Assessing Bottlenecks Concerning Biodiversity and Traditional Knowledge in the Brazilian Phytopharmaceutical Sector: An Expert Panel Approach.

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Resumo

This article is aimed at understanding the barriers to innovation in the Brazilian phytopharmaceutical sector. Specifically, on the challenges imposed by the: legal and regulatory framework for accessing Brazilian biodiversity and the traditional knowledge (TK) of the indigenous and local communities; investment level; and vegetal input supply. This study presents the outcome of an expert panel, in which an interdisciplinary group of 10 experts on phytotherapy, pharmacology, biochemistry, anthropology and intellectual property indicated the mainstream bottlenecks regarding the Brazilian phytopharmaceutical sector. This investigation resulted in the identification of two significant “bottlenecks”: bureaucratic and legal restrictions for R&D based on biodiversity and TK and low level of research investments and incentives for the sector. We conclude that adjustments in legal and regulatory aspects and in the behavior of the councils responsible for permitting access to biodiversity and TK partnerships need to be done.

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ABSTRACT

This article is aimed at understanding the barriers to innovation in the Brazilian phytopharmaceutical sector. Specifically, on the challenges imposed by the: legal and regulatory framework for accessing Brazilian biodiversity and the traditional knowledge (TK) of the indigenous and local communities; investment level; and vegetal input supply. This study presents the outcome of an expert panel, in which an interdisciplinary group of 10 experts on phytotherapy, pharmacology, biochemistry, anthropology and intellectual property indicated the mainstream bottlenecks regarding the Brazilian phytopharmaceutical sector. This investigation resulted in the identification of two significant "bottlenecks": bureaucratic and legal restrictions for R&D based on biodiversity and TK and low level of research investments and incentives for the sector. We conclude that adjustments in legal and regulatory aspects and in the behavior of the councils responsible for permitting access to biodiversity and TK partnerships need to be done.

KEY WORDS: Herbal Medicine Industry. Regulation. Intellectual property. Traditional knowledge. Government Policy. Indigenous and local communities. Biodiversity. Barriers to innovation. Bureaucratic and legal restrictions for R&D. Expert panel.

1 Introduction

The Brazilian pharmaceutical market is classified as one of the most promising and attractive for investments. In the last ten years, Brazil has been among the ten largest pharmaceutical markets in the world (Castro and Albiero 2016). However, the current context of the herbal medicine market is still very incipient. In a recent survey, the Brazilian Association of Companies in the Phytopharmaceutical Sector (ABIFISA) estimates that the national herbal medicine market accounts for only 3% of the total medicine market (Nov 30, 2018 posting by Trentini to Centrolfora Group Blog; unreferenced). If we apply this percentage to the total revenue of the pharmaceutical sector, evaluated by the Pharmaceutical Products Industry Union (Sindusfarma) at R$ 78 billion (factory price), we reach a figure equivalent to US$ 500 million in annual sales of phytopharmaceuticals, or a consumption of US$ 2.5 per inhabitant. (SINDUSFARMA 2021).

Worldwide, the herbal medicine market is estimated at US$30 billion. With Germany as a benchmark and the world's largest herbal medicine market, with estimated sales of US$ 3 billion annually, which represents half of the European Union (EU) market, and with annual consumption per inhabitant of US$ 39. (Castro and Albiero 2016; Simões and Schenkel 2002).

The main objective of this investigation is to measure the possible bottlenecks for the development of the herbal medicine market in Brazil. Among the possible origins, we sought to verify whether regulation and legislation impose (or not) excessive restrictions on this development. Likewise, we sought to understand whether and the bodies responsible (agencies and councils) for research authorizations, accessing Brazilian biodiversity registration of medicines and partnerships with local communities, as well as the structure of supply of plant inputs and research promotion, could also be operating as bottlenecks for this development.

This paper is structured as follows. Section two provides a literature review on the Traditional Knowledge (TK) in the world and in Brazil. Additionally, we will bring a brief report of the literature on Brazilian biodiversity, the offer of standardized plant inputs and the Brazilian regulatory and legal environment on the subject of the treaty. Section three provides the materials and methodological aspects. And the sections four, five and six the results, discussion and conclusions, respectively.

2 Literature Review

2.1. Traditional Knowledge

According to Dagne (2014) from the Convention on Biological Diversity (CBD) “the international community has widely recognized the need to protect traditional knowledge (TK)” (Dagne 2014, p. 26) in such a way that this protection generates rewards for the “guardians of biodiversity” when using these resources. This convention is an agreement established within the scope of the United Nations (UN) and integrated by 188 countries whose objectives are the conservation of biological diversity, the sustainable use of its varieties and the fair and equitable sharing of benefits arising from the exploitation of genetic resources.

Along the same lines, Latulippe (2015) reiterates the recognition of international multilateral bodies and ecological science in order to protect TK. However, this author points out a lack of consensus in the literature regarding this term, where “different conceptualizations of TK reflect the different contexts in which they are situated and have meaning” (Latulippe 2015, p. 119). Lakshmanan and Lakshmanan (2014) point out that in certain circumstances modern legal systems are absent or ineffective in protecting these ancient scientific inventions, despite efforts by the international community such as the World Intellectual Property Organization (WIPO).

But, in the end of the day, what is traditional knowledge? For Dagne (2014), in terms of the CBD resolutions, ‘it is a shorter form of the phrase “knowledge, innovations and practices of indigenous and local communities that incorporate traditional lifestyles”’ (Dagne 2014, p. 27). This author highlights the lack of precision in the literature, and in international regulation, about the term and the risks inherent in the exclusion of certain people or communities that do not clearly fit the definition of “indigenous communities”. Latulippe (2015) understands that the answers to these questions are discordant and have a semantic rigidity, which does not suit the concept, especially when looking from the operational perspective. Lakshmanan and Lakshmanan (2014) report a definition considered broader, in line with WIPO, where this definition is put in these terms:

> tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields.(Lakshmanan and Lakshmanan 2014, p. 31)

Dagne (2014) emphasizes that international Intellectual Property (IP) forums have sought to substantively distinguish “a descriptive broader concept (*lato sensu*), and TK in a stricter legal and policy sense (*stricto sensu*).” (Dagne 2014, p. 29). The first refers to the knowledge content that is associated with "the genetic resources that are frequently

intertwined with TK. 'In other words, "technical" knowhow and the underlying biodiversity.' (Dagne 2014, p. 29). The second category is related to "technical know-how, knowledge, and also folklore/traditional expressions and manifestations of cultures in the form of music, stories, paintings, handicrafts, languages (...)." (Dagne 2014, p. 29). For a clearer overview of this segmentation we turn to Lakshmanan and Lakshmanan (2014), summarized in table 1 below:

