CANNABIS *SATIVA* L. IN THE UNIFIED HEALTH SYSTEM

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ABSTRACT

The use of medicinal plants is as old as the history of humanity, however, with the advancement of technology there was an inertia in the use of plants, that the popular movement caused a real uproar in the race for the increasing use of medicinal plants. In this way, the development of integrative and complementary practices gradually began. Although integrative practices are implemented in the Unified Health System (SUS), it is still not a reality throughout the country, many resistances, lack of information and incentives, make it not a practice offered to the entire Brazilian population. Primary Health Care must be exercised with managerial practices, democratic assistance with popular participation, with this thought the Family Health Program emerged in 1994 and in 2006, it became the Family Health Strategy. In 2010, the Ministry of Health published ordinance 886 that established the Living Pharmacy, which, like its creator, Prof. Francisco José de Abreu Matos, would be an impulse for the Health Secretariats of Brazilian municipalities, however, it is verified that it has not yet become a reality. Currently, the demand for the use of *Cannabis sativa*, the Unified Health System seeks, in a way, a way to meet the needs of Cannabis prescribers. In RDC 18 of 2013, which provides for Good Handling Practices for Medicinal Plants and in PL 399/2015, which provides for the safety and storage of *Cannabis sativa*, several mechanisms have emerged for the insertion of the species in Living Pharmacies. Many advances have been observed in this fight, however, the Ministry of Agriculture, Livestock and Supply must be involved to discuss the insertion of *Cannabis sativa* in family farming.

Keywords: Medicinal Plant. *Cannabis sativa*. Family Farming. Living Pharmacy.

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INTRODUCTION

PHYTOTHERAPY IN THE UNIFIED HEALTH SYSTEM (SUS)

With the impetus given by popular movements, reports from numerous national and international conferences and the recommendations of the World Health Organization (WHO), there was the insertion of practices related to the use of medicinal plants and herbal medicines in the public health scenario in Brazil, especially Primary Health Care services.

This gradual inclusion of integrative and complementary practices, initially with community experiences and non-governmental organizations, at the municipal and state levels and later in public health systems, has been promoted by the WHO since 1970 and several countries have developed public policies to integrate these practices into Primary Health Care, as is the case of Brazil with the National Policy of Integrative and Complementary Practices.

Despite the importance of traditional medicine, it is verified that the use of medicinal plants and herbal medicines in public health services, even those included in PHC, is not yet a national reality. This data can be justified by the scarcity of scientific studies on native species or the lack of systematization of research already carried out.

Primary Health Care (PHC) can be characterized by a set of health actions, in the individual and collective fields, including diagnosis, treatment, promotion, protection, rehabilitation, and health maintenance. It must be developed through the use of democratic and participatory management and care practices, with teamwork, directed to specific populations, in well-defined territories, for which health responsibility is given. Its practice considers the subject in his individuality and in his sociocultural reality and seeks to reduce damages that may impair his ability to live in the healthiest way possible.

Inserted in Primary Health Care, the Family Health Program (PSF) was created in 1994 by the Ministry of Health, with the objective of reorganizing care practices, focusing on the family understood and perceived based on its physical and social environment. Based on this conception, the FHP teams have an expanded understanding of health with practices that go beyond the curative perspective, expanding health promotion, prevention and rehabilitation. In this model of care, there is the assumption of valuing health practices that go beyond biomedical practices.

In 2006, the government launched Ordinance No. 648, of March 28, 2006, which changed the status of the PSF from a program to a permanent strategy of Primary Health Care, becoming known as the Family Health Strategy, since the program has a fixed time and the strategy is permanent and continuous.

The multiprofessional teams (doctor, nurse, dentist, nursing technician or assistant, oral health technician or assistant, and community health agents – CHA) that work in the ESF enable comprehensive and multidisciplinary care for the enrolled population. These teams are responsible for monitoring the health situation of a certain number of people and families who live or work in the territory close to the health unit, allowing the establishment of bonds, commitment and co-responsibility between the health professionals who work in the FHS and the population.

The Living Pharmacy Program has a great impact within the Family Health Strategy, as this program proposes to promote health considering the reality of life of the community in its various aspects, and in this reality, it finds the medicinal plants inserted in the family's health care even before seeking the health unit and the doctor. The Living Pharmacies program, in this context, is a health tool as it offers safe and scientifically validated medicinal plants with guidance on cultivation, preparation and use techniques.

