ARTIGO ORIGINAL

Institutional barriers to the traditional production of medicinal plants and herbal medicines as an environmental protection agent

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ABSTRACT: Medicinal plants are important natural assets for several cultures, mainly due to their use in phytotherapy. Having said that, in order to ensure the quality of products and to boost the advancement of the sector, a number of institutions were created as the result of the National Policy on Medicinal Plants and Phytotherapeutics. However, they pose challenges to the base of the production chain, which is constituted by strategic agents to the consolidation of this sector in Brazil. This paper highlights, through documentary research and comparative analysis, the value of phytotherapy performed by traditional communities as a critical point of success in the development of the chain, promoting opportunities for income generation, culture recognition and the conservation of biomes that provide genetic resources to the production of herbal medicines, proposing a strategic guideline for the institutional improvement of the sector from this perspective on.

Keywords: traditional production of herbal medicines - institutional barriers - ethnobotany and bioprospecting - environmental conservation.

RESUMO: Barreiras institucionais à produção tradicional de plantas medicinais e fitoterápicos como agente de proteção ambiental. As plantas medicinais são bens naturais importantes para diversas culturas, principalmente devido seu uso na fitoterapia. Frente a esta relevância, e a fim de assegurar a qualidade dos produtos e impulsionar o avanço do setor, um conjunto de instituições se desenvolve a partir da Política Nacional de Plantas Medicinais e Fitoterápicos, entretanto, contraditoriamente estabelecem entraves à base da cadeia de produção, constituída por agentes estratégicos à consolidação deste setor no Brasil. Este trabalho, por meio de pesquisa documental e analise comparativa, destaca o valor da fitoterapia realizada por comunidades tradicionais como ponto crítico de sucesso no desenvolvimento da cadeia, a partir da geração de renda, reconhecimento da cultura e conservação de biomas provedores de recursos genéticos à produção de fitoterápicos, propondo diretriz estratégica ao aprimoramento institucional do setor a partir desta perspectiva.

Palavras-chave: produção tradicional de fitoterápicos – barreiras institucionais – etnobotânica e bioprospecção – conservação ambiental

INTRODUCTION

Medicinal plants constitute a functionality category of certain plant species that, due to their pharmacological active principles, when consumed directly or under different forms of processing by humans, are intended to promote or facilitate the cure of a number of diseases.

The use of medicinal plants can be considered a cultural factor in Brazil since nearly 82% of the population uses phytotherapy as the first option for treating or preventing diseases (Ministério da Saúde 2012). It should also be noted that the country is fortunate in terms of floral diversity as there are more than 46,000 plant species currently cataloged in the country, which shows Brazil's wide range of potentially medicinal species (BFG 2021).

Since a large part of the population resorts to natural extracts of medicinal plants, pharmaceutical industries have increased the manufacture of herbal medicines found on their portfolio of products offered on the market (Terra-Jr et al. 2015). According to Castro and Albieri (2016) the world market for herbal medicines moves about US$ 26 billion annually, especially in Europe, which accounts for 30% of

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the total; Brazil moved R$ 1.1 billion in the same year. However, these numbers represent a small portion of the global and the Brazilian market for pharmaceutical products, with total revenues of US$ 965 billion and US$ 28.5 billion respectively in 2012 according to CNQ (2015). In addition, according to Perfeito (2012), the production of synthetic drugs can cost up to 1.5 billion dollars and take around 10 to 15 years to be completed, while herbal medicines need investments as low as 5 million dollars, which shows how promising this market is.

Despite the sector's current size and development potential, it is possible to identify a number of challenges faced to its expansion in Brazil (Lourenzani et al. 2004; Oliveira et al. 2016; Hanseclever et al. 2017). Said challenges have a close connection to the base of the production chain, which originates from traditional knowledge (TK) and is responsible for supplying information that generates innovation (Lourenzani et al. 2004). In this sense, science, technology and public policies can be highlighted as the institutions responsible for defining the scenario for the appropriation of knowledge in these communities.

That being said, this paper aims to discuss the institutional challenges, highlighting a strategic guideline that consolidates science, technology and political instruments for the development of the herbal medicine sector in Brazil. Therefore, it uses a documentary research technique on the main norms that regulate the production of medicinal and herbal plants in Brazil, which are confronted, according to a comparative method, with evidence from the literature on the state of the art in medicinal and herbal plants, allowing to propose a strategic guideline for the sector by answering the following question: which strategic guideline would be able to promote greater effectiveness in the preservation of biomes based on the National Policy on Medicinal Plants and Phytotherapeutics?