Table 1 – Categories of TK

Traditional Knowledge	Traditional Cultural Exp.	Genetic Resources
Agricultural innovations and practices	**Artistic**	**Genetic material of actual or potential value**
Ecological/Environmental knowledge	**Literary**	**Material of plant anima microbial or other origin**
Biodiversity conservation	**Music**	**Containing functional units of heredity**
Natural resources Management	**Dance**	
Architecture	**Spirituality**	
Construction Technologies	**Handicrafts**	

Source: Adapted from Figure 1 of (Lakshmanan and Lakshmanan 2014, p. 32)

According to Dagne (2014), the protection of TK is justified for two reasons. First, "because of the value and importance that TK offers to ILCs (Indigenous and Local Communities) and to the world population at large." (Dagne 2014, P. 30), And second, because "TK protection is required in response to the threats and challenges posed to TK systems from the global IPRs (Intellectual Properties Rights) system itself." (Dagne 2014, P. 30). All this in order to preserve the whole social, ecological, cultural and spiritual context so that TK can continue to be produced and reproduced. In other words, the TK, in addition to the preservation aspect of its cultural significance, would also be justified by its contribution to biological diversity and ecological integrity, improving and preserving socioeconomic conditions and contribution to scientific discovery and biotechnology development.

Lakshmanan and Lakshmanan (2014) report a significant aspect to the research proposed in this article that "modern medicine can be benefitted hugely by incorporating attributes of ancient wisdom from these traditional medicinal practices that can enhance

effective medical cures for several diseases" (Lakshmanan and Lakshmanan 2014, p. 34). Therefore, "many modern researchers and pharmaceutical industries have been making progress by utilizing TK and genetic resources to produce novel pharmaceutical medicines and therapeutical procedures to the world as part of modern innovations" (Lakshmanan and Lakshmanan 2014, p. 34). However, this author reports, there is still a difficulty in remunerating or rewarding traditional communities due to "their indirect and direct contribution to the development of modern science and technology" (Lakshmanan and Lakshmanan 2014, p. 34).

There are currently three levels of interests in the world - and corresponding actions - with the aim of protecting TK, or even mitigating the above-mentioned difficulties: 1) At the level of supranational organisms: there is a long-term interest in the conservation of genetic resources and knowledge traditional 2) at the national level: there is an interest of home nations that host genetic resources and TK to regulate access for conservation and benefit-sharing purposes and 3) at the local level: compensation to indigenous and local communities in the form of sharing benefits through their local customary laws. (Gehl Sampath 2003).

At the international level, since the 1980s, organizations have been making efforts to recognize the TK and promote regulation for it, such as the Food and Agricultural Organization (FAO) of the United Nations (which includes its Commission on Genetic Resources for Food and Agriculture), International Union for Conservation of Nature (IUCN), United Nations Environment Program (UNEP), Convention on Biological Diversity (CBD) and the World Intellectual Property Organization (WIPO). (Lakshmanan and Lakshmanan 2014).

Faced with this challenging scenario, researchers and organizations have proposed agreements, such as the Trade Related Intellectual Property Rights Agreement (TRIPS), with the purpose of establishing propositional norms for the protection of ICL's rights and enabling the development of innovative products. We quote some of these propositions:

- "The Member States are required to develop national TK databases for defensive protection of TK to prevent erroneous grant of patents and to promote transparency, certainty, conservation and transboundary cooperation." (Lakshmanan and Lakshmanan 2014, p. 15);
- "Access and Benefit Sharing (ABS) - system to regulate the conditions for access to and use of genetic resources and the sharing of benefits from their utilization with ILCs."(Dagne 2014, p. 39);

- “One of the prominent proposals among the sui generis variation is referred to the “defensive community patent” system (…) The owners of IP rights, ILCs would be in a position to prevent third parties' establishment of IP rights over their resources.”(Dagne 2014, p. 42);

2.2. TK in Brazil

In the regulatory aspect, Brazil has had more than 15 (fifteen) years a “National Policy and Program of Medicinal and Herbal Plants”, introduced by Decree No. 5.813, of 2006 Jun 22. In addition, since 1992 is signatory of the Convention on Biological Diversity (CBD), which complies with recommendations of the World Health Organization (WHO), in order to enable the development of public policies to facilitate the integration of traditional medicine and alternative complementary medicine in national health care systems. (Brasil, 2006).

In 2015, Law No. 13,123 was enacted, which regulates item II of § 1 and § 4 of art. 225 of the Federal Constitution, Article 1, subparafigure “j” of Article 8, subparafigure“c” of Article 10, Article 15 and paragraphs 3 and 4 of Article 16 of the Convention on Biological Diversity. "This Law provides for access to genetic heritage, protection and access to associated traditional knowledge and the sharing of benefits for the conservation and sustainable use of biodiversity." (Brasil, 2015). However, according to Hasenclever et al (2015), if on the one hand this has brought the benefit of protecting the genetic heritage, on the other, it has had the effect of creating a bureaucratic barrier to the production and use of new scientific knowledge, creating, equally , a barrier to innovation and the creation of new products. This authors reports testimonies of two renowned Brazilian researchers corroborate this thesis:

> According to Prof. Glauco Villas-Bôas, from the Oswaldo Cruz Foundation, the systematic application of fines [by the Genetic Heritage Management Council - Cgen], which have long ceased to be guided by the guidelines of a protection policy, which in turn should be backed by a robust information system, has been a disincentive. It promotes uncertainties without being able to obtain effective protection, neither of genetic heritage, nor of intellectual property, nor the sharing of social benefits. (Hasenclever et al 2015, p. 16).

Continues Hasenclever et al. (2015):

> In turn, Prof. João Batista Calixto, from the Federal University of Santa Catarina, one of the main people responsible for the development of the drug Acheflan,states that "currently, the vast majority of researchers who work with natural products in Brazil, especially those who carry out research at universities, are unable to obtain authorization from the CGEN to access and collect the samples necessary for these studies." (Hasenclever et al 2015, p. 16).