Medicinal plants represent important savings for the Public Health System because they are cheaper and, if used correctly, also represent a lower risk of adverse events related to the medication. This happens because Live Pharmacies produce the herbal medicine using the active ingredient still in the plant and its extracts, unlike the pharmaceutical industry, which performs sophisticated procedures for the isolation of the active ingredient or imports it into other countries, which makes the procedure time-consuming and expensive.

In this way, Live Pharmacies can be used in public health services as a way to ensure safe medicines, with good acceptance by the community, as they already empirically know the benefits of the plant that gave rise to the medicine, and cheaper for managers, especially small municipalities, which suffer from the shortage of pharmaceutical services (LEÃO, 2015).

LIVING PHARMACIES: *CANNABIS SATIVA* L. NO SUS

The demand for patients in continuous treatment with *Cannabis* in Brazil is growing and these patients face many steps and bureaucratic challenges to get the medication, which has given visibility to the urgency of regulating the national production of this species, for the public health network. Thus, as the State is responsible for guaranteeing the right to health of the Brazilian population, the production and distribution of cannabis-based medicines through Live Pharmacies can be a viable alternative, promoting access in line with the fundamental principles of the SUS.

Initially, for a better understanding of the present proposal for the inclusion of *Cannabis sativa* L. in Live Pharmacies, it is important to know what they are and their models in order to adapt this proposal to an achievable reality.

LIVE PHARMACIES

The historical milestone in the development of Phytotherapy in Brazil was the creation of the Living Pharmacies, a social program based on the scientific use of medicinal plants and herbal medicines, idealized by Professor Francisco José de Abreu Matos in 1983, under the influence of the principles of the World Health Organization (WHO). At the time, this notable pharmacist and researcher from Ceará, knowing that more than 20 million people in the Northeast were outside the primary health care system, in addition to other regions of Brazil, who had as their only treatment option the medicinal plants available in the environment where they lived, asked:

I. What are the plants used in folk medicine?

II. How is it possible to select them by the healing activities assigned by the people? Which ones can be used without risk to health and life?

III. How can the plant selected according to the criteria of efficacy and safety reach the people and be used correctly, without encouraging self-diagnosis and self-medication?

It was seeking answers to these questions that Prof. Francisco José de Abreu Matos idealized the Living Pharmacies to bring medicinal plants and herbal medicines to communities with proven therapeutic efficacy and safety, defined as follows:

"*LIVING PHARMACIES are pharmaceutical units installed in governmental or non-governmental communities, where their users receive medication prepared with plants that have had confirmation of the activity attributed to them, harvested in the gardens themselves, which allow their users access to a list of truly medicinal plants and their products" (F. J. A. Matos).*

LIVING PHARMACY MODELS

The Farmácias Vivas aims to offer, on a non-profit basis, herbal pharmaceutical assistance to communities through the promotion of the correct use of plants of local or regional occurrence endowed with scientifically proven therapeutic activities.

Based on the types of activities developed, such as cultivation of medicinal plants, pre-processing, preparation of home remedies with medicinal plants and preparation of

herbal medicines, three models of Live Pharmacies are established, according to State Decree / Ceará No. 30016/2009 (Figure 1):

Figure 1 – Representation of the Living Pharmacy Models at the three levels of complexity.

Farmácia-Viva I

This model applies to the installation of medicinal plant gardens in Community Living Pharmacies units and/or SUS units maintained under the supervision of state/municipal public phytotherapy service professionals. The vegetable raw material, processed in accordance with Good Cultivation Practices (GCP), must come from official or accredited gardens and/or gardens. This model aims to carry out cultivation and guarantee the assisted community access to medicinal plants *in natura* and guidance on the preparation and correct use of home remedies, carried out by trained professionals.

Community health agents, rural agents or similar, duly trained and integrated into a Living Pharmacy unit, may participate in the orientation process regarding the correct use of medicinal plants.

Pharmacy-Viva II

It is intended for the production/dispensation of dried medicinal plants (plant drug), intended for the provision of SUS health units. The vegetable raw material, processed in accordance with Good Cultivation Practices (GCP), must come from official or accredited gardens and/or gardens.

The vegetable raw material will be subjected to primary operations, in specific areas, in accordance with Good Processing Practices (GMP).

Farmácia-viva II may also carry out the activities planned for Farmácia-Viva I, in compliance with its technical specifications.

