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Promotion of Herbal Medicines as a Sustainable Development Strategy

A case study on the Brazilian Amazon

Master's thesis in Industrial Ecology

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Abstract

Medicinal plants have provided humankind with curative treatments for millennia, however, their use has declined mainly due to the growing synthetic medicine industry and the disqualification of traditional knowledge. This trend, threatening the remaining knowledge and cultural practices, increases the risk of biodiversity loss considering the new economic interests and unsustainable competitive utilization of the standing forests, such as mining, logging, and soy production. Therefore, the promotion and integration of herbal medicines into primary healthcare is crucial and should be considered a sustainable pathway to achieve adequate enhancement capacity. It holds the potential to enable new drug discoveries, wider access to healthcare, conservation of forest resources, support in narrowing socio-economic gaps, and meet the Sustainable Development Goal (SDG) as well as the World Health Organisations' (WHO) promotion of herbal medicines. Furthermore, research on medicinal plants plays an essential role in developing new drugs, which should not be neglected in light of the Covid-19 pandemic.

To study the promotion of herbal medicines as a sustainable strategy we have chosen Brazil as a case study. Possessing the largest share of the Amazon and with six different biomes, it is a country with a megadiverse flora and rich cultural diversity, making it a potential hub for herbal medicine production. Despite this, the country struggles to integrate herbal medicine into its healthcare system, which serves the objectives of this study to examine and discuss the opportunities and challenges of such integration.

We have focused mainly on the Amazon region and the implementation of Brazil's Living Pharmacies (*Farmácias Vivas*) program, an ongoing policy to integrate state-approved herbal medicines into the public healthcare system. Besides reviewing the relevant literature in English and Portuguese, we have carried out two months of fieldwork between the country's North and Southeast Regions in early 2022. During that period, we conducted 21 interviews with Brazilian key informants, mainly in the Amazon region, including stakeholders from local communities, local experts in academia and industry, and representatives of environmental organizations.

The interviews have been analysed alongside a review of relevant herbal medicine literature to create a comprehensive picture and to locate existing knowledge gaps. We have identified initiatives promoting the use and preservation of knowledge on herbal medicine in the Brazilian Amazon but found that they struggle with stringent regulations, scant financial support, lack of managerial knowledge, and regular supply of plant material to produce standardized regulated herbal medicines. Besides such logistic, economic, and regulatory challenges, there is also a question of limited social acceptance reinforced by medical doctors' general lack of formal training. Despite these challenges, continuous development of a comprehensive regulatory framework promoting herbal medicine and its associated traditional knowledge is the foundation for achieving the Sustainable Development Goals and the World Health Organizations Traditional Medicine Strategy.

While this area holds promise, it has during the study become clear that the herbal medicine production as a sustainable development strategy requires adequate value-chain development, that the society would benefit from education on herbal medicinal use and that local actors require much more capacity enhancement. Additionally, a value chain based on medicinal plants can enable a bioeconomy transition and the preservation of the standing forest. The pathways highlighted not only hold great potential for Brazil, but it is applicable to other countries across the tropics where inhabitants are dependent on nature as a source of livelihood and where local biodiversity-based initiatives have the potential to prosper.

Keywords: Herbal Medicine, Sustainable Development, Healthcare, Medicinal Plants, Bioeconomy, Traditional knowledge, Brazil.

Resumo

As plantas medicinais têm proporcionado à humanidade tratamentos curativos há milênios, entretanto, seu uso tem diminuído principalmente devido à expansão da indústria de medicamentos sintéticos e à desqualificação do conhecimento tradicional. Essa tendência que ameaça o conhecimento e as práticas culturais remanescentes, também aumenta o risco de perda da biodiversidade dados novos interesses econômicos e atividades que competem pela utilização insustentável das florestas, como mineração, extração madeireira e produção de soja. Assim, a promoção e integração de fitoterápicos nos cuidados de saúde primários é crucial e deve ser considerada como um caminho sustentável para melhora da capacidade. Essas abrangem o potencial de descobrir novos medicamentos, o acesso mais amplo aos cuidados de saúde, a conservação dos recursos florestais, o apoio na redução das desigualdades socioeconômicas além do potencial de auxiliar no cumprimento dos Objetivos de Desenvolvimento Sustentável (ODS) e do uso de fitoterápicos promovido pela Organização Mundial da Saúde (OMS). A pesquisa com plantas medicinais desempenha um papel essencial não só no descobrimento mas também desenvolvimento de novos medicamentos, o que não deve ser negligenciado face a pandemia de Covid-19.

Para estudar a promoção de fitoterápicos como estratégia sustentável, escolhemos o Brasil como estudo de caso. Possuindo a maior parte da Amazônia, seis distintos biomas, flora megadiversa e rica diversidade cultural, o País tem grande potencial como polo produtor de fitoterápicos. Apesar do potencial, a integração de fitoterápicos no sistema nacional de saúde é um embate e objeto de estudo nesse trabalho que visa examinar e discutir as oportunidades e desafios dessa integração.

O estudo teve como principal foco a região Amazônica e a implementação do programa Farmácias Vivas, uma política existente que visa integrar medicamentos fitoterápicos aprovados pelo governo ao sistema público de saúde. Além da revisão de literatura relevante em Inglês e Português, realizamos dois meses de trabalho a campo entre as regiões Norte e Sudeste do País no início de 2022. Nesse período, realizamos 21 entrevistas com informantes-chave Brasileiros, principalmente na região Amazônica. Entrevistados abrangeram representantes de comunidades locais, acadêmicos, especialistas da indústria e representantes de organizações ambientais.

As entrevistas e revisão da literatura relevante foram analisas de forma conjunta para criar um retrato abrangente e identificar lacunas no conhecimento. Identificamos na Amazônia brasileira

iniciativas que promovem o uso e a preservação do conhecimento sobre fitoterápicos, mas observamos que essas defrontam-se com regulamentações rigorosas, apoio financeiro escasso, falta de conhecimento em gestão e de fornecimento regular do material vegetal para a produção padronizada de fitoterápicos regulamentados. Além desses desafios logísticos, econômicos e regulatórios, a aceitação social limitada também é questão de interesse e reforçada pela falta de treinamento formal dos médicos nesse campo. Apesar desses desafios, o desenvolvimento contínuo de um quadro regulatório abrangente que promova a fitoterapia e o conhecimento tradicional associado é o principal embasamento para alcançar os Objetivos de Desenvolvimento Sustentável e a Estratégia de Medicina Tradicional da Organização Mundial da Saúde.

Embora esta área seja promissora, durante o estudo ficou claro que a produção de fitoterápicos como uma estratégia de desenvolvimento sustentável em torno requer o desenvolvimento das cadeias de valor, que a educação sobre o uso de fitoterápicos seria de grande benefício a sociedade e que atores locais requerem maior capacitação. Ademais, a cadeia de valor baseada

em plantas medicinais pode possibilitar uma transição com ênfase na bioeconômica e preservação da floresta sem necessidade de conversão. Os caminhos destacados não só têm um grande potencial para o Brasil, mas são aplicáveis a outros países nos trópicos, onde os habitantes dependem da natureza para subsistência e onde as iniciativas locais baseadas no uso da biodiversidade podem prosperar.

Palavras-chave: Fitoterápicos, Desenvolvimento Sustentável, Cuidados a saúde, Plantas Medicinais, Bioeconomia, Conhecimento tradicional, Brasil.

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Muito muito obrigada

Amanda Martvall, Gothenburg, June 2022

Klara Lindberg, Gothenburg, June 2022

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List of Abbreviations

Anvisa	National Health Surveillance Agency *(Agência Nacional de Vigilância Sanitária)*
CBD	Convention on Biological Diversity
FB	Brazilian Pharmacopeia *(Farmacopéia Brasileira)*
FFFB	Phytotherapic Form of the Brazilian Pharmacopoeia (Formulário de Fitoterápicos da Farmacopéia Brasileira)
GMP	Good Manufacturing Process
HM	Herbal Medicine
SUS	Unified Health System (*Sistema Único de Saúde)*
PNPIC	National Policy on Integrative and Complementary Practices *(Política Nacional de Práticas Integrativas e Complementares)*
PNPMF	National Policy on Medicinal Plants (Polí*t*ica Nacional de Plantas Medicinais e Fitoter*á*picos)
RENAME	National List of Essential Medicines *(Relação Nacional de Medicamentos Essenciais)*
RENISUS	National List of Medicinal Plants of interest to SUS (*Plantas Medicinais de Interesse ao SUS)*
THP	Traditional Herbal Products

1 Introduction

The evolution of human societies have heavily relied on the use of biodiversity, where plant species, particularly those with medical properties, have been crucial for human survival (Leite et al., 2021). Medicinal plants have provided humankind with curative treatments since their earliest beginnings dating back to 8 500 BC (Leite et al., 2021), where Traditional Chines Medicine and Ayurveda are two of the noteworthy practices rooted in and still contemporary in its application (Patwardhan et al., 2005).

Herbal medicines can according to the World Health Organization (WHO) be defined as a practice which includes herbs with therapeutic properties originating from plants, where the herbs can be derived from plant parts such as leaves, flowers, fruits, seeds, bark or other plant parts (WHO, 2000). Today, 80% of the world's population is said to be dependent on herbal medicine (Brazil, 2006b) and developing countries stand out to be particularly reliant on natural resources to access primary healthcare (Ekor, 2014). The WHO recognized this reliance already in the 1970s and therefore implemented strategies, supporting the member countries to integrate herbal medicines with the aim of reassuring that knowledge about medicinal plants is sustained, making health accessible for all (Brazil, 2012). In spite of the member states' commitments, approximately 2.9 million people die every year in developing countries due to a lack of access to healthcare (Goldschmidt & Pate, 2019). Moreover there is still much to be done to further integrate herbal medicine into modern medicinal practices and to achieve WHOs goal (Leite et al., 2021).

Besides their direct use, medicinal plants have served as an inspiration for a great number of conventional drugs currently on the market, used to treat both acute and chronic diseases (Leite et al., 2021). Substances from medicinal plants are being often manufactured into synthetic derivates used in clinical drugs, expanding the range of conventional medicines (Vyas et al., 2021). However, the growing industry of conventional medicines has resulted in a gradual phasing out of the traditional knowledge on how to use medicinal plants. That is based on a combination of skepticism towards herbal medicines and the industrial interest in scaling production, something more easily done with synthetic medicines (Leite et al., 2021). In other words, there is a noticeable downward trend in the use of traditional knowledge due to the easy access to synthetic pharmaceuticals and the absence of research, resulting in limited proven scientific basis and standardization for the effectiveness of herbal medicines (Patwardhan et al., 2005). The drastic decline in plants' use to treat diseases has left the traditional knowledge threatened (Leite et al., 2021). There are, however, nations that have prospered with their integration of traditional knowledge. China is such an example where ancient practices have been transformed into a regulatory framework for herbal medicines, rooted in the scientific approaches (Patwardhan et al., 2005).

The Covid-19 pandemic has offered a sober reminder on the importance of herbal medicines since they are vital in the race to develop effective drugs and further extend public healthcare for all. According to Gomes et al. (2022), herbal medicine has several advantages, such as being applicants for new antivirals, often having fewer side effects than synthetic drugs, and having a remarkable capacity to impede the reproduction or synthesis of some virus genome. Additionally, a recent clinical study by Kumar et al. (2022) showed improved recovery from the Covid-19 and its side effects, such as impaired respiration when supplementing conventional medicines with herbal medicines.

Besides having the possibility to expand access to health and meet Sustainable Development Goal (SDG) number 3 - Good Health and Well-being - herbal medicines play a role across different spheres of social, economic, and environmental sustainability. Growing social-economical inequalities and the threatening effects of climate change around the globe have turned herbal medicines into a topical issue also on the production side (Palhares et al., 2021). Medicinal plant cultivation can be used as a strategy to support income generation, to conserve biodiversity, and promote local economic development in ways that keep forests standing (Malhi et al., 2008). Forest conservation, in turn, is critical for avoiding runaway climate change. The Amazon, for one, is key for regional and global water cycling and a critical carbon sink, besides its local sociocultural value (Bastos Lima et al., 2021; Lovejoy & Nobre, 2018). Drastic changes in land use, particularly those associated with large scale deforestation and associated forest degradation have shown to have severe impact on precipitation patterns, not only locally but globally (Chagnon & Bras, 2005), making the valuing of herbal medicines and its potential halting of forest destruction more important than ever.

The value of herbal medicine has also been recognized for the promotion of a bioeconomy, as it embraces economic activities and value chains based on biodiversity (Bastos Lima, 2022; Palhares et al., 2021). Additionally, bioeconomy has become crucial for the phasing out of fossil-resources and to meet climate change mitigation goals, avoiding a global temperature increase beyond 1.5–2 ◦ C. That can happen also in line with the Nagoya Protocol, aiming to protect resources and traditional knowledge by fostering benefit-sharing to deaccelerate plant extinction and biodiversity loss (Palhares et al., 2021). The protocol is particularly important for regions characterized by poverty and direct dependence on local natural resources for the livelihoods of people living in these areas (Brown, 2014). Considering a bioeconomy in Brazil and increased use of herbal medicine can contribute to people finding employment within this sector. Also possibly resulting in people leaving the less sustainable employments currently occurring, such as mining and logging. Therefore, besides an income, a bioeconomy may result in an increased industry that has the potential to help and protect the natural ecosystems against destructive land use activities. However, the development is linked to the risk of an increased pressure on the natural ecosystems, and the value chain needs to assessed ensuring that all activities are sustainable. In this context, further research on herbal medicine promotion, examining its challenges and benefits, is key for understanding how it can indeed help ensure healthcare access, biodiversity conservation, and socio-economic development.

1.1 Aim and justification

Numerous studies across scientific disciplines, in addition to the WHO, have recognized the importance of extending the reach of herbal medicines and the socio-economic benefits it entails. In this context, the objective of this thesis is to identify the challenges and opportunities of integrating herbal medicines into public healthcare systems and their role in addressing access to healthcare, social inequalities, and countering unsustainable use of natural resources. Building this understanding is crucial given the complexity of transforming traditional knowledge into an ideal framework that promotes the use of herbal medicines, making it an effective complement to conventional treatments.

We have chosen Brazil as a case study because of its extraordinary biodiversity, consisting of a megadiverse flora rich in medicinal plants. The country also possesses a rich culture and an

ancient history of medicinal plants treatment that may facilitate the successful integration of herbal medicines. Besides enabling access to health in the country, an increased utilization of medicinal plants found in the Amazon can also be acknowledged as a sustainable development strategy. Thereby, the study seeks to answer the following question: how does the promotion of herbal medicines take place in Brazil? This study is a complementary piece striving to fill the existing gaps of research with native species and production of herbal medicines in the country. This by bringing attention to the topic, hoping to spur and enable further research in the area.

Besides conducting a literature review, we spent a period of two months in the North and Southeast regions of Brazil between February and April of 2022. During that fieldwork, we collected primary data both in the form of participant observations and of semi-structured interviews to generate knowledge on the topic. We conducted a total of 21 interviews with different stakeholders, including producers of herbal medicines, academia, medical doctors and environmental organizations – mostly in the Brazilian state of Amazonas. In parallel, we collected secondary data in materials suggested by stakeholders and by reviewing official documents and regulations. The data collected in the field was interpreted and analysed by incorporating literature. The outcomes were concluded in barriers and opportunities taken into consideration for a successful promotion of herbal medicines in Brazil, but also for nations around the globe.

1.2 Structure of the thesis

After this "Introduction" (*Section 1*), which presents the importance of the topic and the aim of the study, a background "The importance of herbal medicines across history" (*Section 2*) is given to provide information on the context of medicinal plants worldwide including its historical use, health benefits, present promoters, commitments, and an explanation on how the topic is related to bioeconomy. Further, the "Methodology" (*Section 3*) describes the research approach and the main methods for data collection and data analysis. It is followed by section "The Brazilian context" (*section 4*), which presents descriptive findings derived from existing literature to understand the Brazilian perspective and how herbal medicines are supposed to be accessed in Brazil's public healthcare system. The section "Brazil´s current efforts to promote Herbal Medicines" (*section 5*), presents the results from the field study and how the accessibility of herbal medicine takes place in practice. The section is structured progressively, divided into two parts where subsection 5.1 is more descriptive and subsections 5.2 compares and interpret the findings in conjunction with literature. The "Discussion" (*Section 6*) compares and analyses the finding from the case study by placing them in relation to the conceptual background. Lastly, a "Conclusion" (*Section 7*) brings together the final remarks and future suggestions.