More recently, Legislative Decree 136/2020 was approved by the National Congress, which considers Law No. 13,123/2015 as the domestic law for the implementation of the Protocol of the Treaty of Nagoya. This international treaty establishes rules for the division between the countries of the benefits, monetary and non-monetary, resulting from genetic researches with biodiversity and the use of TK by indigenous and local communities. In March 2021, Brazil deposited with the United Nations (UN) the letter of ratification of its adhesion to the Nagoya Protocol. This regulation is expected to facilitate the establishment of joint ventures, the financing of new research, the sharing of results, and the transfer of technologies and training. It also determines the prior consent of the country holding genetic resources to their use by another country. (Verdélio, 2021; Senado, 2020).

On the one hand, there seems to be a consensus in the literature regarding the undue exploitation of resources arising from biodiversity, especially from indigenous and traditional peoples, despite regulatory advances and the efforts of international organizations in the opposite direction. (Lakshmanan and Lakshmanan 2014; Dagne 2014; Latulippe 2015; Hasenclever et al 2017). On the other hand, in the Brazilian case, it seems to us that the simplifying solution of creating excessive bureaucratic obstacles, which hinder the research and development of products based on biodiversity, is also not an appropriate solution to the problem. As he relates Hasenclever et al (2015):

> Although the effort to protect the genetic heritage and the rights of holders of traditional knowledge is commendable, the slowness of authorization processes and the need to go through several administrative instances have discouraged researchers and companies from investing in the development of herbal medicines from medicinal plants Brazilian companies. (Hasenclever et al 2015, p. 16).

In this same line of arguments we find conclusions of Nascimento et al. (2015) regarding this conflict:

> On the other hand, Brazilian legislation has been reinforcing the safety and efficacy criteria that scientifically validate herbal medicines, establishing requirements for their registration. On the other hand, due to the profile of the productive structure of this industry in Brazil, regulatory standards end up working as barriers to the production and development of new products, since to obtain the registration of an herbal medicine it is necessary to carry out different validation tests to ensure the safety and effectiveness in the use and quality of the product. For most companies, the validation costs that go through stages ranging from bioprospecting to preclinical and clinical trials pose serious obstacles. (Nascimento et al. 2015, p. 241).

2.3. Brazilian Biodiversity

Countries with a tropical climate have the primacy in the world for the variety of existing plants and biological diversity. World biodiversity highlights are: Brazil, Colombia, Peru, Ecuador, Venezuela in South America. Mexico in Central America; United States, in North America; Democratic Republic of Congo, South Africa and Madagascar in Africa; as well as Malaysia, Indonesia and Australia in the Pacific.(Villas Bôas 2004).

South American countries hold 50% of the planet's biodiversity, with half of the superior plants on Earth. The eleven countries with the greatest biodiversity concentrate around 60% of the world's plants. If the entire tropical area of the planet is considered, this proportion rises to 70%, being, therefore, the region with the highest concentration of biodiversity. (Joffe and Thomas 1989).

In the particular case of Brazil, a relevant feature that must be reported is the great occurrence of endemism. Endemism occurs when the genetic distribution of an animal or plant species is restricted to a certain region of the planet and is not verified in any other region (Cunningham 1996). For instance, in Germany, 16 endemic species were identified, while in the United Kingdom, 73. However, in Mexico, located in a tropical region of the planet, the number of endemic species rises to 3,376. This phenomenon is even greater in the Amazon region, with between 25,000 and 30,000 species found, which only occur there, as illustrated in table 2.

Table 02 - Endemic Species

Country/Region	**Endemic Plant Species (Number)**
Switzerland	1
Germany	16
United Kingdom	73
Mexico	3.376
Amazon Region	25.000 a 30.000

Source: Adapted from Cunningham (1996).

This scenario led Rodrigues and Carlini (2002) to reach an interesting conclusion that: 'Brazil, as it is among the seven "mega diversities", should be the priority focus of pharmacological investigation of new drugs, and of conducting research to rescue popular/indigenous knowledge in relation to genetic resources.' (Rodrigues and Carlini 2002, p. 5).

2.4. Inputs supply

The Brazilian regulation for the pharmaceutical sector imposes on drug manufacturers the responsibility for the quality of their products, with guaranteed safety and efficacy. This responsibility extends to the inputs used in the manufacturing process, and the final manufacturer is responsible for creating mechanisms with suppliers to ensure compliance with regulatory and legal requirements (Castro and Albiero 2016).

In this sense, the pharmaceutical industry that produces phytotherapeutics, regulators and academia have a double challenge in shaping their supply chain: to maintain their supply flow of plant inputs and establish procedures for qualifying their suppliers. (Simões and Schenkel 2002). However, adversities related to this second challenge have been observed.

Deficiencies in the supply of genuinely Brazilian plant inputs for the pharmaceutical industry is aggravated by the fact that the production base is composed of small producers, who, in general, have difficulties in accessing support from research institutes. A study carried out in the State of Paraná concluded that 80% (eighty percent) of the vegetable inputs produced in that state were below standard, such as microbiology and content of active ingredients (Trento Filho et al. 2010). The authors conclude that the absence of infrastructure and good practices and production techniques results in the inability of small producers to obtain certificates that are requested by regulatory bodies from the pharmaceutical industry.

According to the Ministry of Health, US$ 50 million were invested in the current century in order to encourage the production of herbal medicines and productive arrangements for the production of medicinal plants. Only In 2012, the Ministry of Health invested more than R$ 30 million in 78 projects with medicinal plants and herbal medicines within the scope of the Unified Health System (SUS). There were 31 initiatives for local productive arrangements (LPA's), 44 for pharmaceutical assistance and three for the development and sanitary registration of herbal medicines from the National List of Medicines (Rename) (Ministério da Saúde 2016).

As seen above, the evidence shows that, despite the Brazilian plant wealth, the availability of land for planting, the favorable climate and some government incentives, the Brazilian phytopharmaceutical sector has not yet been able to solve the structuring of a production chain of vegetable inputs that supports the demand of the entire industry. This subject will be investigated in the experts panel if, in fact, is a significant restriction for the expansion of the Brazilian herbal industries.

2.5. German Case - Benchmark

References in the literature estimate a world market for herbal medicines to amount between US$30 and US$44 billion per year. Europe accounts for approximately half of registered sales of herbal medicines in the world. (Castro and Albiero 2016; Simões and Schenkel 2002; Nascimento et al. 2015).