Pharmacy-Viva III

It is intended for the preparation of herbal medicines for the provision of SUS units, in compliance with the specifications of the NUFITO Form. The plant drug for the preparation of these herbal medicines must come from official or accredited gardens and/or gardens, as long as it is processed in accordance with Good Processing Practices (GMP). . Herbal medicines are prepared in specific areas for pharmaceutical operations, in accordance with the Good Practices for the Preparation of Herbal Medicines (GMP), contained in the Regulation.

Model III may also carry out the activities foreseen for models I and II, in compliance with their technical specifications.

The Living Pharmacies, in their three levels of complexity, models I, II and III, must adapt their activities in the most convenient way to the health system in which they are inserted, respecting the limitations of financial, human and logistical resources, making the health of the system user prevail. In practice, there are two operating systems, described below:

These models of Living Pharmacies are adopted by several states in Brazil, although they are not described in RDC No. 18, of April 3, 2013, ANVISA, it is possible to distinguish between the lines models II and III, according to the activities described in this RDC, which deal with obtaining the drug of plant origin and preparing herbal medicines, respectively.

The Living Pharmacies aim to contribute to raising the level of health and quality of life of individuals and the community, integrating their activities with health actions, for the promotion, prevention and recovery of the individual and the community, through the correct and safe use of medicinal plants and herbal medicines. We can highlight the following guidelines:

- Articulate and coordinate Phytotherapy actions;
- Provide cooperation and technical advice to municipalities for the implementation of Live Pharmacies;
- Encourage the development of family farming with medicinal plants;
- Promote ecological educational actions for the conservation of medicinal plants;
- Promote standardization and regulation to promote the rational use of medicinal plants and herbal medicines;
- Ensure the insertion of medicinal plants and herbal medicines in primary health care;
- Establish and define attributions of health professionals and related professionals in the area of phytotherapy;

- Claim from the competent authorities a system of agreement of pharmaceutical inputs for the Municipal Live Pharmacy units;
- Promote educational actions with the community on the correct use of medicinal plants;
- Promote the development and training of health professionals and the like;
- Provide guidance on the correct use of medicinal plants and herbal medicines;
- Develop investigations and research as an instrument for evaluating the quality of herbal medicines;
- Develop pharmacovigilance of herbal medicines and clinical follow-up of patients using herbal medicines;
- Provide an internship field and training of specialized personnel;
- Increase new technologies for the advancements and consolidation of phytotherapy.

POLITICAL AND TECHNICAL GUIDELINES FOR THE VIABILITY OF LIVE PHARMACIES

The National Policy on Medicinal Plants and Herbal Medicines, instituted by Presidential Decree No. 5,813 of June 22, 2006, aims to guarantee the Brazilian population safe access and rational use of medicinal plants and herbal medicines.

The Ministry of Health, through Ordinance No. 886, of April 20, 2010, established the Living Pharmacy within the scope of the Unified Health System (SUS). This Ordinance considers Living Pharmacies to be those that carry out the stages of cultivation, collection, processing, storage of medicinal plants, preparation and dispensation of magistral and officinal products of medicinal plants and herbal medicines.

The Living Pharmacies was established by the Ministry of Health through Ordinance 886/2010, which was revoked by Consolidation Ordinance No. 5 of September 28, 2017:

The Living Pharmacy in the context of the National Policy of Pharmaceutical Assistance must carry out all stages, from the cultivation, collection, processing, storage of medicinal plants, manipulation and dispensation of magistral and officinal preparations of medicinal plants and herbal medicines. Emphasizing that the commercialization of medicinal plants and herbal medicines is prohibited.