2 The importance of Herbal Medicines across history

The section given provides information on the context of medicinal plants worldwide including its historical use, health benefits, present promoters, commitments, and an explanation on how the topic is related to bioeconomy.

2.1 Herbal Medicines and their regulatory framework

Medicinal plants have long been used by humans as an art of healing and to treat diseases (Abdala & Carlos, 2020; Vyas et al., 2021). It takes place in a great variety of ways in countries all over the world and can be traced back to ancient history where the oldest literature records of herbal medicines can be found in India, China, Greek, Roman, Syrian, and Egyptian can be dated back to approximate 5000 years ago. The use of plants as a therapeutic resource is originally based on skills and practices with origin from indigenous and local communities, a term defined as traditional knowledge (SCBD, 2007). The practices has taken place at homes as well as health centres where most of the traditional knowledge has been transmitted verbally from generation to generation and lack written documentation. (Leite et al., 2021; Rates, 2001). In this setting, the ones practicing herbal medicines preserve invaluable knowledge about different medicinal plants and their properties for relief of symptoms for diseases (Vyas et al., 2021).

Today, even the ones stating they only use non-traditional medicine are likely to be medicinal plants reliant in one way or another since 25 % of the drugs prescribed originate from plants (Balandrin et al., 1993; Vyas et al., 2021). Natural compounds from medicinal plants have served as an inspiration for a great number of modern medicines presently used. For example, the *Cinchona officinalis L.* tree found in the Amazon rainforest and its bark was used to produce the world's first anti-malarial drug (BBC, 2020; Cueva-Agila et al., 2019). Nonetheless, as the modern medicine industry grew stronger the use of plants drastically decreased, leaving the biodiversity and the traditional knowledge threatened because of new anthropocentric interests and unsustainable use of natural ecosystems (Cueva-Agila et al., 2019; Leite et al., 2021). For one, the *Cinchona officinalis L.* tree now a threatened species due to unsustainable harvesting methods and high rates of deforestation.

Despite the decrease of use, 70-90% of the current population in developing countries is said to rely exclusively or mainly on traditional medicine (Brazil, 2006a; Brazil 2006b; Brazil, 2012). Implying there is a great number of people who depend on herbal medicine and plants to maintain their primary health, in both industrialized and developing countries (Valli et al., 2018). Where in some industrialized countries such as Canada, France, Germany and Italy, the use of traditional medicine, however, is refer to as complementary, alternative, or unconventional treatments (Brazil, 2012). Recently the pharmaceutical market has gained renewed momentum and the industries have showed an increased interest in investigating in plants species. Considering they can both serve as an important and beneficial resources for the development of new medicines and contribute to preservation of biodiversity (Palhares et al., 2021; Valli et al., 2018).

With the growing interest in investigating plants as a therapeutic resource, nations all over the world have started to set up regulatory frameworks for manufacturing and marketing herbal medicines (Vyas et al., 2021). That is key since many of the used plants have not been

investigated for their safety and effectiveness, while negative consequences have been reported for some (Patwardhan et al., 2005; Vyas et al., 2021). Vyas et al., (2021) states that transforming herbal medicines, which has been developed over generations, into a modern regulatory framework comes with challenges. However, two nations that have prospered in this transition are China and India which have integrated formal training as a part of their national health program to assure that the traditional medicine attains high quality in the delivery of healthcare (Patwardhan et al., 2005). In this aspect, China stands out as, their science-based approach includes extensive education of traditional medicines and investments on research that has contributed to herbal medicines being used to treat both outpatients and inpatients at hospitals (Patwardhan et al., 2005). In 2007, 95 % of the hospitals in Chinas had traditional medicines departments. Their successful approach of incorporating elements alongside conventional treatments can therefore be a source of inspiration, guiding research and actions needed to take in other nations.

To understand the usage of medicinal plants it is important to bear in mind that there are certain conceptual distinctions when discussing herbal medicines. Medicinal plants can be used either as a remedy, prepared at home in a tea, a research object acting as an inspiration for new medicines or as a substance for industrialized herbal medicines (Balandrin et al., 1993; Rates, 2001). Considering the market of herbal medicinal products, Mexico, another country with longstanding traditions around the use of medicinal plants, have categorized them into herbal remedies and herbal medicinal products (Vyas et al., 2021).

Under the Mexican framework definition, the herbal remedy contains parts of the medicinal plant prepared, alone or together, into a pharmaceutical form documented in popular knowledge efficient for the relief of symptoms. It should not contain any attributes of risking human health and all plant material needs to sanitized according to specific regulations. Herbal medicinal products, on the other hand, are subject to higher quality requirements including standardized plant material or derivates, that are manipulated into different pharmaceutical forms. The medicinal plant used in the herbal medicinal product must be documented to be safe and efficient having a monograph in the national pharmacopeia. Where a pharmacopoeia is an official document used to authentication of medicinal plants and includes monographs that defines the medicinal plants by a detailed written study (Oxford Learner´s Dictionary, n.d.-a; Oxford Learner's Dictionaries, n.d.). Meaning the herbal remedy withstands lower safety measures but is easier to produce and hence access.

In addition to the three conceptual distinctions mentioned above, substances derived from plants can be sold as food products but also as dietary supplements. Where Lenssen et al., (2019) state that products containing medicinal plants often fall in the category between food and medicinal products. Resulting in many of herbal medicines being sold as dietary supplements (Patwardhan et al., 2005). Classification for herbal medicines is, in the end, a question of the jurisdiction's regulatory framework where the requirements for safety and efficiency increase with classification level (Lenssen et al., 2019). For example, the United States surveillance agency Food and Drug Administration (FDA), has virtually no requirements for dietary supplement manufacturers (Lenssen et al., 2019), in contrast to the requirements for manufacturing and marketing herbal medicines, which require evidence of safety. Products containing medicinal plants with therapeutic properties require surveillance considering even though they are used as supplement or home remedies, they have the potential to have side effects (Lanini et al., 2012).

2.1 Health, poverty, and livelihoods

The quality of health in developing countries, mainly tropical regions is impinged by high cultural diversity but characterized by poverty and infectious diseases (Geck et al., 2020; Mphande, 2016). Since the 1940s, over 300 infectious diseases have emerged, resulting in 15 million people dying every year globally. Additionally, 1 billion people of the world's population are affected by neglected tropical diseases (Mphande, 2016), and since these are endemic to the rural areas with minimal resources, their livelihoods are strongly exposed. Besides this, chronical diseases are increasing in the very same regions. Again, using Mexico as an example, the second largest economy in Latin America, a country still facing problems with the inclusion of the rural population and poverty (The World Bank, n.d.). Despite their efforts and the rapid transition of their healthcare systems, with measures including establishment of 3,000 rural healthcare posts and 71 rural hospitals (Geck et al., 2020). The transition has resulted in in a double burden on their healthcare system where disease related to poverty coexists with modern lifestyle disease.

Mphande (2016), explains the correlation between health, poverty and livelihoods and claims that livelihood strategies of the population living in developing countries are determined by health and economic status. It is more widely understood that f the source of income is limited, it can directly move families into poverty. Nonetheless, a worsen health status can also lead to poverty, although indirectly as the ability to provide for their families is limited. This situation creates a vicious cycle where all the three pillars which are crucial for a life in prosperity are threatened. The linkage between health, poverty and livelihoods are presented in Figure 1, where also the indicators for each factor are showed.

Figure 1. The linkage between health, poverty, and livelihood with indicators for each attribute (Author's own adoption based on Mphande, 2016).

Additional challenges that will not only influence health conditions in tropical regions, but in all places on earth, is urbanization. According to Kookana et al., (2020) it will be one of the 21st century's greatest transformative trends where urban centres will absorb significant rural migration. Today, more than half of world's population is living in urban areas, corresponding to 4,2 billion people and by 2041 the number is said to increase to 6 billion (Kookana et al., 2020; Kuddus et al., 2020). As argued by Kuddus et al. (2020), problems faced by developing countries and poor regions such as the spread of infectious and chronical diseases, pollution, and poor nutrition, among others, will be equally important for city dwellers. Where the persistent trend of urbanization will result in major health problems and be of global matter since a substantial amount of the world's population will be affected (Kuddus et al., 2020). The rising health problems from urbanization will directly impacts individuals' quality of life and will put pressure on public health system and their resources. Recently, seen by the outbreak of Covid-19, a pandemic significantly greater than previous ones impacting cities of dens population, large scale and with high mobility (Yang et al., 2020). China that since 1978 has undergone rapid urbanization stands out as an example, where the inhabitant in Wuhan was greatly exposed threatening Chinas public health system and the economic and societal development.

2.2 Sustainable development and global commitments

Given the widespread use of medicinal plants in the world, it is important to see the value of natural resources and the social benefits they bring. But looking through the lens of environmental history, it is characterized by actions where humans have exploited nature to supply their own needs. Actions that has led to inequalities where industrialized countries have maximized their consumption levels, without considering the need for developing countries (Hedenus et al., 2018). An anthropocentric view, that has contributed to a huge number of environmental problems resulting in medicinal plants and natural resources now being endangered.

When substituting the use of medicinal plants with synthetic pharmaceuticals, the concept of weak and strong sustainability can be applied (Hedenus et al., 2018). Where weak sustainability entails that natural capital can be substituted with man-made capital, while strong sustainability entail that it cannot. The use of medicinal plants can be seen as a weak sustainability since the humankind have been possible to substitute the natural capital with man-made synthetic medicines. The severe consequences of species being endangered may however, result in a different viewpoint, advocating that the use of medicinal plants implies strong sustainability and should therefore be valued as one. Promoting biocentric perspectives where species and ecosystem are important to provide value for individuals (Hedenus et al., 2018).

Since the publication of the Brundtland Report in 1987, a report which defined sustainability as "meeting the needs of the present without compromising the ability of future generations to meet their own needs" (WCED, 1987,), sustainable development has been an important development strategy to conserve the endangered ecosystems, promote sustainable value chains and to ensure long-term access to resources that shape a less intensive and destructive economy for the planet (Morton et al., 2017).

It is a concept, based on the three fundamental dimensions, the ecological, economic, and social, that must work together to ensure economic growth simultaneously as the social and environmental needs are fulfilled (Hedenus et al., 2018).

In this setting, an environmental movement has built up, leading to the UN Conference on Environment and Development, held in Rio de Janeiro in 1992. The Earth Summit, as it is referred to, emphasized the urgent need for a global sustainable strategy where work at the national, regional, and local levels is needed, resulting in Agenda 21 which included 120 initiatives for action (Hedenus et al., 2018; Morton et al., 2017). Agenda 21 has through the years been adopted by the UN Millennium Development goals, and most recently by the Sustainable Development Goals (SGDs). They were adopted in 2015 and consists of 17 goals and 169 targets stretching over a wide cluster of areas that need to be addressed and incorporated to ensure that people needs now and in the future are met. Viewing the aspect of health and the need to value medicinal plants as part of the primary healthcare, a successful promotion and integration of herbal medicines could result in an increased use of medicinal plants and a development of the herbal medicine supply chain. A development that can be seen as a strategy to achieve sustainable development and directly addresses the SDG 1 (No poverty), SDG 2 (Good Health and well-being), and SDG 15 (Life on land) (United Nations, 2021).

- SDG 1 - No poverty
  Poverty extends beyond the economic dimension and can interfere with freedom, health, and education (Global Goals, 2022). Especially noticeable in developing countries where rural poverty is driven by poor provision of infrastructure and services, rural inequalities, and environmental degradation (Suttie, n.d.). With the alarming environmental problems, the world needs to build resilient system to combat sustainability disasters, where agroforestry and integration of medicinal plants can contribute to increased livelihoods and an eradication of poverty in all its forms (Global Goals, 2022).

- SDG 3 - Good health and well-being
  Good health and well-being are essential for sustainable development and an integration of herbal medicines in healthcare systems have the opportunity to grant greater access to health both in rural as well as in urbanized areas. Especially important considering the effects from the Covid-19 pandemic and the spread of diseases such as aids, malaria and neglected tropical diseases (Global Goals, 2021a). Medicinal plants are also essential in the search of new medicines to extend the healthcare.

- SDG 15 - Life on Land
  Sustainable use of land is important for protecting, restoring, and promoting ecosystem services and biodiversity. Two attributes crucial for the population living in tropical regions who are on dependent on natural resources to maintain their livelihood strategies and to face the upcoming challenges of climate change (Global Goals, 2021b). In this context, increased use and demand for medicinal plants can lead to the standing forest and its biodiversity being reconned and valued. Creating a direct link between biodiversity and medicinal plants that stimulates the conservation of species and ecosystems as well as equitable sharing of genetic resources.

To achieve the SDGs, ensuring healthcare for all, the WHO is one of the key players, promoting the use and the value of preserving medicinal plants to ensure global access to healthcare (Brazil, 2006a; Brazil, 2006b). During the International Conference on Primary Healthcare held in Alma Ata, Kazakhstan in 1978, the WHO and the United Nations International Children's Emergency Fund (UNICEF) highlighted the urgent need for global action (WHO, 1978). The WHO has since then continued to recognize the importance of herbal medicine and maintained the promotion of its use, resulting in a Traditional Medicine Program where the latest version cover the years 2014-2023 (WHO, 2013). The program aims to support the member states in designing and implementing a strategic plan in accordance with their own national capacities, priorities, relevant legislation and circumstances (WHO, 2013, p.12). Which can be linked to Yvas (2021) who states that promotion of herbal medicines is essential to create a complementary option to conventual practises (Vyas et al., 2021).

In addition, the program also aims to assist the member states in determining and prioritizing their needs, to provide for effective delivery of services, to support appropriate regulations and policy development and to ensure that these products and practices are applied safely. The aims can according to WHO be reached by implementing three strategic objectives: 1) building a knowledge base for active management of traditional and complementary medicine through appropriate national policies; 2) strengthen quality assurance, safety, proper use and effectiveness of traditional and complementary medicine by regulating products, practices and practitioners; 3) promoting universal health coverage by integrating traditional and complementary medicine services appropriately into health service delivery and self-healthcare (WHO, 2013,).

Another important milestone is the Convention on Biological Diversity (CBD), established at the Rio de Janeiro summit in 1992 (Hedenus et al., 2018). The three main topics of the convention are: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from it (Ribeiro & Filho, 2022). The CDB in time led to the establishment the Nagoya Protocol in Japan in 2010. This protocol formally known as The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, which aims to successfully implement those three overarching CDB topics by setting up rules for the parties and to enable benefit-sharing.

2.3 Bioeconomy

The bioeconomy has emerged as a new paradigm where the industrial sectors have been driven to re-evaluate their goals, characterized by renewability and sustainability, and to steer the development towards finding new sustainable solutions (Aguilar et al., 2019). This means using renewable resources from land and sea, such as forests, crops, and microorganisms, to produce the building blocks that are necessary for human life. It initially started as a concept on the table for policymakers and political leaders but has become well-known in the public, research, and development, and the financial as well as the industrial sector. After the European Union (EU) adopted its economy strategy in 2012, the concept has evolved quickly in the member states' economies.

Aguilar et al., (2019) and Valli et al., (2018) claim that the bioeconomy is not just a scientific discipline or a business segment, but the basis for integrating all the important sectors and activities derived from bio-based products into an innovative sphere. Nowadays, bioeconomy strategies and initiatives exist in over 50 countries, both industrialized countries ones as well as transition economies and developing countries around the world.

The bioeconomy concept has developed into a broad approach, When EU in 2018 updated its strategy, the importance of integrating sustainability and circular economy became notably predominant in the transition to a sustainable market economy (Aguilar et al., 2019). Considering the local biodiversity of economies, which is mentioned as one of the key elements of an influential bioeconomy strategy, there are no universal definitions. This is since, countries' presumptions vary depending on their industrial development, climate, and agriculture practices, among others. Further, a holistic approach and mutual interaction are aspects to simultaneously achieve collaboration among all sectors.