Germany is a true global outlier, presenting itself as the world's largest market for herbal medicines, with sales of US$ 3 billion per year, with annual consumption per inhabitant of US$ 39. This phenomenon is due to a consistent government policy that encompasses several aspects sector: research, training of professionals in the middle area, qualification of input and final product producers. France, with 26.5% of the European Union market, is in second place. (Nascimento et al. 2015).

The success factor for the German case is the developed infrastructure for the supply of vegetable inputs existing in that country. According to Castro (2016), in 2014, a total of 12 suppliers of vegetable pharmaceutical inputs for Brazil was identified. As noted in table 03 below, Germany and Brazil shared the leading position in numbers of supplier companies, 33.33% each. These 12 suppliers were responsible for supplying the industry with 25 different active raw materials (non-excipients). (Castro and Albiero 2016).

Table 03 - Number of companies supplying inputs, by country

Country of Origin	Number of Companies	Participation
Germany	4	33,33%
Brazil	4	33,33%
China	1	8,33%
Spain	1	8,33%
United states	1	8,33%
France	1	8,33%

Source: Adapted from Castro (2016).

However, when we look in more detail at the quantity of products supplied by each supplier, we can see, once again, the leading role played by Germany. In table 4 below, we can see that this country accounted for more than 50% (fifty percent) of supplies that year of vegetable inputs to Brazil. In that year, Brazil represented only 20% (twenty percent) of the total supplied, a fact that signals that we did not obtain the intended results in terms of structuring a production chain of plant inputs for the pharmaceutical industry, despite federal incentives.(Castro and Albiero 2016).

Table 04 - Number of plant inputs, by company and country

Supplier	Number of Inputs	Participation (%)	Participation By Country (%)
Germany 1	11	44	56
Germany 2	1	4	
Germany 3	1	4	
Germany 4	1	4	
Brazil 1	1	4	20
Brazil 2	2	8	
Brazil 3	1	4	
Brazil 4	1	4	
China	1	4	4
Spain	1	4	4
United states	1	4	4
France	3	12	12

Source: Adapted from Castro (2016).

In summary, when we compared the German case with the Brazilian case, we reinforce the suspicion of the incipience of the supply of vegetable inputs by Brazilian companies, despite its biodiversity.

2.6. Legal and regulatory environment

As seen above, Brazil is a signatory to the Convention on Biological Diversity (CBD), and for over a decade has had a "National Policy and Program of Medicinal and Herbal Plants" (Brasil 2006). More recently, Legislative Decree 136/2020 was approved by the National Congress, which considers Law No. 13,123/2015 as the domestic law for the implementation of the Protocol of the Treaty of Nagoya, which establishes rules for the division of monetary benefits between countries and non-monetary, resulting from genetic research on biodiversity and the use of TK by indigenous and local communities. This legal framework, although meritorious, has had the undeniable effect of creating a bureaucratic barrier to the production of new scientific knowledge and the use of this knowledge, as reported by researchers presented above. (Verdélio 2021; Senado 2020).

In the regulatory aspect, ANVISA, through the publication of the Resolution of the Collegiate Board of Directors (RDC) No. 26/2014 May 26, regulated the procedures for the registration of herbal products (ANVISA 2014). Despite this new regulation provided a simplification for the registration of 66 (sixty-six) plant active ingredients of Traditional Herbal Products (recognized by the secular traditional use of substances and the numerous studies on them in the international literature), the perception of the market is that still there

are an excessive bureaucratic/regulatory restrictions for the registration of products based on Brazilian biodiversity. As a reflection of this we observe a small number of valid records of phytomedicines (505) when compared to the total of others medicines in Brazil (8.831), and the consequent low relevance of those products, according the databases of ANVISA and from organizations in the pharmaceutical sector. (ANVISA 2021; SINDUSFARMA 2020; Trentini 2019).

3 Materials and methods

The main objective of this investigation is to measure the possible bottlenecks for the development of the herbal medicine market in Brazil. Among the possible origins, we sought to verify whether regulation and legislation impose (or not) excessive restrictions on this development and access to the biodiversity and Traditional Knowledge (TK). Likewise, we sought to understand whether and the level of investments, as well as the structure of supply of plant inputs and research promotion, could also be operating as bottlenecks for this development.

In methodological terms, this investigation has an exploratory, analytical and descriptive nature, in an essentially qualitative approach, based on two aspects that are important to be highlighted:

1) An literature review, summarizing the concepts found in publications related to the subject matter of the investigation. The bibliographic search was carried out in databases indexed with Scielo, E-papers, Research Gate, CAFe and Google Academics. Some legislation and secondary data was obtained from the organizations' websites, such as the Federal Government, Ministry of Health, Sectorial Unions, in addition we consulted the database of the ANVISA to confirm the portfolio of products registered by the Brazilian pharmaceutical industry;

2) In order to identify the most important bottlenecks in the Brazilian policy framework for the Phytopharmaceutical sector, we adopt an expert panel method. In essence, as pointed out by Almomani et al. (2020), an expert panel method contributes to validate research proposition based on the opinions collected from a set of experts with a strong reputation and extensive experience in a certain area of knowledge. Thus, in our study, we have selected an interdisciplinary group of 10 experts on phytomedicines, pharmacology, biochemistry, and intellectual property. The members of the expert panel received a questionnaire with questions indicating possible policy bottlenecks in the Brazilian Phytopharmaceutical sector, which were formulated based on our literature review.

Some aspects of the expert panel deserve to be clarified before analyzing the results. The questionnaire was answered between 08/17/2012 and 09/15/2021 by 10 (ten) experts working in the herbal medicine sector, from 04 (four) different areas within their respective organizations, as table 5 below. Being the expert panel composed of 60% (sixty percent) of women and 40% (forty percent) of men.

Table 5 - Area of expertise of experts in their organizations

Area	Number of respondents
Research and Development	7
Intellectual Property and Biodiversity	1
Marketing	1
Legal Advisor	1

Source: Developed by the authors

It is also important to highlight the characteristics of the institutions to which the respondents are linked. As we can see in Figure1 below, four types of different institutions were identified, being "fito sector association", "company of the sector" and "research institution" with an individual proportional weight of 30% (thirty percent); and "university" with a weight of 10% (ten percent). This fact is assessed as positive, as it reduces the possibility of institutional bias. We also observed a lack of concentration in the respondents' academic education, with the most frequent areas being biology (03) and pharmacy (02), as shown in table 6 below.

Figure 1 - composition of the panel of experts, by related organization.