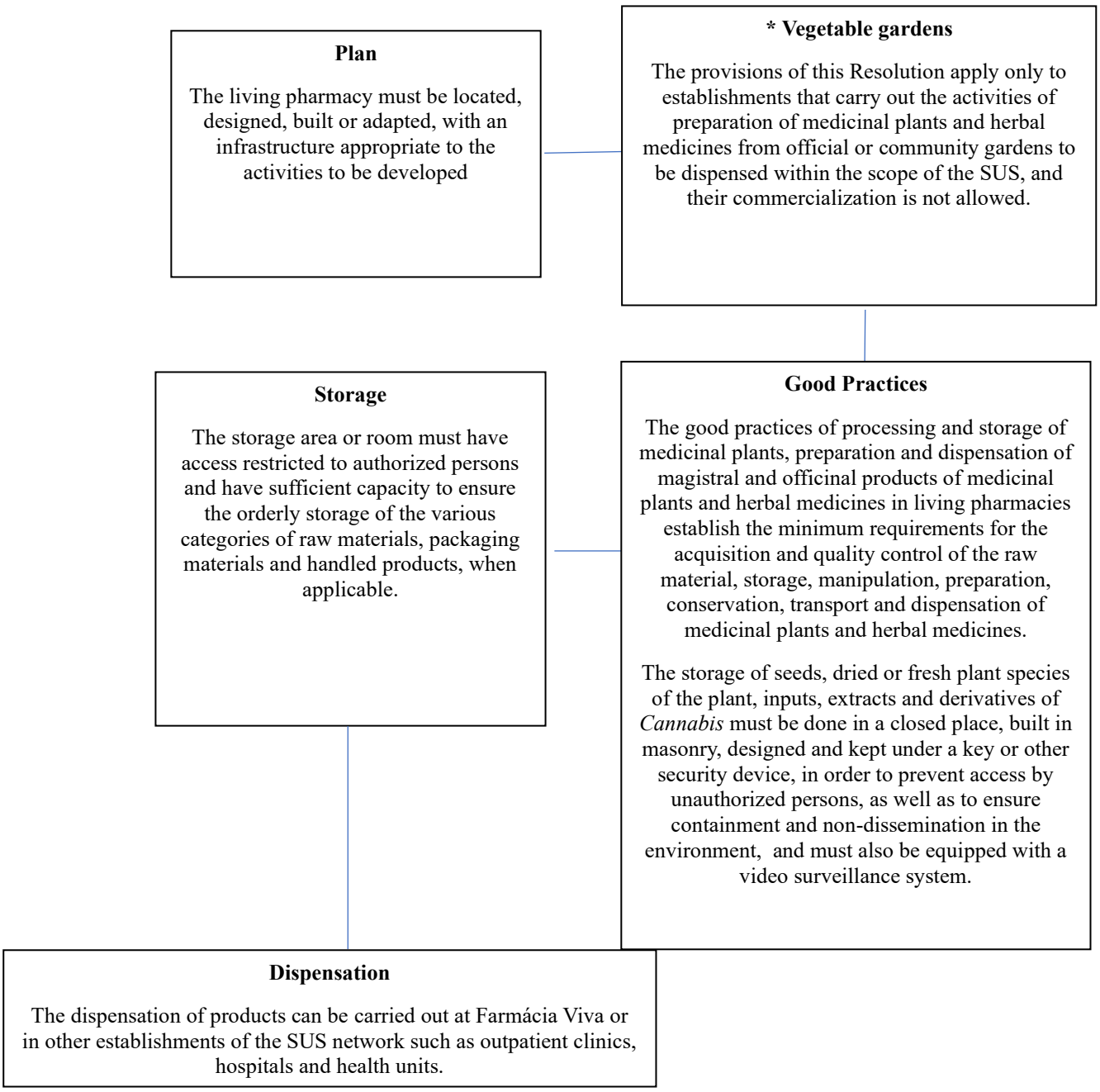
In this context, the National Health Surveillance Agency (ANVISA) approved Resolution – RDC No. 18, of April 3, 2013, which provides for good practices for processing and storage of medicinal plants, preparation and dispensation of magistral and officinal products of medicinal plants and herbal medicines in Living Pharmacies within the scope of the Unified Health System, as demonstrated in Scheme 1.

It is important to note that this ANVISA resolution compared to the proposal of Bill No. 399/2015, still on the agenda for approval by the Federal Chamber, which regulates the planting of marijuana, called *Cannabis sativa*, for medicinal purposes, in technical-scientific terms are convergent, but diverge mainly in the limitation of the planting of *Cannabis* which, in this should be equipped with a video surveillance system at all entry points, with access restriction and an alarm and security system, which does not currently occur with the medicinal plants of Farmácias Vivas.

Also, while RDC No. 18/2013 prohibits the sale of medicinal plants and herbal medicines in Farmácia Viva, the proposal of Bill No. 399/2015 allows the sale of medicines that contain extracts, substrates or parts of the plant, with proof of tests that validate the levels of the main cannabinoids present in their formula, including, minimally cannabidiol (CBD) and *delta-9-tetrahydrocannabinol (Δ9-THC*).