Medicinal plants and herb medicines – the state of the art in confrontation with regulatory institutions

According to Correa and Alves (2008) medicinal plants serve as raw material for several segments: in the pharmaceutical industry they are used for the production of herb medicines[1] and the extraction of active principles and essential oils for allopathic medicines; in the cosmetics industry they are used for personal hygiene and toiletries items; and in the food and beverage industry they are used as flavor and flavor agents. Also state that the use of plants as a medicinal resource is associated in popular culture with magical, mystical and ritualistic practices with the purpose of spiritual healing (Santos et al. 2007).

The contact of Brazilian society with the medicinal benefits of plants stems from Indigenous, African and European cultures, and is part of the nation's cultural formation since the colonial period (Bruning et al. 2012; Badke et al. 2016).

For traditional populations the custom of using medicinal plants is a result of knowledge transference that, when passed from generation to generation, perpetuates values, beliefs, eating habits and the group's specific way of life (Silva et al. 2012).

In the midst of the vast national flora, permeated by an accumulative process of knowledge about the various uses of medicinal plants, traditional communities (indigenous, quilombolas, herbalists and others) hold the knowledge on the use of these plant resources as part of their culture (Silva et al. 2015). These communities are responsible for the origin of several medicines used by the population today (Pereira et al. 2008).

According to Resende (2008) about 70% of the world population depends on products whose application was derived from traditional knowledge on the use of medicinal plants, which stimulated the domestication of these species for commercial production. Traditional knowledge on useful properties or products derived from the raw material provide the necessary clues for researchers to identify active principles that will later be incorporated into products to be launched on the market (Benini et al. 2010).

The popular use of medicinal plants is associated with the consumer's interest in a more accessible, regarding costs and prices, and safer alternative in terms of side effects when compared to synthetic products from industries, especially pharmaceuticals (Correa et al. 2008). Such interest may stimulate the cultivation of these plants for commercial purposes, strengthening production chains based on therapeutic species, and encouraging the preservation of these species and their original biomes, which become a germplasm bank for new discoveries (Souza et al. 2012).

In order to assure that Brazilian population make rational use and have safe access to medicinal plants and their derivatives, public and private institutions, which are responsible for the regulation and development of the herb medicine production chain in Brazil, use the National Policy on Medicinal Plants and Herb medicines (PNPMF) as reference. It was enacted in June 2006 based on Decree 5,813 (Brasil 2006a).

The PNPMF regulates the production of medicinal plants in two fronts: (i) agro-industrial and (ii) traditional (or from tradition), the first consisting of

[1]According to the Health Surveillance Secretariat, Ordinance No. 6: herb medicines are medicines technically obtained from plant raw material with prophylactic and curative purposes, due to the active substance.

the cultivation, distribution and use of raw material and products for herb medicines produced by the pharmaceutical industry; and the second consists of management, cultivation, production, distribution and use of medicinal plants produced by traditional peoples and communities.

In the (i) agro-industrial front, the regulations must ensure the final product's quality, efficacy and safety, since the cultivation and throughout management and production techniques/systems, taking into account the botanical, chemical and pharmacological aspects and aiming at obtaining quantifiable active principles and standardized markers according to the particularities of agribusiness and the large pharmaceutical industry.

In the second front (ii), that of traditions in the use of medicinal plants, regulations should be aimed at safeguarding, preserving and supporting traditional and popular knowledge and practices in medicinal plants, as well as home remedies and other health products that are based on ancestral and immaterial principles, in sustainable extractivism and family farming. To this end, the validation and guarantee of these products' safety, efficacy and quality are endorsed by tradition, and have these agents' support for technical and sanitary improvement, encouraging the insertion of this knowledge's keepers and of its products in the SUS (Universal Care System) and other markets.

The PNPMF, which is an integral part of public policies on health, environment, economic and social development, establishes guidelines and priorities when it comes to actions aimed at bringing improvements to Brazilians life quality.

The National Policy on Integrative and Complementary Practices (PNPIC) is another legal instrument whose objective, to name one, is to introduce the use of medicinal plants as a common practice in health care. It was elaborated by the Health Department (Brasil 2006b) and published in 2012 on the Basic Health Care Guidebook and on the Health Department's National Program of Medicinal Plants and Herbal Medicines (Brasil 2009). It includes guidelines aimed at the introduction of medicinal plants and herbal medicines in the Universal Care System (SUS).

These public policies stimulated the use of medicinal plants as an alternative in the Universal Care System, promoting the integration between phytotherapy and the public health sector and determining guidelines aimed at guaranteeing the regular supply and quality of the raw material.