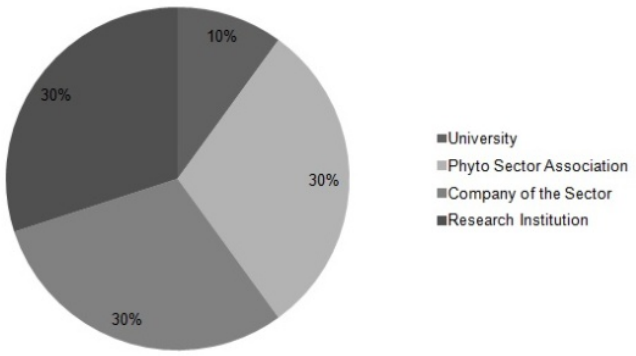


Table 6 – Scientific background of the experts

Scientific Background	Number of respondents
Biology	3
Pharmacy	2
Anthropology	1
Legal law	1
Nutrition	1
Psychology	1
Veterinary	1

Source: Developed by the authors

In order to measure this perception with the experts who participated in the panel, we prepared the questions transcribed in table 7 below, which focused on understanding the possible bottlenecks arising from the performance of the Brazilian regulatory agency (ANVISA) in the research authorization processes and registration of phytomedicines; the possible sources of excessive restrictions in Brazilian legislation; the possible sources of excessive restrictions on Brazilian agencies and councils; restrictions on the supply of vegetable inputs; and the limitations of research funding. This is through the use of biodiversity and partnerships with local communities to absorb knowledge.

The answers to the questions had two formats: the first, categorical and mandatory, gave the expert the option to "agree", "strongly agree", "disagree" or "strongly disagree" with the questions. Based on the answers, an index was developed based on a Likert scale, where the following weights were assigned to the categorical answers: "strongly agree" = 4; "agree" = 3; "disagree" = 2; "strongly disagree" = 1. A second format (not mandatory) allowed the expert to freely express their opinion on the proposed topic, in the dissertation format, as shown in table 7 below.

Table 7 – Questions about possible bottlenecks

Question Subject	ANVISA's regulation	Brazilian legislation - biodiversity	Brazilian legislation – TK	Brazilian agencies and councils – biodiversity and TK	Supply Inputs	Research Funding
Questions	Do you think that the regulation of ANVISA (RDC	Do you think that Brazilian legislation (Law No. 13,123/2015	Do you think that Brazilian legislation (Law No. 13,123/2015 and Decree	Do you think that the Brazilian agencies and councils that are	Do you think the offer/production is adequate of standardize	How do you assess the availability of funding

	26/2014) imposes excessive bureaucratic restrictions for the registration of herbal medicine (not traditional)?	and Decree 136/2020) impose excessive restrictions on the research and development of medicines based on Brazilian biodiversity?	136/2020) imposes excessive restrictions on research and development of medicines based on the absorption of TK in partnerships with indigenous or local communities?	responsible for authorizing research based on biodiversity and/or on partnerships with indigenous or local communities for the absorption of TK impose restrictions beyond the legislation?	d plant inputs for the production of herbal medicines?	lines for research and/or developme nt of herbal products and plant inputs in Brazil?
Question number	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6

Source: Developed by the authors

Table 8 – Independent variables and types of answers

Variables	Constructs	Type	Scale
Independent	ANVISA's regulation	likert	1 to 4
Independent	ANVISA's regulation	dissertation	Qualitative
Independent	Brazilian legislation – biodiversity	likert	1 to 4
Independent	Brazilian legislation – biodiversity	dissertation	Qualitative
Independent	Brazilian legislation – TK	likert	1 to 4
Independent	Brazilian legislation – TK	dissertation	Qualitative
Independent	Brazilian agencies and councils – biodiversity and TK	likert	1 to 4
Independent	Brazilian agencies and councils – biodiversity and TK	dissertation	Qualitative
Independent	Supply Inputs	categorical	Yes, Partially, No
Independent	Supply Inputs	dissertation	Qualitative
Independent	Research Funding	dissertation	Qualitative

Source: Developed by the authors

See in the next item the results obtained of the expert panel.

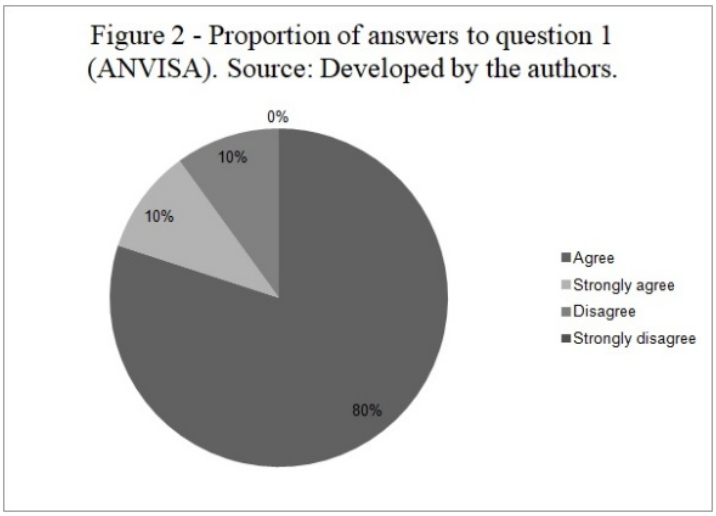
4. Results

4.1. Regulation and Legislation

4.1.1. ANVISA (question 1)

Regarding question 1, 10% (tem percent) strongly agreed and 80% (eighth percent) of the experts agreed that ANVISA imposes excessive bureaucratic restrictions on the phytomedicine registration processes, and only 10% (ten percent) disagreed. See figure 2 below. In addition to the analysis of the relative proportion of responses, a mean of 3 on the Likert scale was observed, which is therefore higher than the average of the scale with a value of 2.5. Both analyses, corroborating the idea that the subject of question 1 operates as a bottleneck for the industry.

Figure 2 - Proportion of answers to question 1 (ANVISA). Source: Developed by the authors.



Some of the dissertation answers to question 1 were summarized below, which somehow corroborate the categorical answers above, as reported by Expert 2 where, according to him, in the ANVISA process for registration of herbal medicines "there are some requirements that are not relevant in the legislation, such as the analysis of pesticides, which are more than 200, many not even used in Brazil". In the opposite opinion, Expert 3 states that the regulation is "well written to guarantee the safety, efficacy and quality of the products".

