal regimes aimed at encouraging inventiveness, creativity and commerce by granting inventors, creators and men of commerce certain limited exclusive rights to stop other people from dealing with their invention or works of their creation. One of the purposes of intellectual property is to guarantee that the owners of the rights so protected can maintain a market monopoly over their products thereby offering an opportunity to recoup their investment in time and money. Patents cover inventions and innovations. Copyright covers works of artistic creation such as books, music, art, films and broadcasts. Trademarks cover marks, logos, etc., used in the course of trade. The most useful and generally utilized form of intellectual property protection for the products and processes in industry is the one provided by the general patent law through patents. Approximately 70 - 80% of the world's stores of proven, viable and directly useful technologies are contained in patent documents. Patent documents are therefore important sources of essential technological information. The patent system can boost the development of botanical medicine and enhance investment in research. It makes dissemination of technology information possible, since no patent protection is obtained unless the new technology is published thereby ensuring industrial utilization of botanical medicines. Publication further reduces the likelihood of duplication of effort by others and provides a basis for further advancement of the technology involved. The patent system will continue to be the most important tool for strategic development and should be utilized appropriately for botanical medicine development. It will stimulate the utilization of indigenous knowledge and serve as an instrument for licensing of process and products nationally and internationally (Olembo & Sese 1997).

Article 16.2 of the CBD stipulates that access to technologies shall be subject to the protection of intellectual property rights. Although this paragraph does not discriminate between individual or community rights holders, it has been taken to apply to private rights held mostly by corporate interests. The community management system has always allowed reward for labour input. Any charge for the biomass embodying biodiversity on a unit weight or volume basis, or any monetary charge made for the technology on a piece of hardware (an implement) basis is for paying for the labor used for production, not for innovation, and fits in well with the community system.

However, trying to charge for the community's intellectual achievement or innovation in botanical medicine is fraught with difficulties. These include, among others:

(a) The problems of identifying the beneficiaries; If the community as a whole is to be the beneficiary, the following problems arise:

- (i) Are all individuals in any part of the world who originated from the community or communities in question entitled to benefits?
- (ii) If so, will the community have the organizational and the technical capacities for its additional task of ensuring the inclusion of all beneficiaries?
- (b) If the community is to act as a single legal individual in direct competition with individual and corporate northern entities, additional problems arise:
 - (i) Raising the money required to register patents (it is estimated at about 10-20 thousand dollars for application only and requires annual payments of additional amounts);
 - (ii) Deploying the personnel and managing the global industrial espionage system that would be required to prevent unauthorized use of the patented technology, and affording this financially in hard currency. (It should perhaps be noted that IPRs are now used in the north to control markets, and preventing unauthorized use of patent, usually costs more than the royalties it can fetch. It is estimated that, on average, maintaining a patent for its lifetime in the US costs about US \$250,000);
 - (iii) Dealing with the near certain private patents on roughly the same technology and/or biodiversity which modify the community technology only a little (e.g. substituting extraction procedure with a different solvent).

These and many other problems arise because we are trying to force one system to run entirely under the norms of another. There is need for new innovative arrangements instead of the old fashioned approach that is hardly flexible enough to accommodate people's wishes. For instance, the recognition and protection of proprietary rights in intangibles before the introduction of modern intellectual property in Africa is not new (Richards 1980). That is, the intellectual property system though introduced by foreigners, does not establish completely "foreign" concepts. Earlier proprietary rights in intangibles vested exclusively in groups such as families, clans, age or sex groups, cults, professional guilds, or individuals such as particular elders, chiefs or kings. The enforcement of these rights was based on magical or religious beliefs or punishments administered by the groups.

Traditional doctors protected their trade by a system of trade secrets, magical beliefs, magical practices and tricks. The trade secrets were maintained because, in

most cases, only members of their families were trained. This helped reinforce the belief that only that lineage had magical powers to heal. They demanded things like goats, chickens, kola nuts, and yams and often offered sacrifices before administering the healing. It was believed that such sacrifices had positive metaphysical influences on herbal preparations. They wielded great influences that were used to fight or kill those who breached the norms. This ensured that their art was protected. The products or skills identified the guilds, or industrial groupings such as soap making, black-smithery, ceramics, carving and textiles. The head of the guilds took large orders and represented the guild before the rulers of the community.

On the other hand intellectual property laws in industrialized economies were founded on sound policies. They evolved to resolve challenges faced by traders, guilds and the governments in different territories. Almost every trader was regulated and controlled by a guild. Their goal was to foster the interest of the trade by controlling the activities of members and lobbying for measures that could guarantee their monopoly over the trade. "People of the same trade seldom meet together even for a merriment or derision, but the conversion ends in a conspiracy against the public or in some contrivance to raise prices".