The use of herbal medicines has for long been important to many forest-based livelihoods and it is now experiencing growing momentum under an emerging bioeconomy. According to Bastos Lima (2022), a bioeconomy transition in tropical regions has the potential to conserve and restore habitats, increase the knowledge on biodiversity, valorize livelihoods, improve social participation, and lastly moving away from the commodification of nature. Up until today, the bioeconomy concept has been questioned as it puts increased pressure on natural resources leading to overexploiting. The emerging bioeconomy paradigm has also resulted in a discussion of tradeoffs between energy, food and land (Aguilar et al., 2019; Bastos Lima, 2022). Seen as in the example of biofuel production competing with the use of land to feed the world's population. Further, the bioeconomy concept has heavily focused on extracting goods from nature undermining important aspects that ecosystems provide people (Bastos Lima, 2022). A development of the herbal medicine value chains, supported by the Nagoya Protocol, can however increase the chances of ecosystems being preserved while still providing the population with valuable products. To ensure prevention of overexploitation such value chain needs to be assessed to guarantee that all activities from cultivation to distribution are sustainable and that local producer's benefits.

3 Methodology

This study takes a qualitative research approach to study how the promotion of herbal medicines takes place in developing countries focusing on Brazil. A qualitative method generally has a broader set of research questions that are narrowed down to a range of issue as the research prosper (Bell & Waters, 2018), which is consistent with this study. This enables to understand human conditions in a perceived environment rather than engrossing in quantitative facts and variables (Bell & Waters, 2018).

Brazil is chosen as a case study where fieldwork laid the foundation for data collection. Doing fieldwork enriched the investigation and we could create an overpass between literature and practice, providing an opportunity to study the integration of herbal medicines in-depth. During the stay in Brazil, the premise was to create knowledge about social attributes by studying the natural setting where culture and people interact. Which, according to Bell & Waters, (2018) is an underlying requirement in qualitative methodology for constructing an overpass between theory and practice.

The fieldwork took place in locations of the North and Southeast regions in Brazil for two months between February and April 2022, and data was collected data through semi-structured interviews and participant observations. Most interviews were carried out in the city of Manaus, capital of Amazonas State where fieldwork spanned a four-week period. Fieldwork proceeded with primary data collection in the cities of Santarém and Belém, also in the north region but in the state of Pará. Lastly, the data was collected in the cities Rio de Janeiro, Campinas, and São Paulo, all located in the Southeast region but within different states. We selected the interview cases by applying the snowball sampling method but also by ourselves as knowledge was disseminated during the fieldwork. For most of the interviews, a local interpreter was used, and extensive field notes were taken along with translation. To analyze the findings, we have done triangulation by combining multiple data sources. Using multiple data sources increases the credibility of the results (Bell & Waters, 2018; Bryman, 2012). This created a holistic perspective on the accessibility and integration of herbal medicines in Brazil.

The study consists of three main methods for data collection, reviewing, and gathering of literature, key-informant interviews as well as participant observations, all presented in Figure 2. Incorporation all these methods of data collection created a holistic perspective on the accessibility and integration of herbal medicines in Brazil.

Figure 2. Main methods for data collection (Author's own elaboration).

3.1 Literature review

The collection of literature had several sequences during the study since new findings and observation emerged along the way resulting in new perspectives to investigate and include.

Prior to the fieldwork, existing literature was reviewed to gain knowledge about the subject and create a conceptual background on the history of medicinal plants and global sustainability frameworks. Further, literature was gathered on Brazil´s historical and recent national commitments made to integrate and promote herbal medicines. This created a robust and comprehensive basis and increased our knowledge on potential bottlenecks and defined the scope of the study. The collection of literature was conducted in Google Scholar, Chalmers Library, Scopus and ScienceDirect, among others where general search term included *herbal medicine, traditional knowledge, medicinal plants, Brazil, native plant species, supply chain, regulations.*

Parallel to the interviews in the field, the collection of data proceeded covering a wide spectrum of topics to understand Brazil's regulatory framework of herbal medicines. A particular focus was given to books and scientific publications disseminated from stakeholders by consulting experts on the topic of the study. Additionally, primary data including official documents, ordinances, standards, list of monographs and normative instructions was collected and review by the researchers themselves. This information provided a deeper insight that conceptualized the regulations for herbal medicines and the requirements that stakeholders must meet, enabling marketing and distribution for herbal medicine products to reach the Brazilian healthcare system

3.2 Key-informant interviews

The main sources of primary data used in this thesis is through semi-structured interviews. As stated by Bryman (2012), semi-structure interviews using open-ended questions allow the interviewees to be elaborative in their answers. That contributes to a dynamic approach resulting in responding question on the topics comprehended as most significant and relevant according to the interviewee. We selected the interviewees by applying the snowball sampling method, where the chosen cases originate from a small group of people that the researchers see as relevant, which later mediated additional contact with other study people (Bryman, 2012). However, as the availability and relevance of the interviews played a role, the chosen cases did not exclusively follow this method, and contacts with interviews were also done elsewhere by the researcher themselves.

In the thesis a total of 21 interviews were held with various key-informant stakeholders immersed in the field of herbal medicines including local producer of herbal medicines in the state of Amazon, researchers, university students, non-governmental institutions, and medical doctors. To present the interviewees in a transparency way, each of the stakeholders has been given a reference number which they from here and onwards will be referred to. The table also present the interviewees area and role to mediate a sense of expertise, seen in Table 1. Additionally, if the interviewee is related to any an initiative meet during the case study, it is indicated in the last column. The initiatives are presented in subsection 5.1.

Table 1. List of interviewees.

Reference number	Area	Role	Related to initiative
1	Cosmetics	Herbal cosmetic producer	Initiative A
2	Cosmetics	Herbal cosmetic producer	Initiative B
3	Academia	Non-governmental employee	Initiative C
4	Herbal medicine	Herbal medicine retailer	Initiative D
5	Herbal medicine	Researcher	Initiative E
6	Herbal medicine	Living pharmacy coordinator	Initiative F
7	Herbal medicine	Living pharmacy coordinator	Initiative G
8	Medicine	Compounding pharmacy coordinator	Initiative H
9	Healthcare	Medical doctor	
10	Healthcare	Medical doctor	
11	Academia	Researcher	
12	Academia	Researcher	
13	Academia	Researcher	
14	Academia	Researcher	
15	Academia	Researcher	
16	Academia	Researcher	
17	Academia	University student	
18	Academia	University student	
19	Academia	Non-governmental employee	
20	Academia	Researcher	
21	Academia	Researcher	

The interviews were mainly held on-site except for a few who participated through zoom, and approximately 60 min was set aside for each conversation. Due to the language barriers, and that Portuguese is the primary language, some of the interviews were conducted with the assistance of a locally recruited interpreter. The interviews were generally not recorded instead, extensive field note by both researchers was taken alongside the translation. However, whenever we could carry out the interviews in English we did, corresponding to a total of nine of them. Additionally, one interviewee chose to respond in writing assuring an ideal translation and reducing the risk of misinterpretations. The questionnaire was constructed beforehand and due to the range of stakeholder, several different outlines were prepared focusing on topics depending on expertise of the interviewee. Subjects covered were ethnobotany, traditional knowledge of medicinal plants, access to healthcare, biodiversity, livelihood strategies in rural communities, market analysis and medicinal practices. The information was documented in writing, and an excerpt of the asked questions are:

- How do people access herbal medicines in Manaus?
- When going to the market, what are the most common medicinal plant species you find?
- How do you know how to prepare and use medicinal plants?
- What commitments on federal level, are needed to boost the integration of herbal medicine in Brazil health system?
- What barriers can you identify as a stakeholder in the supply chain of herbal medicines?
- If you get sick, where do you go to get treatment?
- What are the disadvantages with using herbal medicines?
- Why do you think there is no Living Pharmacy in the North region considering its rich biodiversity?
- What is required to market and sell the products as herbal medicines?

Besides the number of interviews, numerous informal conversations were held with the general public, which supported the broad contextual understanding around access and use of herbal medicines

3.3 Participant observations

Some of the empirical findings in this thesis were made from participant observations in the field, a common method in quantitative research to allow a close visual understanding of the social context (Bell & Waters, 2018). The field activities included visiting different locations such as gardens, markets and companies producing and selling herbal medicines. Additionally, other initiatives were visited, however not mentioned in Table 1, since there were no interviews taking place. Examples of such places were a botanical garden possessing medicinal plants, healthcare units, shops selling unregulated products containing medicinal plants and an initiative enabling food production to promote women entrepreneurship. Two of these are further explained in section 5.2.1 and called *initiatives I* and *initiative J*.

3.4 Data analysis

After the interviews was conducted, the process of data analysis began, where the field notes from the interviews were refined into codes. The process included reading through the initial set of transcripts repeatedly, comparing and interpreting the data to analysis the significance and to avoid biased conclusions. Also, to minimize the loss of social context, which is described as a downside when using the coding approach (Bryman, 2012).

As a first step, each author summarized the field notes, highlighting opportunities and barriers from the interviews. Then in agreement with both authors, a common set of themes, which had emerged from the interviews was identified. The themes were thereafter compared with found literature where some of the findings could be reinforced, and other stood out, contributing to new findings. Further, to descriptively mediate the social context and provide an explanatory interpretation of the data, quotes were used to represent the stakeholders' own views. The selection of the quotes used throughout the text was made by both authors, with the aim to in provide the reader with a first-hand representation of stakeholder´s voices that conveyed issues raised.

To create a more comprehensive understanding of the promotion of herbal medicines and its challenges, triangulation was applied to analyse the findings from the interviews in relation to literature. Conveyed by Bell & Waters (2018), triangulation results in a better understanding that incorporates different perspectives by corroborating and complement data gaps. Using triangulation was helpful to confirm the results as well as significant discrepancies, which led to new findings.

3.5 Limitations

For this study, a qualitative research approach with semi-structured interviews has been conducted to let the stakeholders raise their voices and express their opinions in their perceived environment. However, there are several aspects regarding the study´s credibility that can have affected the results. Where one is objectivity, which refers to the extent the data collection has impacted the outcomes (Björklund & Paulsson, 2014) implying that the data collected might be biased or not fully comprehensive (Bryman, 2012). The objectivity in this study was affected in two main ways. Firstly, by the choice of sampling method for the located interview cases. Where Bryman (2012) states that snowball sampling entails risks associated with the studied cases not reflecting the true distribution of the population since people tend to recommend people they are well connected with (Bryman, 2012). Secondly, since the interviews and the participant observations were not structured, the researcher gathered information available to them, as time proceeded. Resulting in only an overarching idea on how to access herbal medicines.

Another aspect when considering the credibility of the research is reliability, which refers to whether the results are repeatable or not (Björklund & Paulsson, 2014; Bryman, 2012). Important to remember when questioning the reliability is that the study has been conducted through the lenses of the researchers which makes it inevitably to exclude personal interpretations, decisive for possible replication. Additionally, the prior knowledge and the experience built along the way may differ from researcher to researcher, making the topic unique and resulting in various outcomes.

Worth adding is also that the reliability of this study has been impaired by language barriers since none of the researchers were fluent in Portuguese. During several interviews, the use of an interpreter was required to translate the information into English, resulting in the risk of losing details or having misunderstandings. There has neither, due to time limitation, been any following up on the questions asked. However, both the researchers have sought to minimize as far as possible any misinterpretation by processing, reviewing, and comparing the field notes to make sure that no information is overlooked, forgotten, or misunderstood. The fact that the report has been written in English also limits the access and our ability to share our result and key conclusion for those who do not read English in Brazil.

The final limitation worth mentioning is the geographical and temporal boundaries that may have influenced the result. Given that Brazil is a huge country more time would have been required to further delve into the topic and to visit additional regions, collecting supplementary information and perspectives.

4 The Brazilian context

This section presents descriptive findings found in literature to understand the Brazilian context and how herbal medicines are supposed to be accessed in Brazil, the measures taken at national level to promote and integrate herbal medicines into to the healthcare system is framed, including the concept of Living Pharmacies.

4.1 The Amazon

The Amazon rainforest, 62 % of which is within the Brazilian territory, holds natural resources that are vital, not only for the people living in the rainforest but also for the function of the world's ecosystems and the climate balance on earth (Garrett et al., 2021; Malhi et al., 2008; Valli et al., 2018). Its vast surface includes extensive rainforests with a unique composition of wildlife, plants, and the Amazon River. The river is the largest source of freshwater on earth, consisting of 15-20% of the global river flow (Chagnon & Bras, 2005), flowing from the Andes Mountain of Peru to the Atlantic Ocean, supplying South America with infrastructure and resources (Science Panel for the Amazon, 2021). The rainforest has been inhabited by people for at least 12 000 years and holds high biocultural diversity as it is home to many of Brazil´s Indigenous people. They have coexisted with the diverse nature and which has provided opportunities for hunting, fishing, and basic means of life (Garrett et al., 2021). Nowadays, the rainforest is occupied by a great variety of people, living in remote villages along the Amazon River, indigenous territories, regional towns, and cities. The cities have experienced rapid urbanization, making them stand for the greatest share of inhabitants. The livelihood strategies in rural areas are many, from small-scale agricultural communities to larger ranches, farms, and mining camps which are important sources of employment and income (Garrett et al., 2021). Additionally, seasonal economies are especially important to families depending on the rainforest for living.

In the past few decades, the Amazon rainforest, and the livelihoods of those that depend on its resources have been threatened due to economic activities advances have contributed to tremendous losses of ecosystem services and increased inequalities (Science Panel for the Amazon, 2021; Global Landscape Forum, 2021). The high rate of forest destruction and degradation of both terrestrial and aquatic resources is a result of the increased competition for land-use to accelerate the international commodities demand. Characterized by a basic monocultural system, which has subsequently deteriorated the soil, livestock, mining, and timber extraction (Garrett et al., 2021; Ometto et al., 2011).

Deforestation has not only driven climate change but interfered with human health. Hazardous pollutants from fires in 2019 resulted in up to 2000 hospitalizations because of respiratory diseases (Garrett et al., 2021). It is a result of water contamination from interfering with the hydrological cycle. Deforestation also contributes to an increasing number of inhabitants in new areas, increasing the potential transportation for infectious diseases due to intensification of livestock and humans (Garrett et al., 2021). In parallel to the destruction, the voice of the Amazonian population both in rural and urban areas has been overshadowed by distant politicians, businesses, researchers, and financiers who have utilized Amazonas and its wealth for their own interests (Science Panel for the Amazon, 2021). Altogether this change in land use adds additional pressure on the people living in the already exposed areas, forcing them to consequently adapt to find alternative ways of preserving the forest to meet their needs.

To preserve biodiversity and supply the growing population interests, the Brazilian government needs to find sustainable pathways where the natural resources found in the Amazon rainforest can be sustained and provided for all generations to come (Global Landscape Forum, 2021). In this context, the Bioeconomy play an important role for Amazonas, and as conveyed by literature (Aguilar et al., 2019; Global Landscape Forum, 2021) it is important to root the model in society and to engage a multilateral dialog. The Science Panel for the Amazon (2021) contends that the accumulated knowledge generated by forest people in the Amazon must play a role in a global emergence of a bio-based economy. Today, there are very few products from the rainforest that have been commercialized (Simonetti & Pereira, 2021), concluding there is a lack in representation on the socio-biodiverse economy the forest holds. Even though non-timber forest products, such as medicinal plants, have been progressively recognized they are still in their early stage of commercialization.

Despite the low representation of products with origin from the Amazon on the global market there are cases that have succeeded to reach commercialization. This is the case of Brazil nuts, which are one of the most recognized food products with origin from Brazil. Its value chain includes 60 000 families from small community-based businesses resulting in Brazil being the largest producer in the world (Science Panel for the Amazon, 2021). Another important food product is the seasonal fruit Açaí *(Euterpe Oleraces Mart.)* which provides important income for thousands of families living in riverside communities in the Amazon. Due to its high energy content, it has since the 1990s been increasing recognized for its health benefits resulting in a widespread use in many of the Brazilian states and on the international market (Junior et al., 2019). The increased demand for Açaí can be reflected by its production revenue increasing from €40 million (EUR) in 2010 to €100 million (EUR) in 2016 (Science Panel for the Amazon, 2021) and if integrated correctly into the agroforestry systems it is said to have the potential to generate a higher income than soy.