Table 9 – Dissertation Answers - Question 1

Expert	Scientific Background	Institution	Response
Expert 2	Biologist and PhD in Biotechnology (UFRJ)	Association -	"THE ANVISA is currently formulating a change in the herbal medicine legislation which, according to ANVISA,

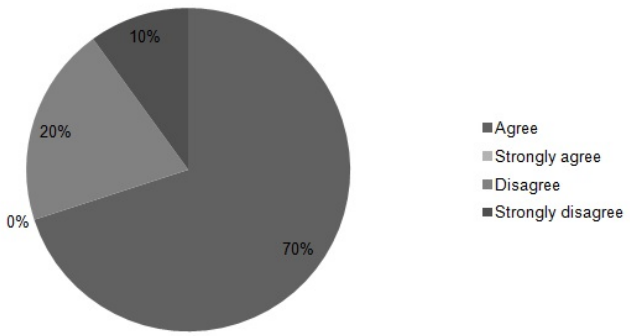
		Phyto Sector	will reduce bureaucracy in herbal medicine registries. There are some requirements that are unrelated to the legislation, such as the analysis of pesticides, which are more than 200, many of which are not even used in Brazil.”
Expert 3	Pharmacist Masters and Doctorate in Natural Inputs	Company of the Sector	"The RDC26 is well written to ensure safety, efficacy and quality of products on the market”.
Expert 5	Psychologist	Association - Phyto Sector	"This poses difficulties”
Expert 9	Pharmacist Masters and Doctorate	University	"There is a less arduous way to register traditional and notified medicines”

Source: Developed by the authors

4.1.2. Legislation/Biodiversity (question 2)

Regarding question 2, 70% (seventy percent) of the experts agreed that Brazilian legislation imposes excessive restrictions on research based on Brazilian biodiversity, 20% (twenty percent) of the experts disagreed and 10% (ten percent) strongly disagreed. See figure3 below. In the answers to question 2 the mean was 2.6, this is also higher than the average of the Likert scale scores (2.5).

Figure 3 - Proportion of answers to question 2 (Legislation/Biodiversity). Source: Developed by the authors.



Some of the dissertation responses to question 2 are summarized in the table 10 below, which corroborate the categorical responses summarized in chart 3 above, that Brazilian

legislation imposes excessive restrictions on research based on Brazilian biodiversity. As reported by Expert 2, and along the same lines, Expert 4. Still in the critical line, Expert 9 states that the legislation imposes excessive barriers, especially “in the area of absorption of traditional knowledge”. In the opposite opinion, Expert 3 states that the laws “brought legal certainty to the sector."

Table 10 - Dissertation Answers - Question 2

Expert	Scientific Background	Institution	Response
Expert 2	Biologist and PhD in Biotechnology (UFRJ)	Association - Phyto Sector	"Unfortunately, Law 13.123/15 did not bring clarifications to the Academy that would facilitate the registration of activities in SisGen, which again led to the illegality of several researchers. Many choose to abandon Brazilian biodiversity in order not to get involved with SisGen, even with Brazil's adhesion to the Nagoya protocol.”
Expert 3	Pharmacist Masters and Doctorate in Natural Inputs	Company of the Sector	"The 2001 interim measure was a major disaster. Law 13,123, despite still lacking regulation, is considered a modern law and brought legal certainty to the sector. We have not had any problems regarding this issue.”
Expert 4	Microbiologist	Research Institution	"Regulatory barriers often end up making research unfeasible and maintain our dependence."
Expert 9	Pharmacist Masters and Doctorate	University	"I would say yes, but mainly in the area of absorption of traditional knowledge”.
Expert 10	Law Specialist	Company of the Sector	"I believe that Brazilian legislation and the Nagoya Protocol are essential for regulating the issue in Brazil and in the world. The Brazilian legislation is the most advanced and has several facilitation mechanisms compared to the norms of other countries"

Source: Developed by the authors

4.1.3. Legislation/TK (question 3)

In question 3, 40% (forty percent) of the experts agreed and 20% (twenty percent) strongly agreed - totaling 60% (sixty percent) - that Brazilian legislation imposes excessive

restrictions on drug research and development based on partnership with local communities to absorb their traditional knowledge, 30% (thirty per cent) disagreed and 10% (ten per cent) strongly disagreed. See figure4 below. An average index of 2.7 was obtained, which was higher than the average of the Likert scale scores (2.5). The dissertation answers also indicate that most experts attribute a restrictive condition to Brazilian legislation for access to TK, as reported in table 11 below.

Figure 4 - Proportion of answers to question 3 (Legislation/TK). Source: Developed by the authors.

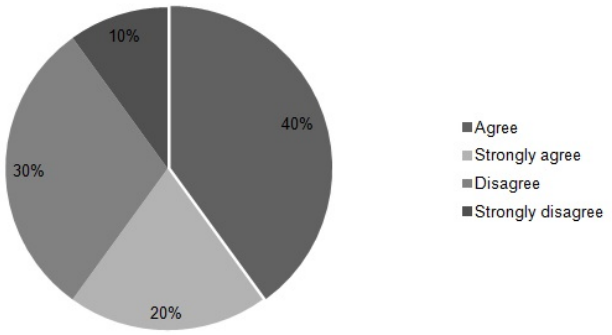


Table 11 - Dissertation Answers - Question 3

Expert	Scientific Background	Institution	Response
Expert 7	biology, M.Sc. Social Anthropology, D.Sc. Public Health	Research Institution	"With the proper articulation and agreement of the community, the process is much more viable than MP 2.186/2000 was."
Expert 9	Pharmacist Masters and Doctorate	University	"Researches with traditional knowledge are being carried out in a much smaller number due to the difficulty of meeting legal requirements."
Expert 10	Law Specialist	Company of the Sector	"I believe that Brazilian legislation and the Nagoya Protocol are essential for regulating the issue in Brazil and in the world. Brazilian legislation is the most advanced and has several facilitation mechanisms compared to the norms of other countries."

Source: Developed by the authors.

4.2. Agencies and Councils/Biodiversity and TK (question 4)

With regard to the role of agencies and councils to authorize access to biodiversity and establish partnerships with local communities - question 4 - 60% (seventy percent) of experts strongly agreed or agreed that these bodies impose restrictions on these questions, and 40% (forty percent) of them disagreed with this hypothesis. See figure 5 below. In the answers to this question, an average index of 2.7 was obtained, against 2.5 of Likert scale scores. In other words, like the previous ones, this statistic also served to demonstrate that the perception of most Experts attributes to the boards the condition of barrier. As same as in the dissertation answers, as table 12 below.