Access Restrictions

The most promising immediate opportunities for capturing greater benefits from medicinal plant biodiversity involve access restrictions, contracts, and local value-added industries. National legislation regulating medicinal plant collecting activities will provide a more formal mechanism for ensuring that the rights of local communities are respected. Collecting permits should be mandatory for collectors and prior informed consent should be obtained before collection begins. The terms by which access would be given to land or to local knowledge must be properly negotiated.

The Organization of African Unity (OAU) at its 34th Summit in Ouagadougou in 1998 endorsed a model law on Community Rights and Access to Biological Resources prepared by the OAU Scientific, Technical and Research Commission, and the government of Ethiopia. The summit passed a resolution urging African countries to make their respective national laws based on the model law.

The main elements of Community Rights in the model law are following. They have rights to:

- The protection in perpetuity (for all times) of the biological resources in their areas, their knowledge and technologies;
- Grant access only after they have been given full information and weighed it in advance of granting their consent. This is referred to as prior informed consent;

- Refuse access when they want to, and to restrict access when they feel that giving it in full could affect them negatively;
- Develop, keep, use, exchange, sell or share biological resources without any interference by governments or private natural or legal persons who claim IPR protection; and
- Obtain at least 50% of share of benefits obtained from any commercial use of the biological resources in their areas, or benefits obtained from their knowledge and/or technologies.

Regardless of how they are characterized (license, permit, or contract) genetic resource access arrangements are essentially contractual in nature. As such, contractual negotiations and principles (including the concepts of prior informed consent and mutually agreed terms) form the basis for many (perhaps most) current legislative, policy and strategy documents and principles relating to access.

Nevertheless, this too has its problems. Under the CBD, the concept of "ownership of genetic resource" is also dicey. Unlike "biological resources" (an all-inclusive concept), the term "genetic resources" refers only to "genetic material of actual or potential value" (Article 2). It is generally agreed that the "value" of genetic resources, is in encoded genetic information, which may be used for a variety of purposes, including pharmaceutical and agricultural products development and research. Thus, the gross mass of the biological material from which genetic information is developed is of insignificant "value" in this context compared to the information itself.

Benefit sharing and genetic resources

The CBD assumes that when a state allows access to a sample of genetic resources, it is in turn entitled to insist on a number of benefits. It provides that research activities on the genetic resources have to be done in its territory to help it build capacity (Article 15, paragraph 6). All the information generated by research on that genetic resource must be repatriated (article 17, paragraph 2). Any biotechnology applied on the genetic resource must be made accessible to its source country (Article 16, paragraph 3). A fair and equitable share of the benefits accruing from the use, including from commercial gains, of the genetic resource must also be given to the local community or communities and the state from where it was taken (Article 15, paragraph 7). But all this is to be conditional upon mutually agreed terms in the form of a contract (Article 17, paragraph 4). Many of the industrialized countries have been undertaking major expeditions in the South to collect genetic resources even after the CBD came into force.

The real benefits obtained depend on the legislation in each developing country and the trained human resources and infrastructure put in place to enforce the legislation. In most

developing counties, neither the legislation nor the systems of enforcement are in place.

Conclusions

There is an urgent need to bridge the gap between the increasing interest in medicinal plants and their conservation. The situation in which practitioners prepare their medicines and administer them without reference to any standard or universal protocol is inimical to the survival of medicinal plant species. Issues of poverty, standardization, research and development, information and documentation, education and awareness need to be addressed in order check this threat. The framework laid down in the principles of the CBD is appropriate and should be adopted to guide ownership and sustainability issues in botanical medicine development. However, IPR in its present form may not permit the local communities to capture the full benefits of the utilization of medicinal plants and their conservation. Novel benefit sharing arrangements should be developed at national levels, bearing in mind cultural and traditional norms of the local communities. There is opportunity to carry development to the countryside through the development of conservation and sustainable use programmes for medicinal plants. Sustainable use systems should therefore be evolved at national and community levels, which will guarantee that the local people do realize benefits from medicinal plants resources and this will in turn encourage them to promote medicinal plant conservation. R&D institutions should be able to negotiate directly with local communities within the provisions of national laws, so as to facilitate the direct benefits and returns on medicinal plant prospecting. Developing countries need to be assisted in developing access and benefit sharing legislations and in the training of appropriate manpower for enforcement.

The processes of documentation and standardization must be addressed urgently through adequate funding of R&D, in order to identify, quantify and regulate the utilization of medicinal plants in botanical medicine. There is need to develop the right caliber of manpower and to strengthen indigenous capacity in biotechnology through mass education, training and awareness, for medicinal plant conservation.

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