Furthermore, markets for essential oils extracted from a variety of plants both used in food and for therapeutic properties are flourishing locally. The oils are extracted from *Andiroba* (*Carapa guianensis Aubl.*) seeds and *Copaíba (Copaifera officinalis L.*) trees which has been traditionally used in Brazilian medicine for its anti-inflammatory properties and potentially healing properties (Silva et al., 2021; Soares et al., 2021). The essential oil production is estimated to engage up to 50 000 families corresponding to a total of €9 million (EUR) per year (Science Panel for the Amazon, 2021). There is a general perception among actors in the value chain, also conveyed by Science Panel for the Amazon (2021), that middlemen are the only source for raw material suppliers to access the market making it less profitable.

4.2 Brazil as a country

To create a common knowledge about the country and to increase the understanding for some of the underlying factors explaining the situation in Brazil, background information on the country including the political situation is presented in this section.

4.2.1 The Brazilian geography and its distinctions

With an area twice the size of the whole of the EU, Brazil occupies 47.3 percent of South America's land area (Kiprop, 2020) and is the country with the richest flora in the world (Leite et al., 2021), accounting for more than 15% of all living species, home to approximately 50,000 plant species. The species are spread over the country's six different biomes (Martins et al., 2019), as seen in Figure 3, each with a unique set of geology and climate. Inhabitants of Brazil mediates that the country has several countries within the country, and when traveling from North to the Southeast, there are several different aspects that confirm this say. The North of Brazil, covered in the extensive rainforest known as the Amazon, is home to many plant species and fruits that cannot be found anywhere else in the world. Along the many rivers, one can find both rural communities living in symbiosis with nature and urbanized cities such as Manaus, Santarém, and Belém. Manaus is the largest one and is the capital city in the Amazonas state. It has 2,2 million inhabitants and has historically been characterized by the wealthy rubber production days. In today's economy, one of the most significant benefits of Manaus, seen from a production point of view, is the green free tax zone, which objective is to stimulate the use of raw materials from the Northern region by creating tax benefits for the industries taking advantage of the resources in these regions (Carvalho et al., 2018).

Figure 3. Brazil biomes and regions (Author's own elaboration).

Brazil´s Southeast part is much more urbanized than the North, and it is said to be its economic hub. In the Southeast region, the two largest cities are situated, namely, São Paulo and Rio de Janeiro, with more than 46 million and 17 million inhabitants, respectively in each state (IBGE, 2022). With its many tourist attractions and well-developed infrastructure, it is considered the most visited region and plays a significant role, responsible for the greatest concentration of industrial and agricultural production in the country (Encyclopedia Britannica, 2022).

However, there are similarities between the two regions, and the most noticeable one is the economic inequalities, an issue spread over the whole of Brazil. During the last decades, it has been moving in the right direction, but despite Brazil being one of the world's largest economies, the pandemic left scars. Oxfam Brasil (2022) describes how the inequality endemic in Brazil has been accelerated by the covid19 pandemic resulting in up to 400 Brazilians losing their job every hour during the period of April 2020 to April 2021. Contributed to Brazil reaching the highest income equality level since 2012, which made this Latin American giant the eighth most unequal country on the planet (Oxfam Brasil, 2022). Brazil has, however struggled with inequalities long before the pandemic, and Oxfam has interpreted them into numbers, stating that due to the long history of income equalities, it would take Brazil 75 years to reach the same income equality as the United Kingdom (Oxfam Brasil, 2022). Additionally, between the years 2001 and 2015, the wealthiest 10 percent accounted for 61 percent of the economic growth, and at the current pace of equality progress, Brazilian women will earn as much as Brazilian men in 2047. The same goes for black Brazilians, who would make as much as white Brazilians only by the year 2089 (Oxfam Brasil, 2022).

4.2.2 Politics

Brazil is a Federative Republic consisting of a union, states, a federal district, and municipalities. There is a total of 26 states and one federal district with the country's capital, Brasilia, all of them powered by their own government, elected every fourth year, and with representatives who vote on the state laws (Gender Equality Observatory, 2022). Since the creation of the Federal Republic of Brazil, the country has been subdivided into 5,560 municipalities. The municipalities have local governments, run by a mayor and a legislative body elected every fourth year. The president, directly elected, controls the executive branch and the judiciary in the Brazilian state.

In 2018 Jair Bolsonaro won the election which would later impact the Brazilian social and environmental sphere significantly. Gonzaga (2022) states that Bolsonaro's anti-environmental agenda was never a secret, making it clear that the presidency under his command would not prioritize preserving the Amazon Forest but rather follow in the opposite direction. During the three past years, deforestation in the Brazilian Amazon has increased by at least 52% (Gonzaga, 2022). Not only threatening the country but also the whole world. Given that the Amazon rainforest is crucial for the fight against climate change, increased land clearing will make Brazil climb the list of the world's biggest CO2 emitter, where they today already are in fourth place today (Evans, 2021; Gonzaga, 2022).

Bolsonaro's encouragement of the destruction has aroused significant criticism both from domestic environmental groups as well as from foreign governments, where the 10th of august, 2019, plays a vital role (Bounegru et al., 2022). The day is known as "The day of fire" and have gotten its name from a series of fires in the Brazilian Amazon rainforest, coordinated by farmer and loggers supporting Bolsonaro's wish to clear the forest for increased farming and ranching

(Bastos Lima & Da Costa, 2021). It caught international attention, mainly due to the visible clouds of smoke seen from space. However, as a response, Bolsonaro denied the fires and told other leaders not to interfere with his interest (Gonzaga, 2022). Bolsonaro's encouragement of the destruction has aroused significant criticism both from domestic environmental groups as well as from foreign governments, where the 10th of august, 2019, plays a vital role (Bounegru et al., 2022). The day is known as "The day of fire" and have gotten its name from a series of fires in the Brazilian Amazon rainforest, coordinated by farmer and loggers supporting Bolsonaro's wish to clear the forest for increased farming and ranching (Bastos Lima & Da Costa, 2021). It caught international attention, mainly due to the visible clouds of smoke seen from space. However, as a response, Bolsonaro denied the fires and told other leaders not to interfere with his interest (Bounegru et al., 2022; Gonzaga, 2022).

Another outcome of the vast forest destruction is the gradual increase in violence. MacDonald (2020) highlights that Bolsonaro has pushed Brazil deeper into a cultural war between those preferring traditional values versus those supporting modernised societies. Resulting in Brazil's Indigenous peoples put severe pressure (Global Witness, 2021). The invading of protected indigenous land, done by miners, loggers and land grabbers has resulted in Brazil also reaching the top of the list as the most dangerous country for environmentalists in 2021 (Gonzaga, 2022). With a total of 1576 conflicts related to land registered and a total of 20 killings.

Bolsonaro's actions have been possible due to the weakening of governmental bodies responsible for environmental protection. For example, an institution working on the conservation of biodiversity, known as the Chico Mendes Institute for the Conservation of Biodiversity (ICMBio), got its budget reduced by 32.7%. Likewise, an agency responsible for environmental policies, namely the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) got its funds cut by 30% over a period of three years (Gonzaga, 2022). The same source state that Bolsonaro's administration also has approved 1,500 new pesticides, including pesticides that are banned in Europe due to their hazardous characteristic to human health and the environment, whereas one has been banned for 15 years and can still be found in over 70 commercialized products in Brazil (Gonzaga, 2022).

There are, however, prospective actions where Brazil, in August 2020, ratified the Nagoya Protocol (Palhares et al., 2021). Nonetheless, the nation still lacks policies to meet several of the targets connected to the declaration of plant extinction, prevention of biodiversity loss, conservation of traditional knowledge, and sustainable management of resources. Additionally, compared to many other countries, a strategy on how to improve the bioeconomy in the country is left out, and Valli et al. (2018) state that the country has failed to convert its economy into knowledge. Confirmed by Brazil's high share of unilateral commodity export based on unsuitable large-scale production systems (Valli et al., 2018). However, considering Brazil's unique flora and the latest stimulation of bioproducts made from Brazilian plants, the country possesses an immense potential to be a leader in transitioning towards a market based on renewable resources.

4.3 Brazil´s healthcare system and integration of Herbal Medicines

The Ministry of Health (MS) was created in the year of 1953 and has over the years gone through several modifications in its structure and functionality, attempting to better meet the growing demand for improved sanitary and health regulations in the whole country of Brazil (Gonçalves et al., 2020). Ministry of Health was from the beginning in charge of providing the population with basic public healthcare, such as vaccines. However, it was limited to people who were employed and thus benefited from social security schemes funded by employers' fees paid to the state. Unemployed people, who constituted most people on the countryside, had to rely exclusively on charity-based healthcare provision, such as religious ones, besides natural medicine (Anagnostou, 2005). It was after the Federal Constitution in 1988, when it was considered the state's duty to guarantee the health of the entire population, that the public Unified Healthcare System in Brazil was created (*Sistema Único de Saúde - SUS*) and became free of charge (Gonçalves et al., 2020).

SUS is decentralized and acts at three different levels: federal, state, and municipal. The Ministry of Health is responsible for the coordination of SUS including national policy development, planning, auditing, control, and financing where they distribute the health fund between states and municipalities (Exemplars in global health, n.d.; The Commonwealth Fund, 2020). The decentralization gives social participation for states and municipalities that have the authority to improve their local health policy and measures adjusted to their needs. The state's tasks include regional governance, coordination of strategic programs and transfer of specialized services that have not been decentralized to municipalities, while the municipalities' tasks are to manage SUS at the local level including co-financing, coordination of health programs and setting up health services for citizens (Brazil, 2006a; Exemplars in global health, n.d.; Gonçalves et al., 2020). By establishing the universal system, community participation in SUS is high with health councils and health conferences at all levels. The resulting implementation has led to municipalities having more independence to control their needs while supervision has expended at federal level (Exemplars in global health, n.d.; The Commonwealth Fund, 2020). The construction of Brazil's healthcare system, the different three levels and their main roles as well as the distribution pathways for the national healthcare fund are outlined in Figure 4.

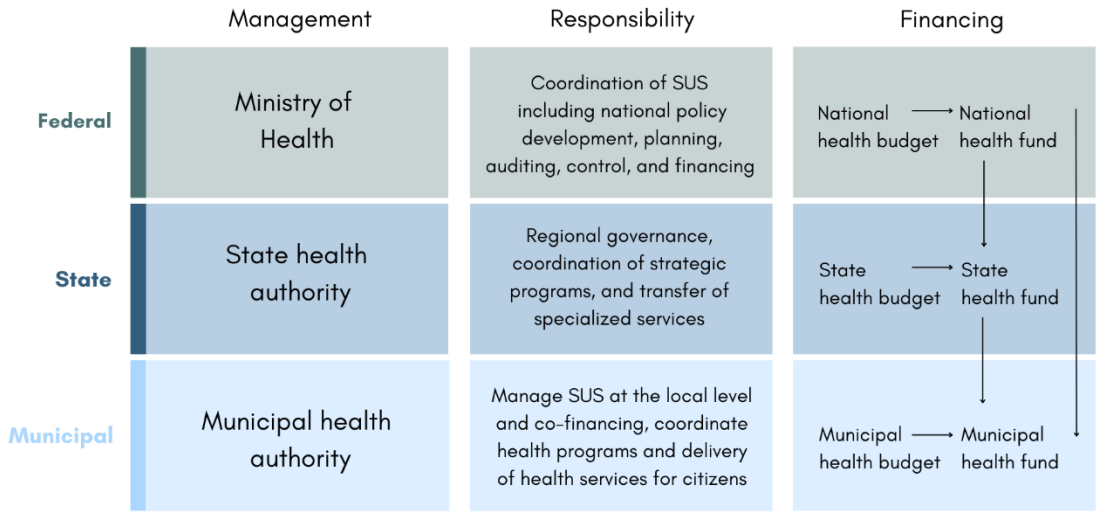

Figure 4. An overview of the National Health System in Brazil (Author's own adaptation based on Exemplars in global health (n.d) and The Commonwealth Fund (2020)).

In parallel with the development of SUS, the National Health Surveillance Agency (Anvisa) was created in 1999 as an autarchy linked to the ministry. Anvisa is the actor responsible to protect the population's health by executing sanitary controls and guaranteeing safe products and services subject to health regulation. The controls are carried out on the production, marketing, related environments, ingredients, technologies as well as consumption (pg. 4, Gonçalves et al., 2020). To guide the country, Anvisa have throughout the years launched several different laws regulating the use of medicines, known as Resolution of the Collegiate Boards (RDC)[1] (Leite et al., 2021). They have during the years been revoked by new and update ones and served as an important source for security and credibility, especially the ones regulating the use of plants with therapeutic properties.

When seeking healthcare in Brazil today you can access it by either going to public or private facilities (clinics, hospitals etc.). The public hospital part of SUS is tax funded with contribution from the government on the federal, state and municipal levels. It is possible for all residents and visitors to access healthcare, including primary, outpatient, mental and emergency care. Even the ones without documents have the right to access help since no application is necessary (The Commonwealth Fund, 2020). Despite this, approximately 25% of the Brazilian population seek care through private healthcare centres to minimize the risk of bottlenecks, where the middle and higher-income residents stand out as the major groups.

[1] Resolução da Diretoria Colegiada

4.3.1 National policies

With the creation of SUS and WHO's promotion of integrating herbal medicines and providing traditional health complementary to conventional practices, the government in Brazil has acted in the same direction (Gonçalves et al., 2020). Making several different initiatives throughout the years leading up to the two national policies which would turn out to have an impact on mainstreaming herbal medicines in Brazil.

Namely, the National Policy on Medicinal Plants (PNPMF) and the National Policy in Integrative and Complementary Practices (PNPIC), both launched in 2006 (Leite et al., 2021). Where PNPIC was established as a need for standardization and harmonization and provides guidelines on how to insert services and products related to traditional medicine into SUS. Its objective is "contribute to the increase of the solvability of the system and expansion of access to Integrative and Complementary Practices, ensuring quality, effectiveness efficiency and safety, in use" (pg. 37, Brazil, 2012). Where the policy document includes: the role of government or institutional responsibilities for policy development, strategies to guarantee the safety and quality of services and products, strategy for education and training of health professionals, recommendations for elaboration or adequacy of legislation for products and processes, and guidelines for promoting the rational use of products (Brazil, 2006a). All, based on the definition of the Integrative and Complementary which is guided by WHO's definitions of traditional medicine and complementary and alternative medicine (Brazil, 2012). Meaning this policy above all supports, incorporates and implements experiences that have already been developed in the public network of other municipalities and states. Acting as another step in the process of expanding SUS by strengthening its fundamental principles (Brazil, 2006a).

In parallel, the PNPMF was developed, when the need of building a national policy that could complement the development of the entire production chain of medicinal plants, was noted (Brazil, 2012). It aims to "guarantee the Brazilian population safe access and rational use of medicinal plants, promoting sustainable use of biodiversity and a development of the productive chain and the national industry" (pg. 20, Brazil, 2006b; pg.3, Leite et al., 2021). Additionally, it supports building a regulatory framework to produce herbal medicine, providing 17 guidelines, covering the entire value chain (Brazil, 2006b). The PNPMF is also expected to generate the development of scientific innovations making the country less dependent of synthetic drugs (Leite et al., 2021).

These two polices are the foundation for all the actions carried out by Anvisa. Their regulations and documents seek to adapt to the policies to ensure the population a safe and effective use of industrialized herbal medicines.

4.4 Herbal Medicines in Brazil

Considering Brazil's great biodiversity and their rich variances in culture, it comes as no surprise that they have a well-rooted and widespread traditional knowledge on how to use medicinal plants (Leite et al., 2021). Where the knowledge is especially important in rural areas where there is a greater lack of access to primary health services as a consequence of geographical and economical challenges. The use of medicinal plants in Brazil dates back to the early colonization of the country when cultural knowledge generated from Indigenous people and the unique Brazilian biodiversity was united with those brought by foreigners and spread within the national territory (Leite et al., 2021).