Figure 5 - Proportion of answers to question 4 (Agencies and Councils/Biodiversity and TK). Source: Developed by the authors.

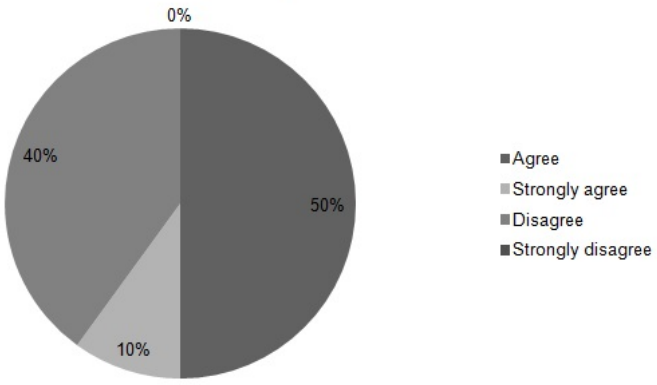


Table 12 - Dissertation Answers - Question 4

Expert	Scientific Background	Institution	Response
Expert 2	Biologist and PhD in Biotechnology (UFRJ)	Association - Phyto Sector	"Yes, many traditional communities are not aware of this law, because the law is part of a different society than theirs. The government did not assist in this dissemination of information either. The link between users and providers is missing, which reduces the sharing of benefits."
Expert 7	biology, M.Sc. Social Anthropology, D.Sc. Public Health	Research Institution	"The authorization process is complicated and bureaucratic. The online platform should make it easier, but more complicated than necessary."

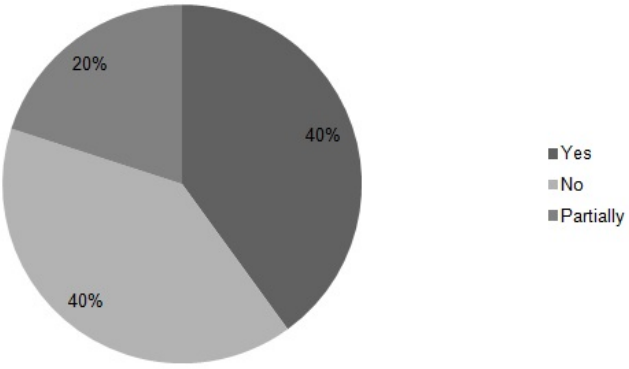
Expert 10	Law Specialist	Company of the Sector	"Unfortunately, we are not getting support from government agencies at the moment as we should, this has been a more complicating factor than the actual compliance with the legislation."

Source: Developed by the authors.

4.3. Inputs Supply (question 5)

In question 5, we sought to obtain the experts' perception related to the self-sufficiency of the national supply of vegetable inputs for the herbal pharmaceutical industry, and whether this could possibly be understood as a limitation. The answers were categorical, "yes" or "no", where 40% said the offer was sufficient, 20% partially sufficient and 40% insufficient. See figure 6.

Figure 6 - Proportion of answers to question 5 (Inputs Supply). Source: Developed by the authors.



This finding does not confirm the current Brazilian scenario of supply of vegetable inputs in relation to what was reported by (Castro and Albiero 2016), presented above, which demonstrates the incipience of the supply structure. This lack of consensus in the perception of specialists becomes more evident when we analyze the dissertation responses, where deficiencies in the production chain are confirmed, but also justified the demand for external suppliers due to the ease of access to clinical data and certifications. As shown in table 13 below.

Table 13 - Dissertation Answers - Question 5

Expert	Scientific Background	Institution	Response
Expert 1	Veterinary	Company of the Sector	"We still have few companies in Brazil dedicated to the production of IFAVs and little incentive to do so."
Expert 2	Biologist and PhD in Biotechnology (UFRJ)	Association - Phyto Sector	"The chain of IFAVs must be strengthened in Brazil. Today, there are few producers of vegetable inputs. The government needs to foster the development of these production chains within bio-economy programs."
Expert 3	Pharmacist Masters and Doctorate in Natural Inputs	Company of the Sector	"Brazil has a manufacturing structure to meet the demand for inputs. The reason that most of the inputs (or plant drugs) are from foreign species is the fact that these species have sufficient clinical data on safety and efficacy for registration."
Expert 9	Pharmacist Phd	University	The process of importing (inputs) facilitates registration by industries (pharmaceutical) by already arriving a package (certifications) ready for this.

Source: Developed by the authors.

4.4. Research funding (question 6)

In question 6, we sought to obtain the experts' perception regarding the sources of funding and incentives for research and development of herbal products (only dissertation). The unanimous position is that there is a lack of funding sources, private or public, for this purpose. Which, obviously, represents a bottleneck for this industry. See table 14 below.

Table 14 - Dissertation Answers - Question 6

Expert	Scientific Background	Institution	Response
Expert 1	Veterinary	Company of the Sector	"Insufficient assessment."
Expert 2	Biologist and PhD in Biotechnology (UFRJ)	Association - Phyto Sector	"Finep has been working for this, but there are still very few development lines in Brazil for IFAVs."

Expert 3	Pharmacist Masters and Doctorate in Natural Inputs	Company of the Sector	"It needs to be expanded, within the order of magnitude of technological development (Drug development in good manufacturing practices and clinical validation)"
Expert 7	biology, M.Sc. Social Anthropology, D.Sc. Public Health	Research Institution	“Highly sparse. If research in general already suffers, this area suffers much more. It is not a priority for funders.”

Source: Developed by the authors.

5 Discussion

The Brazilian Political, Legal and Regulatory framework had the effect of complying with international agreements and protecting biodiversity and the rights of TK holders and preventing biopiracy. They also ensured an improvement in the quality of herbal products, especially given the counterfeits that were common in the past. Regulations and laws are welcome as they seek to protect the rights of consumers, communities and countries.

However, the literature revisited and the answers obtained from experts demonstrate that the effects of bureaucratic excesses arising from this same regulation are perceived as a bottleneck for the sector, as they created excessive barriers, sometimes, even impediments, mainly in the possibility of access to biodiversity and TK. We observed that the averages of the experts' answers were above the average of the scale used, indicating that they, on average, agree that regulation, laws and councils impose excessive restrictions on research processes, access to biodiversity and on the partnership with ILCs , according to table 15 below.