Furthermore, the National Health Surveillance Agency (ANVISA) also regulated herbal medicines in Brazil the same way as conventional medicines were regulated, which means that they must present proof of quality, safety and efficacy. The agency states that once ethnopharmacological surveys of use and subsequent techno-scientific documentation of preclinical and clinical pharmacological and toxicological studies are carried out and presented, herbal medicines will have legal endorsement to be released to the market and be used in the Universal Care System (Health Department 2009).

From a commercial perspective, ANVISA established guidelines for the regulation of herbal products for marketing purposes upon presentation of a certificate, which is awarded based on the Board of Directors Resolutions (RDC's) and the Normative Instructions (IN) (Table 1). However, according to Carvalho et al. (2012) these guidelines are based on standards defined for other categories of products, such as pharmaceuticals and food, and do not cater for the different forms of phytotherapic production, especially not the more traditional ones.

In this sense, despite aiming at promoting the family production sector through minimum and evident safety and efficiency, the rules establish restrictions that can pose real challenges to this category's recognition and expansion, such as the requirement of efficiency recorded in a compendium for each of the components present in the products' formulas, as those sold by family producers in alternative markets, popularly known as "garrafadas", which benefit from the synergy of different species in herbal formulas, according to traditional producers (Silva-Sena 2017). Additionally, they require proof of use with no record of side effects occurrence for a period longer than 30 years in order to be granted the certification (IN n 04 - Chart 1).

In addition, only 28 species of medicinal plants are currently authorized by ANVISA (IN No. 2 – Table 2) to be present in the formula of herbal medicines available in the market (Carvalho et al. 2012). Such species are cataloged according to their use and safety, and presented in a document which is a guideline for society, called the "Herbal Medicine Memento" (Brasil 2016). However, in view of the floral diversity of medicinal plants from Brazilian biomes already cataloged by ethnobotanical studies (Maroni et al. 2006), it is possible to see how limited this amount of medicinal plants endorsed by the ANVISA manual really is. This fact alone is indicative of the need for investment in research in order to prove the efficacy and safety of other Brazilian plant species, with the possibility of developing new markets.

Although there are still obstacles, it is also important to highlight institutional evolution. Oliveira and Ropke (2016) report that for many years the previous legislation (Provisional Measure No. 2.186-16/01) posed a challenge to the acknowledgment of medicinal plants traditional wisdom in Brazil due to the fact that this measure makes the process of

Chart 1. Main regulations for herbal medicines' notification and registration.

Current Regulation	Purpose
RDC No. 26, 05/13/2014	Provides for the registration of herbal medicines and the registration and notification of traditional herbal products.
RDC No. 66, 11/26/2014	Amends Annex IV of RDC No. 26 from May 13th, 2014, which provides for the registration of herbal medicines and the registration and notification of traditional herbal products.
RDC No. 38, 06/18/2014	Provides for herbal medicines' post-registration petitions and traditional herbal products, among other provisions.
IN No. 02, 05/13/2014	It published the "Simplified Registration of Herbal Medicines List" and the "Simplified Registration of Traditional Herbal Products List".
IN No. 04, 06/18/2014	Determines the publication of Guidelines for Herbal Medicine Registration and Traditional Herbal Medicine Product registration and notification.
IN No. 05, 06/18/2014	Provides for the procedures related to the Product Change History protocol and defines the period for analysis of post-registration petitions of herbal medicines and traditional herbal products, based on the provisions of RDC No. 38, 06/18/2014, which "provides for the carrying out of post-registration petitions for herbal medicines and traditional herbal products and other provisions".
RDC No. 13, 03/14/2013	Good Manufacturing Practices (BPF) for traditional herbal products.
RDC No. 69, 12/08/2014	Provides for Good Manufacturing Practices for Active Pharmaceutical Ingredients.

Source: adapted from ANVISA (2015)

deliberation on the legal representative of the local community and on the benefit-sharing agreements arising from the exploitation of this knowledge difficult. However, according to the authors, decree 13.123 enacted in 2015, was a step forward in solving these problems by bringing changes and key concepts that previously held back the advancement of the sector, such as the access to genetic heritage, the association of traditional knowledge and research; the benefit sharing agreement and the material transfer term; and the easing of the process to access genetic heritage, which was improved and now allows for digital recording.

Although these advances are acknowledged, there is still much to be done according to Oliveira and Ropke (2016), since there are still strong disincentives holding back the development of herbal products from Brazilian biodiversity, which exist due to the legal uncertainty and the slow regulatory processes that paralyzed the sector.