Regarding the healthcare provision during this early period, churches across the country played as an important source and it was already in the year of 1549 that the first missionaries of the catholic church travel to Brazil. Hospital services during this time was not provided by the government, leaving the churches and religious organisations responsible of treating the sick.

In Rio de Janeiro it can be dated back to the 1582 when the first Santa Casa hospital was set up, including both spiritual and physical activities (Porto et al., 2008). Considering the development of medicine, the treatment during this period was plant based, and the churches was therefore in charge of and educating the population about medicinal plant use (Anagnostou, 2005). Something that has influenced today's society and where Father Rento can be confirmed as an example. He is one of the priests who in the modern time still promotes and practise the ancient method of healing through medicinal plants (Piovezan, n.d.). Father Renato is however, accompanied by others, as shown in the article of *Faith healing and the field of healthcare in Brazil* which states that faith healing is practiced as a concept of healthcare across Brazil (Puttini, 2008). Confirming that the consumption of medicinal plants has been an appreciated alternative form of medicine. Especially in the north and northeast region of Brazil where WHO has acknowledged a lack of healthcare practises and therefore made recommendations to focus on an extension of primary healthcare, specifically in these regions (Abdala & Carlos, 2020; Leite et al., 2021).

Anvisa, the surveillance agency in Brazil in charge of approving all the products and services subject to healthcare (Leite et al., 2021), and oversees the regulating of the herbal medicines on the Brazilian market today. Anvisa defines herbal medicines as products whose active pharmaceutical ingredient (API) originates from a plant, except for highly purified or isolated substances, with preventive, curative, or palliative purposes (Brazil, 2013).

To further understand how the medicinal plant can be processed into a final product, Figure 5 presents the 6 different steps it can go through. The medicinal plant can either be processed into a plant drug (1) which can be used directly as medicinal tea (2) or manipulated into a capsule or tincture that may contain other substances (3) (Brazil, 2014a). A tincture is a concentrate in liquid form consisting of an API where the plant drug has been soaked in alcohol (Oxford Learner´s Dictionary, n.d.-b). The medicinal plant as well as the plant drug can also be processed into a plant derivate (4)(5) which is obtained from a process where the API is extracted and purified from the plant. The plant derivate can later be used as the main raw material and manipulated into the final product such as a capsule or tincture (6). Commonly for all the industrialized herbal medicines processed into different pharmaceutical forms, is that the plant material needs to be standardized and having a monograph, assuring it does not pose and harm to the user.

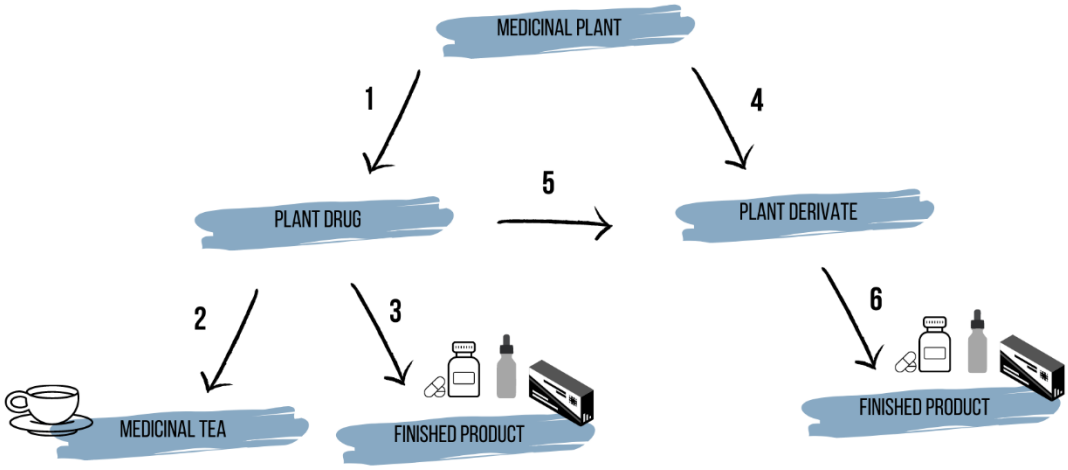

Figure 5. The main concepts for industrialized herbal medicines in Anvisa. (Author´s own adaption based on Normative Instruction No. 4 (Brazil, 2014a).

4.4.1 Ethnobiological efforts and regulations

Despite the fact that Brazil possesses a great variety of plant species, only 8 % have been studied for research and only 1,100 of them for their medicinal properties, making Brazil one of the nations with the smallest share of industrialized herbal medicine products (Carvalho et al., 2018). Leite et al. (2021) states that the few industrialized herbal medicinal products produced in Brazil are based on exotic plants. Today only 25% of them contain medicinal plants found in South America (Carvalho et al., 2011). The low share of native plant species in industrialized herbal medicines is according to Leite et al. (2021) due to lack on information about their efficiency, safety and quality resulting in Brazil today lacking monographs for many native species. Contributing several of the exotic medicinal plants used in Brazil has monographs included in foreign pharmacopeia´s, and that Brazil hence is dependent on other nations research.

Regulations for herbal medicines in Brazil have since 2010 evolved in a process of international harmonization which in 2014 resulted in a regulatory framework - Resolution RDC No. 26 (Brazil, 2014), made by Anvisa. It targeted to ease the licensing procedure of products containing API from medicinal plants with documented traditional use (Leite et al., 2021). The regulatory framework subdivided the licensed products into two categories. Namely Herbal medicines (HM) and Traditional Herbal Products (THP). HM are proven safe and efficient through clinical studies, while THPs are proven safe by demonstrating 30 years of usage through technical-scientific literature. The THP can also, instead of being registered, be subjected to notification if it is included in the Phytotherapic Form of the Brazilian Pharmacopoeia (FFFB) and has a monograph in the Brazilian Pharmacopeia (FB) or in any other nation's Pharmacopeia. Where FFFB presents information on masterful formulations, how to correctly prepare and indicate herbal medicines, as well as restrictions on how to use each specie (Carvalho et al., 2018; Martins et al., 2019). The legislation resulted in an improved control of herbal medicinal products, making Brazil´s regulatory framework more in line with other countries regulations (Carvalho et al., 2018). However, according to Carvalho et al., (2018), few THP has been licensed through notification since the FFFB do not contain the information needed to assist the registration, and that many traditionally used herbal medicines today have not been researched resulting in a lack of monographs for many popular medicinal plants.

Besides the pharmacopeia's there are other actions taken by the Brazilian government to encourage the use of herbal medicines, such as the National list of Essential Medicines (RENAME), launched in 2012 which summaries the substances, essentially used in the Brazilian health sector (Leite et al., 2021). For the area of herbal medicines, there are currently 12 species presented, provided with information on the recommended concentration and in which pharmaceutical form they can be distributed. However, there is only one native to the Brazilian Amazon, known as the *Cat´s claw* (*Uncaria tomentosa*). The plant has been popularly used by Indigenous people living in the rainforest due to its anti-inflammatory properties and where the specie in a recent scientific study (Yepes-Pérez et al., n.d.) also has been evaluated as an effective complementary medicine for Covid-19. Additional species on the RENISUS list are *Mentha* (*Mint*) and *Cynara cardunculus var. scolymus* (*Artichoke*), species that besides being used for therapeutics purposes can be consumed as everyday food.

Another outcome of the policies made is the National list of Medicinal Plants of interest to SUS (RENISUS) launched in 2006 based on a survey on the population that uses herbal medicines (Leite et al., 2021). It is a list of prioritized native plants with the potential to be proven safe and effective enough to be industrializes. However, the species presented on the list requires further research to reach the RENAME-list where only 17 species of the total 71, have worked out monographs. The species without monographs can only be used in its fresh form or as a plant drug, and not in manipulated herbal medicines.

4.4.2 The diffusion of Herbal Medicines

The use of herbal medicines in Brazil increased after the implementation of PNPIC and PNPMF in 2006. According to a survey carried out by the Ministry of Health, herbal medicines were accessible only in 116 municipalities in 2004 but in 346 municipalities in the year 2008 and reached a total of 815 municipalities in 2012 (Brazil, 2006a; L. H. L. Ribeiro, 2019). At the same time, it can be observed that the number of companies producing herbal medicines has drastically declined where during a period of 8 years there were in total 41 companies that quit their production (Carvalho et al., 2018). Viewing the remaining market, it is according to (Carvalho et al., 2018) dominated by a few large companies, producing the greatest share of industrialized herbal medicine products.

On top of that, most of the total 77 existing companies producing industrialized herbal medicines are located in the Southeast region. More specifically 46 of them, where 32 of them are located in Sao Paulo. According to Carvalho et al. (2018) there are no companies in the North region producing industrialized herbal medicines. The geographical difference between the North and Southeast is as well pointed out by the Brazilian government which states that programs and initiatives that include herbal medicines are acting out differently depending on the products and services provided and mainly, due to the different biomes, with different medicinal plants available (Brazil, 2012). Also, the development of policies and regulations for herbal medicines differs between the municipalities and states, depending on how long they have existed and how much research that has been executed.

A national and well-established initiative that has been around since the early 1990 and that remerged again in 2009 is the concept called Compound Pharmacies. They are private enterprises carrying out manipulated medicines tailored after the clients need. The products are usually a mix between modern pharmaceuticals and herbal substances to “soften” their effect (Manderson et al., 2016). The origin is based on the apothecary tradition where a chemist would create formulas at the back of the shop and has in Brazil been well received estimated to hold 10% of the pharmaceutical industry in 2016.

4.4.3 Living Pharmacies

Another national initiative, however in line with SUS, created as an outcome of the regulations PNPIC and PNPMF, is the concept called Living Pharmacies, also known as *Farmácias Vivas* (Brazil, 2012; Leite et al., 2021). It can be traced back almost three decades ago, in the state of Ceará where the Living Pharmacy were conceived as a project by Universidade Federal do Ceará, based on Professor Fransisco Jose de Abreu Matos’s promotion of pharmaceutical assistance to communities by using local flora as the only therapeutic resources.

Professor Matos made, during the early 1980s, together with a botanist countless expeditions throughout the region, visiting communities, collecting species and information on how to use them for their therapeutic characteristics (Ramos, 2017). They interpreted and transformed empirical knowledge into scientific knowledge and their extensive work of ethnobotanical, ethnopharmacological, taxonomic, and bibliographical experiments resulted in information on therapeutic efficiency and safe usage for over a hundred different species. Besides the knowledge base on the ethnobotanical aspects, Professor Matos’s aim was to create a space where the use of medicinal plants can be democratized in a dynamic network of knowledge

giving back scientific knowledge to the communities, teaching them how to properly use the species (Brazil, 2012).

Matos work resulted in three different models of a Living Pharmacy which are based on the activities performed in the space, seen in Figure 6. Living pharmacies are healthcare centres, consisting of a small medicinal garden and a simple pharmaceutical laboratory preparing the species. A plant medicine supply chain, all within four walls where the personnel is trained and given orientation on how to recognize the right species and how to prepare teas or simple pharmaceutical preparations with their own plants (Matos, 2006).

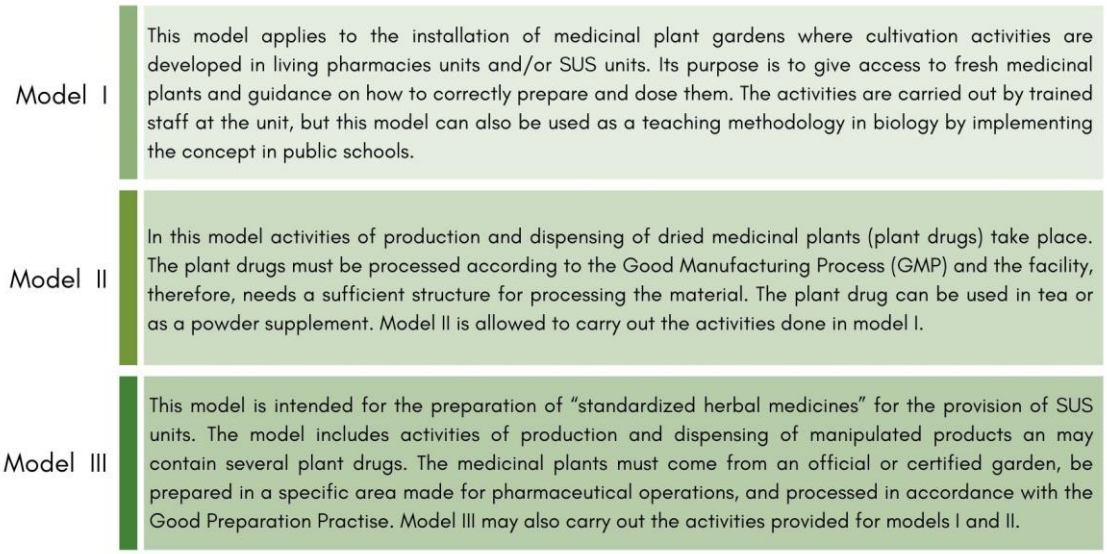

Figure 6. The three different models of a Living Pharmacy including each of the activities performed. (Author's own adoption based on Brazil, 2012 and Ramos, 2017).

The first law on state level covering the concept Living Pharmacy, was settled in the Northeast state Ceára in 1999 when the governor approved the concept as a part of their health system. It is the well-functioning pioneering project in Cearáa together with WHOs recommendations that became a reference for the Northeast region and later, for the whole of Brazil. The concept of Living Pharmacy was institutionalized on a federal level in 2010 when Anvisa launched the Ordinance No.886 which aimed to create a way to access herbal medicines in line with SUS, uncommercialized and free of charge (Brazil, 2010; Ramos, 2017). It is defined as a project to stimulate the use of local plants, selected for their efficiency and safety, to increase the utilization of herbal medicines, decrease the demand for chemically produced medicine, and to increase the access to healthcare for all. Plants that are allowed to be used are those presented on the RENAME-list, and the ones having worked out monographs and included on the RENISUS-list. To assist the staff on how to correct prepare the medical plants, its indication and formulation is provided in pharmacopeias found in FFFB.

To ensure an even safer and more efficient process Anvisa launched, in the year of 2013, a new and revoked legislation namely Resolution RDC No. 18 which consists of tougher requirements on standardization (Brazil, 2013). The law consists of 171 paragraphs, covering everything from management of resources, the out shape of the facility, what the employees should be wearing, what needs to be signed by whom to what other regulations that need to be followed (Ramos,

2017). The tougher requirements have resulted in a production line which demands a high investment cost, which compared to Matos was rather low. Further, it is said that all the activities, from cultivation to dispensing of the herbal medicine must be carried out within the Living Pharmacy itself but, if necessary, the raw material may be purchased from qualified suppliers.

To cover the implementation costs of a Living Pharmacy, the government has in recent years set aside financial support for projects within the area of medicinal plants (Governo do Brasil, n.d). Between 2012-2019 a total of 124 projects received financial support corresponding to a total of 9 million Euros (Governo do Brasil, n.d). For specific Living Pharmacies, the Ministry of Health opened a public call in both 2020 and 2021 to support the structuring of the concept (Governo do Brasil, 2020, 2021). Health Department from all over Brazil could apply for the support but they needed to demonstrate sufficient capacity to execute the project. And since it is up to the state themselves to implement health policies in line with the national guidelines, they must first establish and approve Living Pharmacy regulations in line with SUS. Resulting in regional differences.

4.4.4 The risk associated with Herbal Medicines

Many medicinal plants used today have historically been believed to be harmless due to their natural origin (Lanini et al., 2012). Where medicinal plants are thought of as safe and without possible side effects leading to adverse outcomes and intoxication. Even though several sources have indicated the occurrence of harmful reactions when using medicinal plants, the population of Brazil has struggled to realize the correlation between the two. An article carrying out interviews of plant vendors in Brazil shows that even though herbal medicines are natural, it does not guarantee they are harmless. Lanini et al. (pg. 21, 2012) state that "if herbs have an effect, they are also likely to have side effects," where consumer factors, such as age, disease factors, pregnancy, and adulteration should be specially considered. As well as product-related factors such as dosage, characteristics of the plant, and simultaneous use of other drugs since interactions with conventional drugs can lower the efficacy of other drugs or, in a worst-case scenario, cause a toxic effect (Brazil, 2012; Lanini et al., 2012).