Table 15 - Average answers x Average Likert scale

	Question 1	Question 2	Question 3	Question 4
Investigated Object	Regulation of ANVISA imposes excessive bureaucratic restrictions?	Brazilian legislation impose excessive restrictions on the research on Brazilian biodiversity?	Brazilian legislation imposes excessive restrictions on research based on the absorption of TK?	Brazilian agencies and councils that are responsible for authorizing research based on biodiversity and/or on partnerships for the absorption of TK impose restrictions

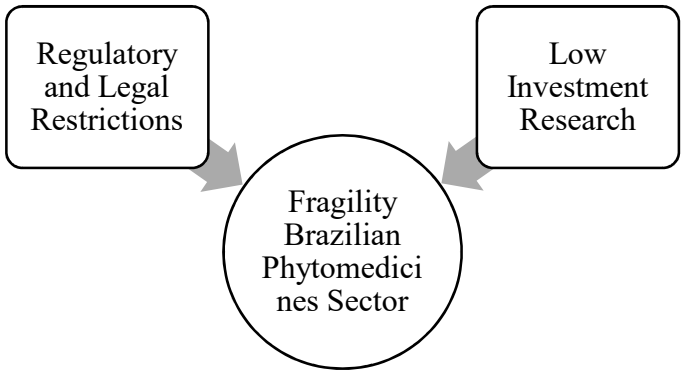
				beyond legislation?
Mean answers	**3.0**	**2.6**	**2.7**	**2.7**
Mean scale	**2.5**	**2.5**	**2.5**	**2.5**

Source: elaborated by the authors

Another aspect perceived by the investigation was that, despite the existence of an investment policy by the Federal Government to promote the development of a market for medicinal plants, Brazil has not yet obtained relevant results in terms of developing a productive base of herbal inputs. Investments proved to be insufficient to promote research and innovation in this sector, a fact that can also be understood as a bottleneck for the flourishing of this industry in a perennial and sustainable manner.

Thus, we can infer that the fragility of the phytomedicine sector in Brazil and its low capacity for innovation are somehow related to two global factors that feed back into each other: 1) excessive regulatory/legal restrictions; 2) low research investment rate, as suggested in figure 1 below.

Figure 7 - Bottleneck factors for the Brazilian herbal medicine industry - Source: elaborated by the authors.



With regard to the adequacy of the Brazilian structure for the supply of standardized plant inputs for the herbal medicine industry, both the average of the experts' categorical answers to question 5 - "yes" and no" - and the dissertation responses were not conclusive in the sense to allow us to state that this factor can be considered or not as a bottleneck for the

sector, even though the previous literature indicates that it is. For Expert 3, for example, Brazil has a manufacturing structure to serve the sector and the reason for the significant use of foreign inputs is due to the fact "sufficient clinical data on safety and efficacy for registration" of foreign species.

In summary, given the above, we realize that the excess of bureaucracy based on the aforementioned laws and regulations had a double effect, since at the same time it complied with the best practices in global health surveillance and the agreements for the economic exploitation of biodiversity and TK, it also hinders and does not encourage research, innovation and production. Similar conclusions that have reached Hasenclever et al. (2015) and Nascimento et al. (2015).

6 Conclusion

From the literature review on Traditional Knowledge (TK), we conclude that Brazil has been creating a legal and regulatory environment to comply with international conventions and treaties. In this sense, it has a clear and stable legal and regulatory environment, supported by: - "National Policy and Program of Medicinal Plants and Herbal Medicines", established by Decree No. 5.813, of June 22, 2006 and RDC ANVISA 26 / 2016; - The legal framework of the law on biodiversity Law n.º 13.123 / 2015 and, more recently, the approval by the National Congress of Legislative Decree 136/2020.

When analyzing the current scenario, it is clear that, despite all the richness of Brazilian biodiversity, pharmaceutical companies have not yet been encouraged to make significant investments to serve a potentially relevant market for plant protection products, which is estimated at US$ 5 billions annually. Neither is it about creating an environment for innovation in this area.

Some factors that we can observe in this investigation: - bottlenecks for innovation, both with regard to legal and regulatory restrictions on access to Brazilian biodiversity, and to the TK of ILCs; - low efficiency and small amount of resources invested by private entities and by public policies of the Federal Government to promote the development of a robust market for herbal medicines and medicinal plants; - The incipience of the production base of quality herbal inputs was not clearly identified as critical for the flourishing of this industry in a perennial and sustainable manner.

Faced with these bottlenecks, we suggest that public policies be directed to adjustments in legal and regulatory aspects and in the positions of the councils responsible for

permitting access to biodiversity and TK partnerships; and expansion of public and private investments in research and development in a more efficient regulatory environment.

Secondarily, investments for the creation of a production vector (based on local production arrangements) and certification of standardized inputs and plant extracts from Brazilian biodiversity, in line with the German model, guaranteeing the homogeneity of inputs and compliance with sanitary rules.

As this investigation is not anchored in an elaborate and systematic process for the analysis of information, is considered as a narrative, has limitations and cannot be considered a formal investigation process.

Brazil has an excellent scenario, with the combination of a favorable climate, the greatest biodiversity in the world and researchers capable of developing a vigorous and innovative herbal medicine industry. However, the policy on access to biodiversity and TK needs to be revised, otherwise this wealth will never be monetized, either by society as a whole or by the ILCs.

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8 Acronyms

ANVISA – Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency).

APLs – Arranjos Produtivos Locais [Local Productive Arrangements].

CBD - Convention on Biological Diversity.

EU - European Union.

FINEP – Financiadora de Estudos e Pesquisa [Research and Study Funder].

FAO - Food and Agricultural Organization.

ILCs - Indigenous and Local Communities.

IUCN - International Union for Conservation of Nature.

SisGen – Sistema Nacional de Gestão do Patrimônio Genético [National Genetic Heritage Management System].

TK - Traditional Knowledge.

TRIPS - Trade Related Intellectual Property Rights Agreement.

UN - United Nations.

UNEP - United Nations Environment Program.

WHO – World Health Organization.

WIPO - World Intellectual Property Organization.

ABIFISA – Associação Brasileira das Empresas do Setor Fitoterápico [Brazilian Association of Companies in the Phytopharmaceutical Sector].

SINDUSFARMA – Sindicato da Indústria Farmacêutica [Pharmaceutical Products Industry Union]

SUS – Sistema Único de Saúde [Unified Health System].

RENAME – Relação Nacional de Medicamentos Essencias [National List of Essential Medicines].