When considering political incentives as opportunities, as well as the legal aspects, it is possible to find other institutions, such as the organizational, scientific and technological ones, that show in their performance gaps in the development of the herbal medicine production sector in Brazil, especially when it comes to valuing the national flora and traditional knowledge.

Hansenclever et al. (2017), while questioning the PNPMF guidelines, concluded in his study that there are still several challenges faced by the medicinal plants and herbal medicines sector:

- The qualification needs of producers and primary suppliers;
- Introduction of technical, scientific and legal support (at different levels for each type of raw material) and according to the main fronts of the PNPMF;
- Dissemination of ethnopharmacological knowledge;
- Conducting demand and production studies in each region of the country;
- Actions to reduce the costs of equipment used in quality control and tests required by regulation (by making these tests available in universities, for instance);
- Greater contribution from the scientific academy so that the diverse knowledge necessary for the development of research and improvement of national production in the area can be gathered;
- Valuing the potential of Brazilian biodiversity.

Castro and Albiero (2016) complement this analysis by mentioning some of the main obstacles to improving the medicinal plants and herbal medicines sector:

- High research, development and innovation costs;

- High stringency in the requirements of documentation and clinical tests by regulatory agencies;
- Great heterogeneity of raw material, which raises doubts about the quality of the final product.

More recently, Oliveira (2017) pointed out contradictions promoted by the National Policy on Medicinal Plants, among them, the stimulus to:

- Appropriation / spoliation of Traditional Knowledge Associated by the institution of patents to herbal medicines, especially considering the high request for patents of Brazilian plants by foreign countries.
- Strong presence of the international pharmaceutical industry in the herbal medicine trade
- RDC No. 26/2014, which regulates the production of herbal medicines for traditional use and states that "only manufacturing companies that have a Certificate of Good Manufacturing and Control Practices (CBPFC) for medicines or traditional herbal products can notify and manufacture the products covered by this Resolution." as follows:

> [...] All actions carried out by Anvisa seek to adapt its regulations and documents to the PNMPF (National Policy on Medicinal Plants and herbal medicines) and to the PNPIC (National Policy on Integrative and Complementary Practices in the SUS), legally allowing the use of raw material, notified plant drugs and medicines handled and industrialized safely and effective for population consumption.. (Brasil 2012 p. 121).

Oliveira (2017) and Ferreira da Silva et al. (2020) also add that the PNPMF and its executive policy, the PNPIC, despite mentioning the production chains development and the preservation of medicinal plant species biodiversity based on the local populations cultivation stimulus, especially of family farmers, does not include guidelines that promote public policies for financing and technically assisting these agents, especially when it comes to the strong demands on good production practices.

In addition to the aspects presented, the biggest challenge for the success of this production chain, according to Hansenclever et al. (2017), is the process to legalize native medicinal plants as raw materials for the production of herbal medicines, which forces companies to comply with broad quality and effectiveness requirements. This perception is still corroborated by Oliveira and Ropke (2016) and Oliveira (2017), and, in this sense, exotic or imported species stand out in the national market, precisely because international companies are able to more readily meet the necessary requirements. This fact has profound implications for the sustainability of Brazilian biomes as a source of genetic resources for the production of herbal medicines, since they are currently undergoing an intense process of replacement by conventional crops, agricultural commodities. (Sano et al. 2008; Ferreira et al. 2016)

The challenges to the sector in Brazil discourage the interest of farmers in establishing themselves exclusively in this type of production as a business alternative, further delaying their technological development, especially when they try to insert themselves in the agro-phyto-industrial business, therefore, the supply of raw materials for the large pharmaceutical industries is increasingly consolidated via importating, reserving the national market for transnational companies (Castro et al. 2016).

A direct consequence of the previously mentioned is the value loss of national biodiversity with negative impacts for its conservation/ preservation, since the scarce information regarding potential native species, production quantity, resale value, production and management processes, industrialization and commercialization of extracted products, among others, lead to the devaluation of these species (Gama et al. 2017).

For Lourenzani et al. (2004) the legal requirements aspect is a source of restrictions to national production and keeps the market of medicinal plants, which comes from a family production model, on the border of marginality and, therefore, underdeveloped, compromising the obtention of information on the occurrence of species, the use and the market potential of native medicinal species.

In addition, Hanseclever et al. (2017) and Oliveira (2017) suggest that industries and companies in the sector, pressured by guidelines similar to those of pharmaceutical products in terms of safety, efficacy and effectiveness standards of the herbal product or national raw material, demand that their technical standards are complied with, resulting in standards that are difficult for new national business to meet, since they are devoid of technologies to meet such requirements.