Lanini et al. (pg. 27, 2012) state that even though complications from herbal medicines are relatively uncommon, they are most likely underreported and occur to a much larger extent than notified. Even though herbal medicines have historically been considered harmless, they require sanitary surveillance to enable the identification of their risks. In today's society, herbal medicines need to be regulated and evaluated to ensure safe and efficient use. Where Vyas et al., (2021) state that "they should not contain any psychotropic or narcotic frug, hormonal product or substances in concentration any risk for human health" (Vyas et al., 2021). According to Jerome (2015) the commercialized herbal medicines should also be labelled with "used with caution" since they are not only plants but have curative properties and should therefore be treated as drugs.

5 Brazil's current efforts to promote Herbal Medicines

This section presents the result from the fieldwork and how the accessibility of herbal medicine takes place in practice. It is structured progressively and divided into two parts. Subsection 5.1 presents descriptive findings derived from interviews, participant observations and literature, including short information about initiatives the researchers came across during the case study. Subsection 5.2 presents the results from the interviews incorporating literature to confirm raised issues as well as to highlight new findings.

5.1 Accessibility of Herbal Medicine in Brazil

Herbal medicine is an international term but is in Brazil referred to as phytotherapics since it in Portuguese goes under the name *fitoterápicos*. Despite the titles, herbal medicine phytotherapics can be accessed in several different ways, and during the time spent in the Northern region of Brazil, herbal medicines are found at numerous different local markets. At these locations, plants with curative properties can easily be bought fresh and, in simple packaging, dried in bulk. In addition, there is a variety of products containing medicinal plants that have been further processed, such as oil extracts, capsules, and creams. It however, became evident, that commonly for almost all of them, that there is not much detailed information regarding indications, curative properties or origin. Some of the products are sold unregulated and others regulated as food products or dietary supplements.

Visiting the local open air markets enables a verification of the fact stated in literature, that approximately 90 % of the plant based drugs purchased is out of pocket and without prescription (Manderson et al., 2016). However, when interviewing 17 and 18, it was comprehended that the society living in the Northern regions, to some extent, have a general knowledge on how to access and use herbal medicines without prescriptions and instructions. A knowledge that originates from traditional knowledge passed down through generations, meaning it does not matter what the labels say, if it requires a prescription or not, people are familiar with species' characteristics.

During the time spent in the North region, herbal medicines are also found in pharmacies where a range of products has been displayed under a specific shelf named *Fitoterápicos.* However, when asking the staff what these products were regulated as, a distinct confusion occurred about whether the products were industrialized herbal medicines or sold as food supplements. Herbal medicines can also be accessed through prescription at a SUS unit and Compound Pharmacies. Lastly, the way which requires the most significant amount of knowledge is to collect or cultivate the medicinal plants yourselves. Either in nature or in your own garden, to use and consume them fresh or prepare them as homemade remedies.

In contrast to the North, the accessibility of plants with therapeutic properties is not available to the same extent in the Southern regions. It is significantly harder to find extracts from Amazonian plants in stores, and when asking about several of them, there is a noticeable unfamiliarity. In pharmacies, there is no specific shelf for herbal medicines, and when asking about *fitoterápicos*, there is a lack of understanding regarding what kind of products they would be. However, the concept of Compound Pharmacy is well recognized in the region and as mediated by interviewees, there is a noticeable health trend for natural products.

On the other side, when talking about herbal medicines, other interviewees content that it is difficult to acquire knowledge about medicinal plants in the Southeast region and that there is scepticism towards using products that are not proven safe and efficient.

5.1.1 Initiatives

To further understand the accessibility of herbal medicines, the field study met with several stakeholder situated both in the north, and Southern regions. To give a descriptive picture on their activities each of them are presented individually.

Initiative A
The company manufactures and sells plant-based cosmetics products, which can be found in pharmacies in Manaus, and their supply ranges from moisturizers to oils and massage creams, all containing various plants found in the Brazilian Amazon. The raw material the company uses are mainly extracts from plants and fruits, and part of the raw material is cultivated by the company, whereas some is bought. The products are sold as cosmetics since the company was forced to step down from producing industrialized herbal medicines as a result of the stricter regulations imposed by Anvisa. The products are therefore possible to find not only at pharmacies but also online and in local shops.

Initiative B
The company is a small start-up that focuses on developing sustainable cosmetic products with high natural content. The raw material is supplied from local communities and agroforestry cooperatives in the outskirts of Manaus that are sourced through contacts in the family. The products vary from oils, creams, and shampoos. The company presently sells the products through social media channels, and the manager has experienced a high demand for the products. Currently, the company does not hold a license due to high costs and investments in production.

Initiative C
The initiative is organized by a non-governmental organization that aims to involve local communities in the production chain of varied forest products, including vegetable oils that can be used in cosmetics and for medicinal purposes. To source buyers and increase transparency, they have developed an app where one can retrieve all information about the cultivation and extraction process and make an order for extracted vegetable oils. The production units are spread throughout the state of Amazon. The raw material is bought from nearby communities that can generate income and continue their living. Customers have received the initiative well, and one production unit sold and distributed products for 770 000 euros in the last two years.

Initiative D
A company situated in Santarem offers retailed herbal medicines where most of the products are purchased from big companies in Sao Paulo. The same kind of products is possible to purchase at the local market, even for a lower price compared to the ones in Sao Paulo. However, this raw material has not been standardized nor regulated and, therefore, not considered an option for the founder. The product sold at the company are all registered and have active substances with curative properties. However, some are registered as dietary supplements due to the legislation. When asked if any of the products sold contain species native to the Brazilian Amazon, the answer was 30-35%, and a small share of raw material is bought from local communities, which later are shipped to Sao Paulo for quality control. To

develop the company further and increase the share of raw material from the Amazon supplied by local communities, it is under construction to become a manipulated pharmacy. A lab has already been installed to control the raw material and avoid the long transportation distance to Sao Paulo. A few initial products have already been produced in the facility, but the founder is currently struggling to find appropriate staff.

Initiative E
Through different projects, the interviewee has spent time working with local communities living in the rainforest to give back knowledge and beliefs on how to use medicinal plants and herbal medicines in home remedies. It has been done to assure that valuable traditional knowledge is not lost and predominantly to increase living conditions and opportunities for those relying on the rainforest to survive. The work is inherently vital since the set of species varies depending on geographical location, even in the Brazilian Amazon rainforest. To spread and diffuse knowledge, the interviewee has written hundreds of books describing the purposes of different medicinal plants and their indication of use. One very significant project was developed together with the government, where a multidisciplinary working system was constructed, and an entrusted person in the community was chosen to lead activities focused on rescuing, documenting, and organizing traditional knowledge. However, as the government went through structural changes, the project leader was chosen randomly, which made it more circumstantial for the external person to reach the communities and create trust among the habitants

Initiative F
A Living Pharmacy project which involved several actors in the city, including the municipal, a university, and a governmental institution. The project has received money to fund the Living Pharamcy model III, and efforts have been made to develop the project in line with Anvisa regulations. Technical knowledge on how to implement the project was obtained from literature and practical experiences. The practical experiences included cultivation techniques, post-harvesting steps (washing, separation, and selection), procedures for processing (dehydration), and stabilization of the raw material.

Initiative G
The idea to implement a Living Pharmacy project emerged due to the Covid-19 pandemic. The local church identified that several communities living in the rainforest experience significant problems with stress and therefore reckoned a need for treatment helping with sleep disorders and depression. Given that medicinal plants have fewer side effects, the slot fell on Passion fruit *(Passiflora edulis*), documented to be very efficient against sleeping disorders and stress. The project's objective will assist six communities living on the outskirt of the city. As a first step, selected communities will be educated on how to cultivate the passion fruit in their villages. Then, the leaves will be shipped to the city to be further manipulated into capsules. In return, the community can sell the fruits or use them in the villages. The project will be conducted with the municipality and a university. As a result of the difficulties receiving funding from the government, the initiatives projects partner, a church in Europe, is the one currently granting the financial support required.

Initiative H

A Compound Pharmacy located in the heart of Sao Paulo produces approximately 50% synthetic products and 50% herbal medicine, where only 10% of the species used originates from Brazil. It is privately owned, and to access herbal medicines, one would need to show up with a prescription from a doctor and pay for the products. All the material entering the pharmacies is analysed and delivered with mandatory certificates. Despite this, the material went through several different quality tests within the Compound Pharmacy, executed by a pharmacist. After the control, the material is manipulated into desired forms such as capsules and creams, where the most common pharmaceutical form for herbal medicine are capsules. During the production process, there are several additional different quality check-ups also conducted by a pharmacist.

Initiative I

The company has an origin that can be traced back to Nicaragua and has emerged as a part of the catholic church. The company performs medical examinations and sells plants and products with therapeutic properties predominantly regulated as food products and dietary supplements. The manager who initially founded the company possesses traditional knowledge about medicinal plants that have been passed on in the family. During the visit, the company had many visitors, and the demand for products was high. They sold everything from different dried plants in bulk, bottles of liquid herbal concoctions with anti-inflammatory properties to tinctures and creams. In an interview with an employee, the company was told to have witnessed an increased demand for products as a result of the burdened healthcare system during the Covid-19 pandemic, and their supply of products had more than doubled, especially those with anti-inflammatory properties. Some of the raw material used in the products is cultivated on a local farm, but most are imported from other states in Brazil but mainly from other countries.

Initiative J

The company is situated in Manaus and is an Indigenous cooperative providing healthcare practices and presumptions for livelihood in rural societies along the rivers in the Brazilian Amazon. The products displayed in the company´s shop is manufactured by people living in rural communities. To deliver the products to the shop, they are shipped long distances by boat. The range of products varies from bottles of liquid concoction containing *Cat´s claw* to tinctures containing extracts from *Copaíba* and *Andiroba*, among others. To learn how to manufacture and prepare the products in the communities, assuring they withstand sufficient quality, they have collaborated with a university in Manaus that has provided both research and resources.

5.2 Challenges in Herbal Medicine promotion: A reality check

In this subsection, the results from the interviews are presented. Additionally, the method of triangulation is applied to justify the barriers and opportunities pointed out by literature in relation to reality.

5.2.1 Inclusion of rural communities and diffusion of traditional knowledge

In the interviews with the different stakeholders, several sustainable aspects are highlighted connected to herbal medicine. Interviewee 5 emphasized the importance of retrieving traditional knowledge about medicinal plants and their curative properties to remote communities living in the rainforest. Since it enables them to solve their healthcare problems, avoid healthcare costs and long transportation distances to reach the nearest town, and secure their living conditions. The importance of preserving traditional knowledge was also emphasized as valuable for the overall society since it is used as a way to primarily prevent getting ill, as claimed by both the interviewee as well as literature (Eddouks et al., 2012; Kim & Oh, 2012). Interviewee 11, an ethnobiologist, confirms and explained that for minor to medium problems, the garden is used as a source of treatment. However, for severe illnesses, a medicinal clinic is usually sought out. Additionally, the diffusion of traditional knowledge on methods for extracting medicinal plants is essential to ensure that natural resources are sustained. In this context, interviewee 5 stated that for a *Copaíba* tree, it takes 30 years before oil can be retrieved, and if it is not done correctly, there is a significant risk of damaging the tree.

Representatives of several initiatives (A, B, C, D, E) also highlight the importance of encountering the fragmented focus between national interest and local sustainability work, including rural communities and family farmers in the supply chain. For example, initiative E have included rural communities in the supply chain where they serve as a first step in providing plant material to the production and, in turn, can generate income to sustain their livelihoods. In addition, their livelihood strategy has increased the family farmers' opportunities, not having to abandon their land to seek income in cities. Interviewee 3 stated that this entails the deforestation not increasing since the land is not free to claim but instead serves a purpose. A similar outcome has been achieved by initiative H where communities along the Amazon River both generate income and knowledge about medicinal plants when producing products that are later shipped and sold in the city centre of Manaus. However, the main barriers to such a complex supply chain were logistics, since the transportation along the rivers could take up to several days.

Interviewee 5, in charge of initiative E, mentioned how there is a future ambition to increase the production to complement the current production of essential oils with herbal medicines. An increased supply and demand for herbal medicines will create value for the standing forests and the rich biodiversity found in the Brazilian Amazon. Further, interviewee 5 explains that herbal medicines based on medicinal plant species from the Amazon would incentive the bioeconomy and express that “the most valuable we have here in Amazonas is the Bioeconomy due to its extraordinary diversity.” However, the supply chain of herbal medicine is also stated to be complex, requiring further research and involvement from more influential stakeholders.

5.2.2 Monographs for Herbal Medicines

Another challenge said to hinder the promotion and development of the integration of herbal medicine from the Brazilian Amazon is the plant-material variability, resulting in a lack of monographs. Simonetti & Pereira (2021) states that the standardization required for large-scale is hindered, since individuals of the same specie may differ because of environmental conditions. Meaning they may have different genetic uniform depending on the location, altitude, difference in temperature, rainfall, humidity, sun uptake, and soil quality.

Additionally, interviewee 15 conveys that the species available have different names in the different regions, creating uncertainties and complicating the national creation of monographs. Interviewee 5 adds to this and says that the lack of monographs complicates standardization which in turn jeopardizes the safety and efficiency of using herbal medicines. Besides having different names, there are species which have the same name but with different characteristics. An example is the specie *Cat´s claw*, where the plant originating from Peru, according to interviewee 4 has therapeutic properties while the one found in Brazil is less effective, creating confusion.

During interviews with academia 11 and 12, the problem with deficient monographs for the plants *Andiroba* and *Copaíba* was brought up. Both plant have therapeutic properties, also noted in the literature (Silva et al., 2021; Soares et al., 2021), but they are not currently included in the Brazilian Pharmacopoeia (FB), and according to interviewee 10, they do not have monographs to be used in industrialized herbal medicines. Instead, they can only be included in products with lower quality requirements that are legislated as food and cosmetics. To overcome dilemmas with insufficient monographs and plant variability, interviewee 19 talked about how the traditional knowledge available in the region must be taken into consideration. A similar opinion was expressed by interviewee 2, explaining that the integration of herbal medicines is hindered by the few existing scientific articles on medicinal plants traditionally used in in Brazil. Stating that resources and research on medicinal needs to expand in order to further promote and integrate the use of herbal medicines in the country, and the Amazonas state.

5.2.3 Social acceptance of Herbal Medicines in society

Despite the diffusion of herbal medicine, social acceptance and awareness have been mentioned as a barrier to the integration in Brazil´s healthcare system. Out of all the available species in the Brazilian Amazon, interviewee 3 states that only a few have reached commercialization and are used nationwide, namely Açai and Brazil nut. The same interviewee states that it can be explained by the fact that the Southern parts, which have the most outstanding share of monetary means, lack understanding of the positive therapeutic effects of several plants found in Brazilian Amazon compared to the people in the north. The lack of knowledge contributes to barriers leaving the production of plant-based products underdeveloped. At the same time, interviewees 3 and 10 sense an upcoming trend with a greater demand for natural and environmentally friendly products, where the Southern regions stand out. According to interviewee 10 the trend is connected to a higher middle-class, which has the monetary means and can access global knowledge on the topic. However, when interviewing 14 situated in the Southern region, there is a concern regarding the safety of herbal medicines and fear of inefficiency if not distributed through the SUS.

As earlier mentioned, the use of herbal medicines has decreased due to synthetic pharmaceuticals. However, as stated by Mafra et al., (2020) due to the Covid-19 pandemic, it has regained momentum and started a debate on how to use plant-based medicines to combat the pandemic and other diseases. However, in a study situated in Manaus during the pandemic, medical doctors showed low interest in recommending it, comprehended from the survey where only 2% answered that they had received information regarding herbal medicines from a doctor (Mafra et al., 2020).

To understand medical doctors' perception and knowledge about herbal medicines, two doctors were interviewed, namely interview 9 and 10. They explain that the low participation in prescribing herbal medicines can be connected to a lack of knowledge and fear, resulting in synthetic medicines being a more accessible and a safer choice. Both interview 9 and 10 mention that there were no mandatory courses on herbal medicines during their time of medical school, and their knowledge on how to use medicinal plants and herbal medicines was their own responsibility to explore. Another statement conveyed by both interviewees was the current focus on how doctors are trained in the Brazil´s health system. Focus is heavily on allopathic therapy, where medicines should provide instant and exclusive care instead of working to prevent diseases and care for the whole human being, unlike herbal medicines. Furthermore, societal resistance and preconceptions about herbal medicine due to its origin in traditional and cultural practices are identified as hindrances, conveyed by both interviewees 9 and 10. A similar opinion was expressed by interviewee 3, explaining that people in the Southeast have preconceived notions about those in the north and expressed, "all of the people in Brazil believe that the people living in Manaus are Indigenous." Further, interviewee 3 continues to explain that the preconceptions have created a culture in Manaus where some inhabitants strive to distance themself from the forest and the indigenous traditions, and instead want to become more urban. Exemplifying the statement by explaining that properties in Manaus without gardens are sold for a higher price than those with a garden.

Even though herbal medicines are not a mandatory part of medical education in Brazil, both medical doctors have acquired knowledge about it from elective courses, experiences in the field, and through traditional knowledge that has been passed on from earlier relatives, and therefore they both occasionally prescribe it. Interviewee 10 however explains that it is often done at the request of the customer, which confirms that the trend is more palpable in the Southern regions. Interviewees 9 and 10 give several examples of herbal medicines they have prescribes such as Passion fruit used for insomnia, personalized herbal medicines distributed through Compound Pharmacies, and anti-inflammatory herbal medicines which have fewer side effects than antibiotic.

During interview 6, a concern for the usage of herbal medicine among the population was expressed, stating that there are too many considering medicinal plants being harmless. The same interviewee convey that it is a drug and should be treated as one. But because of the easy access of unregulated products at markets and well-rooted traditional knowledge among parts of the population in the Northern region, people are self-confident on what they are doing, simply because they heard it from a relative. When asked about the solution and if it includes discounting access to the local market, the interviewee answered that removing the unregulated products would not solve the problem long term, and instead states that the solution is to educate. Preferably the elderly in the families who acts as the link between the past and present and usually is the one imposing the use of herbal medicine.

5.2.4 Regulations

The evolving process of reaching international harmonization for herbal medicines products in Brazil has since 2010 made the regulation for herbal medicines more comprehensive, ensuring their safety and efficiency (Carvalho et al., 2018) but according to several of the interviewees this has instead aggravated the development of the integration into SUS.

Interviewee 1 explains how the company since the year 2010 has been forced to step down, quitting the production of herbal medicine due to the tightening of regulations and instead started to produce herbal cosmetics products. Where some of the products, for example creams containing *Wolf's bane (Arnica Montana)* - a plant possessing antibacterial and anti-inflammatory properties, are produced in the same way as in 2010, containing the same therapeutic plants but with a less restricted legislation process. Meaning the cream containing Wolf´s bane can no longer be sold as industrialized herbal medicines, and instead are sold as cosmetics. Additionally, interviewee 1 states that the terminology herbal medicines is used inconsistently and just because it originates from traditional knowledge it does not mean it is herbal medicine. Further the same interview expresses that "there are no real herbal medicines to be found in the North region".

Besides being tightened, there is a consensus among the interviewees (1, 2, 12, 13) that the regulations have become harder to follow, more complex to understand, and further expensive to meet, making stakeholders not only change legislation process for their products, but neglecting regulating their products whatsoever. Interviewee 2 states the cost as the explanation and conveys that it would cost up to 10 000 euros to consign the production to a company with a license. Partly explaining the findings of the huge unregulated market where products lack tables of contents.

In a country where corruption is palpable, it has during the interviews also been brought up when discussing the regulations. Anvisa, in charge of executing the controls, has been said by both interviewee 1 and 8 to not act supportive and as stated by interviewee 1 rather "show up to simply telling me I am doing wrong". Interviewee 8 also state that it is not the regulations themselves that are uninspiring but the staff conducting the controls. Stating that "it is not like they come here to evaluate and teach us what can be improved. They want us to fail since it means they can fine us."

Interviewee 5 describes the pharmaceutical industry as the perpetrator, making the regulations take shape in a way that benefits them, as a consequence of them possessing the greatest share of money and therefore also the greatest share of power. The government is said to be, just like the others, dependent on income from external sources and therefore subject to the inputs from them with more powerful voices. The same goes for the doctors who according to the same interviewee 5 "are used as pawns, like in a game of chess" to prescribe the products that the pharmacy makes the most money from. Interviewee 4 exemplifies the presence of corruption by telling the story of how he nowadays needs to send his products to Sao Paulo to be approved, after the same business in his hometown in the North region had been forced to close since the major knew someone who got less favourable due to the competitive business. Stating that the big pharmacies rule the market and make everything in their power to keep it that way.

5.2.5 Production barriers

During interviews, it was highlighted that producing plant-based products in the North region of Brazil is challenging due to several different aspects. There was a consensus among interviewees 1 and 2, and confirmed by literature (Carvalho et al., 2018), that the market is currently dominated by large companies located in the South, obstructing the field for smaller companies in the north. Additionally, as the North is located far from the majority of Brazil's inhabitants, industries demands more logistics and capital resources (Simonetti & Pereira, 2021). The interviewees 1 and 2 claims that due to the lack of laboratories in the North, plant material needs to be transported to the Southeast for quality assurance. Making it complex and expensive being a producer of herbal medicines in the Brazilian Amazon. Contribution to that Brazil can´t utilized the natural resources found in the North and it is more profitable to buy plant materials directly from companies in the Southern regions. However, both interviewees 1 and 2 have the ambition to increase transparency by shortening the supply chain and setting up a local production line, assuring high quality and at the same time benefiting their hometown, but mentions the current struggle of locating qualified regional suppliers.

Besides the lack of laboratories in the North, there are few incentives for the large producers of pharmaceutical products in the Southern regions to export to the North considering the industry up there is small. Interviewee 16 exemplifies this by telling how medicinal packaging is limited in the North as a result of the cost and the low priority. On top of that, the transportation within the region faces challenges that other regions do not. Many of the communities producing and collecting the material are located far away from urban centres and since fluvial transport is the main transportation system, the material is often exposed to a difference in humidity and temperature, as well as potential poor hygiene, resulting in possible degradation of the material (Simonetti & Pereira, 2021). To improve the logistic between the urbanized cities and the rural communities and to eventually increase the supply of materials collected and cultivated from the countryside, the rural communities must be able to be traced and offered entrepreneurial support. An issue that initiative C, as earlier stated, has touched upon by creating an application.

Additionally, interviewee 3 highlights that the seasonal variations contribute to the fact that several of the communities cannot be reached by boat during the dry season. Knowledge for people who have not experienced the seasons in the North region, can be hard to gras. Interviewee 3 exemplifies this by stating that the consumers in the Southern regions lack a comprehensive picture of what is demanded to enable a supply all year round. Besides the limited access due to the season variation, Simonetti & Pereira (2021) also confirms the seasonality as a barrier by explaining how the species are produced seasonally, especially fruits since some only carry fruits at a certain time of the year. There are ways to get around these problem by stocking the input; however, this could contribute to increased prices which from an herbal medicine perspective would make certain demands from the healthcare difficult to meet (Simonetti & Pereira, 2021). Especially if the industry would like to go big scale. Additionally, Simonetti & Pereira (2021) also states that to some extent, it does not matter if the species are seasonal or not, the supply of the products from the Brazilian Amazon is regulated by the productivity of nature, an aspect that is hard to regulate, resulting not only in increased prices but also a potentially unsustainable extraction, threatening the extinction of species.

In order to further promote a sustainable use of herbal medicines and to facilitate the conditions for stakeholders in the supply chain, there was a consensus between interviewees 1, 2 and 3, that knowledge support should be given to small and medium-sized companies. This would help start-ups and more established companies in the process of designing a production chain where the materials are handled properly and have the potential to become herbal medicines that meet Anvisas requirements of safety and efficacy and that are produced sustainably. By doing so, the risk of making a wrong investment can be reduced and enhance the market for smaller companies, ensure livelihood for rural communities and preserve the biodiversity.

5.2.6 Living Pharmacies

The importance of how the concept of Living Pharmacies has democratized the use of medicinal plants and provided the population with knowledge on how to focus on sustainable development is a regular topic both in research (Ramos, 2017), as well as in society. Both interviewees 6 and 7, pronounced how the model emphasizes the social part and how it is important to provide healthcare accessible for lower social classes. A similar opinion was expressed by interviewee 4 who stated that herbal medicine distributed through Living Pharmacies provides an alternative to the medicines accessible today which are expensive. Interviewee 7 also stated that the project would help the riverside communities to access health and decrease their vulnerability and that the involvement of communities will lead to increased knowledge about plants. Interviewee 4 agrees and emphasizes that the model would increase the use of medicinal plants native to the Brazilian Amazon, plants that today lack recognition even at the Compound Pharmacies.

During both interviewees 6 and 7, several challenges were however, raised, mainly related to organizational difficulties and the resolution RDC No. 18. Interviewee 6 explains how the initiative had encountered large difficulties on how to outline the production facility to meet the requirements for model III stating that “People do not even know how to do model I, how are they supposed to know how to do model III”, explaining they bit off more than they could chew. Further, the same interviewee stated that if the project were to get a start over, model I or II would be a more reasonable ambition. Considering initiative 6, aiming to implement a Living Pharmacy funded by external sources they were freer to shape the outlines of the project based on their opportunities.

During the field study it has also come to realization that even though the initiative goes under the name “Living Pharmacy”, it is not entitled to be a Living Pharmacy recognized by the current legislation from Anvisa and SUS. This can be confirmed by a literature study by Ramos (2017), which when trying to map the Living Pharmacies throughout Brazil, concluded that there are currently other models practiced, for example Independent Living pharmacies and Local Productive Arrangements. These models are to larger extent focusing on the livelihood’s trough out the whole chain by involving local actors. The study concludes that there is a need to further evaluate how to integrate local actors in policymaking. This could strengthen the Living Pharmacy concept including the social dimension and the potential outcomes its carries. Such as achieving several of the SDGs by valuing the interaction not only with the local actors, but also with affected ecosystem, regional factors, resource availability (Ramos, 2017).

Worth remembering according to interviewee 10 and explained when asking about the poorly diffusion of Living Pharmacies, is that despite the fact that the concept have been institutionalized since 2010, they are at the stage of a pilot project and should be recognized as one. Therefore, space should be given for further research and development

5.2.7 Research and Development

Despite the challenges of integrating herbal medicines in healthcare systems, Simonetti & Pereira (2021) convey the value of a successful pharmaceutical industry since it represents health as an economical source, enabling not only access to health products but also Research and Development (R&D). Up until the 1940s, Brazil followed the growth of the international pharmaceutical industry, but because of the absent of R&D in this industry and in the creation of public policies, and lack of economic resources, Brazil was put in a lock-in situation (Centro de Gestão e Estudos Estratégicos (CGEE), 2017). The Brazilian health industry had neither the means to focus on the developments of new drugs, nor taken advantage of the country´s unique biodiversity. Making them heavily reliant on other nations with more advanced pharmaceutical industries (Leite et al., 2021). Viewing the Brazilian market of industrialized herbal medicines most of the products contains exotic species as the active plant ingredients (Carvalho et al., 2018; Science Panel for the Amazon, 2021). Justified by the fact that there is, as mentioned before, only one species native to the Brazilian Amazon (*Cat´s claw*), that is included in their health system and can be found in RENAME.

Even though there are a lot of initiatives and literature sources stating Brazil is moving towards a pharmaceutical market based on plants are facts stating the opposite. Interviewee 20 states there is an obvious lack of research papers on the use of medicinal plants in Brazil which can be reinforced by a governmental study on the Brazilian pharmaceutical industry published in 2017 focusing R&D on synthetic drugs and drugs obtained from exotic species (Centro de Gestão e Estudos Estratégicos (CGEE), 2017). This opposes scientific reports (Carvalho et al., 2018; Leite et al., 2021) which pinpoints the need for research on this topic and an increased amount of published scientific evidence on medicinal plants therapeutic effects to promote the share of industrialized herbal medicines on the Brazilian market. R&D including monographs on native medicinal in Brazil is important due to the lack of written documentation of traditionally used medicinal plant species, despite long withstanding traditions for many of them. Moreover, Carvalho et al. (2018) and Leite et al. (2021) states that resources should be enforced in conducting clinical trials, for native plant species since they are rare, to benefit Brazil's healthcare system, the population and the bioeconomy.

5.3 Accessibility in reality

When analysing and summarizing the result from the field visits and the interviews, herbal medicines are shown to be possible to access in three different ways. Not only regulated as industrialized herbal medicines by Anvisa, or unregulated from street and open-air markets, but in an additional category namely, regulated by other sectors. This category consists of food products and dietary supplements, if inhaled or consumed, and cosmetics, if used externally. The three possible ways to access herbal medicines and examples of the products are presented in Figure 7, where the unregulated products can be found available in nature and at markets. Product regulated by other sectors can be found at pharmacies, general shops, and at informal health providers. The regulated products are found at pharmacies, Compound Pharmacies, hospitals, and Living Pharmacies in accordance with Resolution RDC No.18.

Figure 7. Availability of herbal medicines and their different levels of regulation based on results from the field (Author's own adoption).

The tightening of the regulations has resulted in companies stepping down from the category of regulated products by registering them as supplements and cosmetics since the process of legislation for these products requires less resources. Resolution RDC No.26 has as earlier stated, also resulted in a possible legislation of plants through proof of traditional use. Meaning plants proven used for over 30 years are possible to notify and sell as regulated product. There are, however, very few traditional herbal medicine products notified in this category due to the lack documentation, resulting in a grey zone, forcing companies to commercialize products as food supplement and cosmetics. This is a topic also notified by literature confirming it is complex to construct a regulatory framework for herbal medicines resulting in many herbal medicines products falling in between categories (Lenssen et al., 2019).

6 Discussion

This discussion is divided into four subsections representing the key subjects of our study. Each of the subsections compares and analyses the findings from the case study by incorporating new literature together with previously mentioned referenced literature. In this context, the objective of the study is broadened by emphasising the importance of herbal medicines world-wide.

6.1 Regulations

The fact that products containing medicinal plants often become regulated by other sectors implies that the integration of herbal medicines into Brazil´s healthcare system is experiencing several challenges. Regulations in Brazil have been constantly changing, creating a rigid relationship between Anvisa and the stakeholder groups producing herbal medicines. Additionally, Anvisa can often be seen as the face of the government considering it is the agency the producers often meet. That is however not the case, and their job is simply to control if the production is done correct or not. This creates a frustration among stakeholders who pinpoint the lack of constructive feedback. Raising the question of whether policymakers take the reality and stakeholders' opinions into consideration. The government must therefore ensure appropriate knowledge mediated to Anvisa and structured regulations to create a dynamic relationship where stakeholder can thrive. Something that in the long run would benefit the government in terms of an increased tax income and an improved bioeconomy for the country.

Nevertheless, while questioning whether the regulations are excessively stringent, it is important to remember that it is a question of safety. The Brazilian government wants to make sure the products provided are of high quality and without severe side effects. That priority is also of interest when acknowledging the lack of social acceptance toward herbal medicine from the people who do not possess common knowledge about the products. As expressed in one of the interviews, accessing herbal medicines through SUS would likely increase their trustworthiness and expand their user range. Since the industrialized herbal medicines accessible through SUS are very limited it can, however, be boiled down to a question of whether the population should be able to access regulated herbal medicines whatsoever. In the current situation, either way, the industrialized herbal medicines products struggle to reach the consumers.