According to Lourenzani et al. (2004), the production of medicinal plants is another alternative for generating employment opportunites and income in several fronts, but it is important to prepare farmers/ extractivists to meet market demands and improve the conduct of this enterprise (appropriate cultivation and exploitation management; selling; organizational and cooperative actions). The authors also suggest that collective actions (cooperatives

and associations) would allow greater access to production techniques and requirements imposed on the market and, together with the sharing of information among producers, it would allow for an advance in learning this production system, which would increase productivity and production efficiency.

Final considerations - strategic guideline for the development of the sector

When considering the environmental services of providing medicinal plants as a public good that meets different human needs, the strengthening of institutions that ensure the continuity of these resources must be a priority on the nation's political agenda. In this sense, it is possible to recommend special attention to public policy instruments that promote the reproduction and conservation of native species, contribute to an increase in the richness of the flora, strengthen the ecological relationships between local communities and natural resources, and maintain the biomes intact, since such instruments can promote social services, income and sustainable alternatives from land use and occupation.

As evidenced throughout this paper, institutional barriers, associated with the public and private scarcity of material and pecuniary resource, intended for research in this sector (Oliveira et al. 2016; Alcântara-Oliveira 2017; Hanseclever et al. 2017), once established the information deficit on the medicinal potential of plant species in relation to Brazil's floral wealth, lead to the loss of research opportunities, genetic resources, sustainability of biomes and business development, evidencing Brazil's technological dependence in the medicinal plants and herbal medicine sector .

Thus, it is possible to suggest a strategic guideline for solving the problems highlighted previously, namely the approximation between the academy and the private sector, whose purpose implies the alignment between basic and applied research (Oliveira et al. 2016).

Following this logic, ethnobotanical studies, integrated with bioprospecting activities, emerge as alternatives to be stimulated via public policies and research fundings. As the science that values plant and cultural diversity (Silva et al. 2015), ethnobotany brings back the dynamics of traditional knowledge about the use of flora, supporting scientific and technological development, which are fundamental for innovation. In addition, collaborative investigations within communities contribute to the appreciation of local, natural and cultural resources (Linhares 2015).

Bioprospecting shortens the research protocol and reduces costs by making use of traditional or indigenous communities' knowledge to gather biological, methodological and genetic resources, providing benefits to society as it highlight the economic value of these resources for the various commercial and industrial segments (Pereira et al. 2008; Borges 2013). In this sense, these segments find a strategic opportunity to act along the phytotherapic chain.

When associated with ethnobotany, bioprospecting also has the potential to consolidate phytotherapy as a profitable activity for traditional communities that work with medicinal plants, allowing for the improvement of species management techniques and production technology, through educational institutions and research together with public policies, thus contributing to sustainable regional development, integrating the environment with agribusiness in favor of the preservation and conservation of biomes (Oliveira et al. 2012; Oliveira 2012; Liporacci et al. 2013; Silva et al. 2015).

As stated by Cavalcanti (2005), when one thinks about valuing natural ecosystems of species with medicinal or food potential, it is essential to relate biological services with socio-cultural ones because that way the maintenance of biodiversity will be increased by the cultural identity of the local population, stimulating the process of ecosystem conservation.

It is from this perspective that the Convention on Biological Diversity proposes objectives based on bioprospecting activities, such as the conservation of biological diversity, the sustainable use of its components and the equitable sharing of the benefits derived from traditional knowledge (Pereira et al. 2008).

However, the financial return for native peoples who cooperate, based on traditional knowledge of the use of plants to promote the manufacture of herbal medicines, has been much lower than that of the pharmaceutical industries that develop the final product. Since local communities do not always have the power to negotiate research results, scientists and companies that carry out bioprospecting have not been equitably acknowledged (Andrade 2006; Pereira et al. 2008), thus lacking support in terms of public representation in terms of consolidation of research aimed at appropriating the traditional knowledge of these communities.

The strengthening of the chain based on the promotion of science and technology, would increase national participation in the production of technology in the sector and would translate into acknowledgement of associated traditional knowledge (CTA) with a consequent stimulus to the demand for raw material and ancillary institutions to its production, such as the advisory

and rural extension programs (ACEX) necessary for good production practices (BPP). The stimulus to production would then be a provider of environmental services that preserve biodiversity, through the acknowledgement of its existing potential value.

AUTHORS' CONTRIBUTIONS

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by K.O.A. and C.E.S.S. The first draft of the manuscript was written by C.E.S.S. and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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