To create a well-functioning regulatory framework with a legitimate process of licensing herbal medicine products, and without jeopardizing their safety, further research and utilisation of the existing traditional knowledge is required. Here China can be seen as an inspiration, considering their management of valuing the traditional knowledge of herbal medicine and to include it in their primary healthcare. An increased number of worked-out monographs for medicinal plants native to the Brazilian Amazon, including the traditional knowledge, would result in bringing Brazil closer to China in terms of research. It would also give rise to an expansion of the RENISUS-list, entailing a greater value for the standing forest since a useful biodiversity commands greater interest in its conservation. With additional research on the species, it could later contribute to an expansion of the RENAME-list, making it possible for herbal medicine products, including native medicinal plants, to diffuse beyond their original place of occurrence, resulting in a wider access of health, moving towards reaching SDG 3 – Good health and well-being as well as SDG 15 – Life on Land.

Considering the great potential Brazil has in terms of biodiversity, the slow development of utilization of the plant species available can be seen as a missed opportunity. An explanation is the neglected research on the topic, where in the latest governmental study (Centro de Gestão e Estudos Estratégicos (CGEE), 2017) the herbal medicines are showed no attention and where R&D instead focuses on synthetic drugs. Still, it is not too late to turn this around and a way to overcome this barrier is the promotion of bioeconomy that make use of the local biodiversity assets sustainably. To do so, the awareness of a potential promotion of herbal medicines need to increase, starting at the federal level. If support, symmetric information, capital, and education were to be provided, for established companies, start-ups, as well as for private persons, the herbal medicine sector would have the potential to blossom and as mentioned by many others, putting Brazil on the map as one of the world's greatest bioeconomy.

6.2 Living Pharmacies

The concept of Living Pharmacies has shown to be an appreciated initiative in Brazil. However, during the field study it became clear term is much broader than the Living Pharmacies related to SUS and recognized by the Brazilian legislation (Brazil, 2013). There seemed to exist plenty of Living pharmacies out there, acting under different regions and regulations. It is therefore difficult to trace and categorize them, resulting in confusion among both interviewees and in literature, which could be an explanation for why there are sources stating there are different numbers of Living Pharmacies (Ramos, 2017). There is, however, a consensus regarding the limited number of Living Pharmacies in the Northern region and during the limited period of the field study, none in line with SUS, were identified.

Additionally, Matos's three models are widely spread and well known among several of the interviewees and mentioned in numerous research papers (Brazil, 2012), but while reading the Resolution RDC No.18, they are nowhere to be found (Brazil, 2013). The information on how to establish a Living Pharmacy in line with SUS for either model I, II or III is not included in the federal official documents. That potentially explains the struggle for initiative F, aiming to implement a model III on the municipality level.

The unstructured information provided together with the conveyed lack of support raises questions on whether the Living Pharmacy concept will be able to reach its full potential and if the resources have been invested and distributed appropriately. When institutionalizing the concept in SUS, Matos's vision was formalized into a policy promoting the creation of herbal medicine production facilities from scratch, yet without possibilities for adequate capacity enhancements. This action can be interpreted as rather counter-productive since what was needed was perhaps knowledge and financial support to encourage stakeholders in the supply chain. Stakeholders who already aimed to provide healthcare for lower and middle classes could have been doing it line with Anvisas guidelines, if they would have been provided support. But institutionalizing the concept of Living Pharmacies can be beneficial where the advantage is the social acceptance. Resulting in that herbal medicinal product is distributed through a legitimate source and not connected with anything else than SUS, potentially increasing the social acceptance for this alternative form of treatment. Striving at strengthening the existing stakeholders which might have roots in religious or spiritual associations might contribute to resistance from the ones not wanting to be associated with that or who simply do not believe in it.

That observation led us to a possible explanation on why there are no Living Pharmacies in line with SUS to be found in the Northern region of Brazil. Besides being surrounded by the rainforest, which according to interviewee 5 "is a living pharmacy itself", the people living in the Norther region have, to a much larger extent than other regions, been surrounded by the traditional knowledge strengthening their knowledge on how to prepare and use these remedies on their own, as well as their acceptance towards their efficiency and safety. The belief and the access to nature, create space and opportunities for people in the northern regions to collect, buy and practice their knowledge even on a low budget. Putting one of the significant advantages of Living Pharmacies on the test which could explain, at the very least, the low demand for a concept supervised by SUS and therefore the slow development and implementation of it.

One may ask if the concept Living Pharmacies in line with SUS is well spent resources in these regions. It is, however, important to remember that the plants possess curative properties with side effects just like conventional drugs and that the unregulated market therefore should be approached consciously. Additionally, the greatest potential benefit of developed Living Pharmacies in the region is the inclusion of people living in the countryside into the supply chain, as claimed by several of the interviewees. The institutionalisation of Living Pharmacies in 2010 has however contributed, to some extent, to neglecting the social dimension of sustainability when suggesting that all activities, including the cultivation and harvest of the medicinal plants, should be done within the walls of the pharmacy itself. If the pharmacy instead decides and manages to purchase them from qualified suppliers, such as people living in rural communities, it will contribute to improved livelihoods. This implies working towards SDG 1 - preventing poverty and SDG 15 - life on land since providing monetary means enables the communities to stay in the rural areas and continue to live convivially with nature. Additionally, as earlier stated by Mphande (2016), an increased economic status does not only benefit livelihoods in tropical regions, but it is also an essential pillar for health since the three aspects are linked to each other. Leading us to the third and last SDG 3 – Good health and wellbeing.

Finally, the concept of Living Pharmacy has several positive aspects serving as a potential motivation and inspiration. For implementation in Brazil as well as other countries. Putting the two contrary points whether the concept is favourable in the northern or the in Southern regions in Brazil, one may think of opportunities and barriers for both. Where the opportunities for the north, possible to relate to the tropics as a whole or other countries with similar conditions, is that belief is strong, accessibility is great, and it has the possibility to increase the livelihood for those included in the supply chain. For the Southern regions however, which can be related to many other more urbanized places with limited supply of plant species, such as Europe and the US, the Living Pharmacy might succeed under completely different motives. With the limited supply of plants species, the Living Pharmacies and its cultivation within the facility provides the regions with plants and knowledge on how to cultivate. The increased health trend results in a perhaps a notable higher demand in these regions and since the concepts is provided with supervision conducted by agencies it increases the chances of a greater social acceptance.

6.3 Biodiversity conservation

Despite the asset of biodiversity in Brazil, the country is, as argued, heavily dependent on other countries and their resources as a source of herbal medicine products. A regional development strategy would, however, leverage the production of herbal medicines making it possible to seek independence. Yet when looking through the lens of history, Brazil has struggled with this, explaining the high rate of exotic species used. Besides valuing the knowledge present in the country, there needs to be action taken to improve the processes of refining natural resources into products. There are several examples of potentially promising resources that due to the regional richness could favour Brazil and its bioeconomy, but due to lack of public policies and low interest in improving the processes, the processes have remained underdeveloped.

Rubber, extracted from *Hevea Brasiliensis* trees, offer an example, and its production has laid the foundation for many of the cities' existence in the northern region of Brazil. Despite the potential, little was invested in terms of infrastructure and policies to improve the process, resulting in other counties eventually becoming more competitive and gradually taking over the production of rubber and the market share (Simonetti & Pereira, 2021). Other similar examples are *Açaí, Andiroba*, and *Copaíba,* where techniques and products have been patented in other countries such as the United States, England, Germany, China, and Japan, to a much larger extent than the patenting made in Brazil. There is obviously a great international interest in the sources available in Brazil, something that should spur the country to create strong and sustainable policies supporting competitive techniques to enhance future exports and make sure that bioeconomy-promoting business does not emigrate.

Another possible explanation for Brazil being dependent on exotic species is the fear of overexploitation. To ensure that this do not occur, traditional knowledge play as an important source and as stated by interviewee 5 "it is only the traditional knowledge that can tell us how to preserve the forest and make sure that the cultivation and collection are done in a sustainable way". The knowledge is also crucial to be able to map the medicinal plants available in the Brazilian Amazon to increase the share of researched native plant species in the country. However, considering the current deforestation, the argument of fear being the reason for why Brazil is dependent on other countries do not feel as likely as the one put into words by Simonetti & Pereira (2021) - namely bureaucracy. They explain how the development of science, technology, and innovations based on biodiversity is hindered by the slow and extremely bureaucratic process to obtain access to genetic heritage, including traditional knowledge. On top of bureaucracy making the process of research in Brazil difficult, the cost for doing research, going from medicinal flora prospection to finalized herbal medicines, is stated to be high, favouring research done on exotic species with already existing monographs (Rodrigues, Nogueira, 2012). It is therefore important that research approaches are analysed in order to generate more knowledge and information on the Brazilian plants special available, to eventually ensure a greater diffusion of herbal medicines.

The process of valuing the existing biodiversity and taking advantage of its resources is essential to ensure a competitive economic alternative to the soy, timber and cattle industries, activities constantly poking its presence as a competitor for the land use. If the country wants to achieve the targets set up in the Nagoya Protocol including deaccelerate extinction of species and conserve land, the standing forest and its unique values needs to be reconned. When viewing current action taken by the government, they however seem to be more focused on

achieving international harmonization for herbal medicines products, assuring their safety and efficiency by revoking regulations, instead of realizing the potential pathway of an emerging bioeconomy.

Not per say stating that a bioeconomy transition is the solution considering this concept also have flaws. It can address fossil-fuel dependence but also the anthropocentric pressure on nature, depending on how it is pursued (Lima, 2021). The terminology should therefore be used cautiously and as brought up during one of the interviews maybe also the transition itself should be used cautiously. Interviewee 21 states that in a country like Brazil, where people being dependent on nature often also are supressed, bioeconomy should be secondarily after assuring peace and human rights for all. Exemplifying it by stating there is a war going on out in the rainforest, confirmed by literature explaining the ongoing conflicts (Gonzaga, 2022), and how this issue should be of priority. (Gonzaga, 2022), and how this issue should be of priority. (Gonzaga, 2022), and how this issue should be of priority. (Gonzaga, 2022), and how this issue should be of priority.

If the standing forest can be proven invaluable and considered competitive it could result in a lower interest of other less sustainable businesses. To achieve such an outcome there is however a need of a significant improvement of infrastructure and policies regulating the production and research to ensure that the herbal medicine sector with origin from the Brazilian Amazon not have to face the same fate as previously mentioned examples and that the biodiversity can be conserved.

6.4 Social acceptance

The preservation of traditional knowledge is essential to enable the integration of herbal medicine into primary healthcare. Despite its importance, the traditional knowledge is as mentioned threatened and is gradually pashing out. Ones again China can be mentioned as an example with their well-established integration of traditional knowledge on plant-based medicines. An explanation beside their governmental action is their strong culture and prevalent belief (Xin et al., 2020). Western science on the other side, is stated to view traditional medicines cautiously and expresses the concerns related to the research regarding their efficiency and safety (Patwardhan et al., 2005). When viewing the two perspectives, a parallel is possible to draw for the two regions studied in Brazil. In the north there is a noticeable belief, considering the ancient history of indigenous culture. While in the Southeast the interviewees stress their concern for credibility. This enables a comparison where the Southeast of Brazil represents the western societies and the north of Brazil, represent China. This, set in correlation to the question on whether Living Pharmacies would be a successful concept in the north, entails that if the success taken place in China is based on the strong belief, the north of Brazil is the place to go about. The belief is there, what they need is the same scientific based research and governmental promotion.

Besides the effect of the growing conventional pharmaceutical industry, the change in culture is comprehended to be a motive where migration to urban centres will characterize the 21 century and the numbers are expected to increase (Kookana et al., 2020) but it will be associated with major inequalities and health problems (Kuddus et al., 2020). Major inequalities since it increases the risk of the few still living in rural communities being even further disadvantaged and lower prioritized. The situation of urbanization in Brazil is no different and

in a city like Manaus, with approximately as many inhabitants like Paris, but which holds indigenous influences and traditional knowledge. There is a noticeable eagerness to prove the preconceptions of being a village in the Amazon rainforest wrong. Resulting in houses without gardens selling for more than those houses with a garden. It is obvious that parts of the population do not want to be associated with the rich history present in the region which, unfortunately, includes the traditional knowledge of herbal medicine use.

Besides enabling access to health, the accumulated knowledge generated by the forest people in the Brazilian Amazon is invaluable for the preservation of biodiversity and a nascent bioeconomy. And even though not everyone in the state of Amazon possesses this valuable knowledge an increased acceptance and appreciation of these resources should be acknowledged. Contrary to the devaluing that has been characterizing the history and present with the oppression of indigenous people and lang grabbing, forcing communities to evacuate. Research and development must therefore be enforced to create a strategy where local actors, with invaluable knowledge, living in the Amazon are benefiting from the development of herbal medicine supply chain. This to lift them out of oppression and poverty as well as to ensure that they are not left out on the opportunity to sustain their livelihoods. Additionally, a developed inclusion does not only provide income for people living in rural communities but can also be used as an argument to ensure biodiversity, a bioeconomy, and prevention of climate change since the knowledge can promote sustainable supply chains. Actions which should be of interest for all countries on the globe considering the importance of rainforest to sustain climate balance on earth.

The main answer to succeed with such successful acknowledgement is to educate, as pointed out by many during the interviews. Provision of information, knowledge, and practical training on medicinal plants, home remedies and herbal medicine is essential, for managers, professionals, health workers and not to forget, the general population. In addition, advanced training courses for actors linked to the supply chain of medicinal plants and herbal medicines should be provided to ensure safe and efficient production and products.

7 Conclusion

The thesis investigated how the promotion and integration of herbal medicines occur in developing countries, focusing on Brazil as one of the key nations. A wide cluster of barriers have been identified and the key ones are summarized: 1 - Stringent regulations in combination with a lack of adequate capacity for producing standardized, safe and efficient herbal medicines, 2- Scant managerial and financial support provided by the government for stakeholder subject to herbal medicines production, 3 - Irregular supply of plant material due to seasonal variability and limited logistics, and 4 - Social acceptance of herbal medicines due to historical association with cultural and religious traditions.

To overcome these barriers, it has become evident that adequate capacity building is essential for people, institutions, and stakeholders in the supply chain to enable refinement of valuable natural resources and knowledge into sustainable strategies, guiding bio-based development. Increased support and investment in research entail further development of safe and efficient herbal medicines. This in turn can enable a successful integration of herbal medicines with origin from Brazil, which is crucial for Brazil in the transition towards a bioeconomy and for biodiversity-based initiative in the Northern regions to prosper.

Considering the barrier of social acceptance, Brazil with the institutionalized concept of Living Pharmacy has a unique opportunity to create a synergy effect. By toning down the associated religious culture, herbal medicines have the potential to become a socially widespread form of treatment, complementary to conventional treatments. Such expanded use of herbal medicines can also be an instrument for raising incomes and improving livelihoods in rural areas, since an inclusive supply chain entails job opportunities and diffusion of knowledge. The concept Living Pharmacies which promote an expansion of medicinal plants could therefore be of interest for other countries with valuable biodiversity to increase social-economical equalities.

Besides medicinal plants being a source for improved livelihoods, they represent countless variations of substances serving as inspiration and a knowledge source for an industry which in the year 2021 generated approximately €1200 billion (EUR). Such revenue has the potential to radically increase if research in new medicine with origin and influences from nature increases. With greater revenues more barriers can be tackled, and it is therefore suggested that all countries, not only the one possessing tropics, show interest in these rich forests and their potential value for improved and developed pharmaceutical industries. If the plants are sustainable collected and cultivated it can ensure future generations access to medicine while still having the chance to experience the rich ecosystems and culture present in tropical regions.

With that said, despite the barriers connected to the integration of herbal medicine into the Brazilian healthcare system, continuous promotion and development is essential to ensure safe access to healthcare, to prevent biodiversity loss, promote socio-economic equalities and to achieve the goals set up by both WHO and SDG. To succeed with such integration traditional knowledge needs to be valued and captured, education needs to be provided on all levels and further research needs to be enabled and conducted. Strategies and actions like these are not crucial only in Brazil, but for all countries striving to meet the SDG goals, where there is no such a thing as poverty, where healthy lives are ensured for all and where sustainable use of land is protected and restored.

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