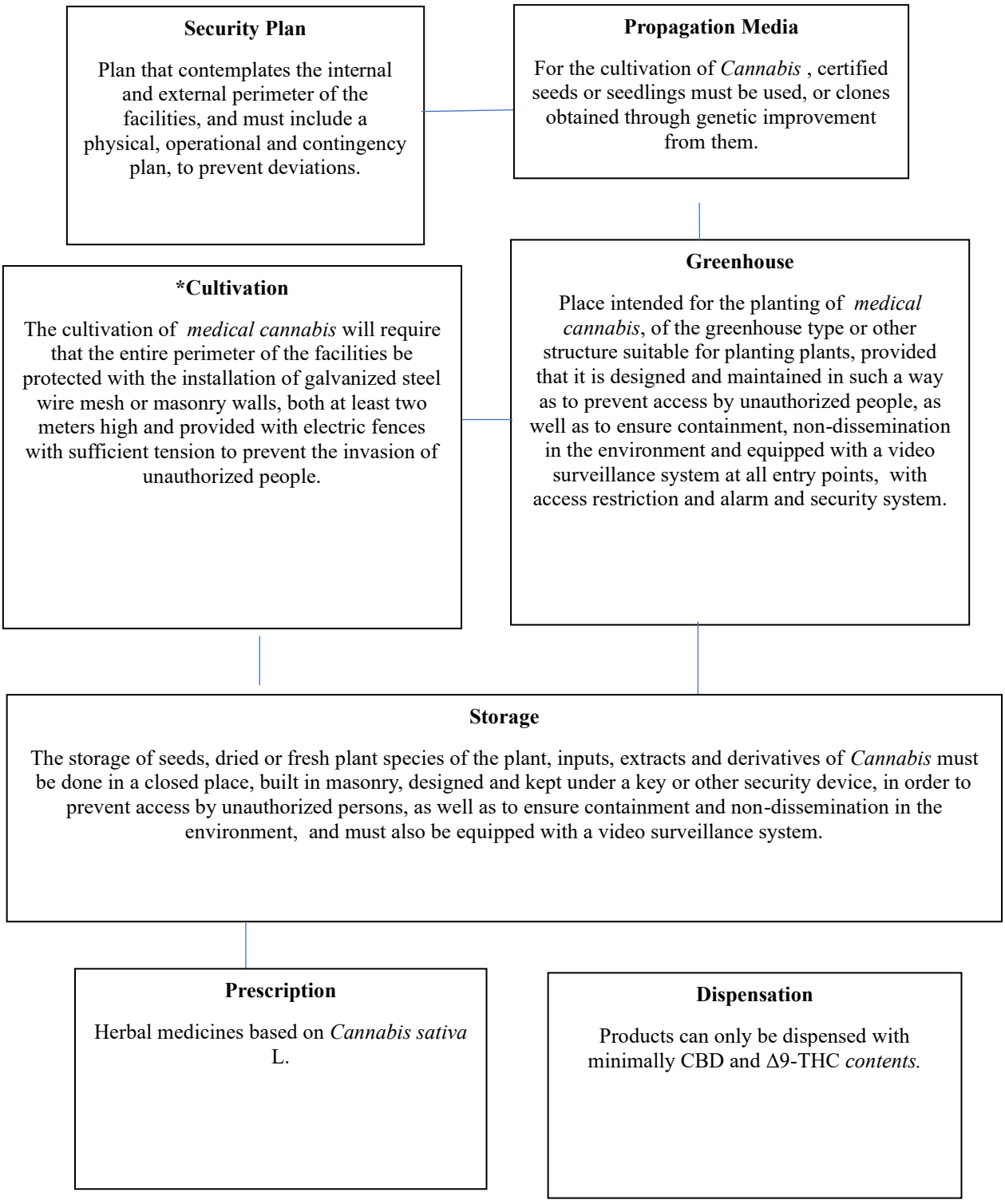
For a better understanding of the aforementioned convergences and differences, by way of comparison, the main recommendations of RDC No. 18/2013 are described in Scheme 1, which determine the minimum requirements required for the exercise of the activities of preparation of medicinal plants and herbal medicines in living pharmacies, while in Scheme 2 the main recommendations of the proposal of PL 399/2015 are described, understanding the security plan for the storage of *medical cannabis*.

Scheme 1 - Main recommendations of RDC 18/2013- ANVISA



(*) If necessary, raw materials of plant origin can be purchased from qualified suppliers.

Scheme 2 - Main recommendations of the Proposal of PL 399/2015



(*) The bill also establishes that the cultivation of *Cannabis* plants for medicinal purposes will be done exclusively by a legal entity, "previously authorized by the government".

PROPOSAL FOR THE INCLUSION OF *CANNABIS SATIVA L.* IN LIVING PHARMACIES: IMPLEMENTATION OF OFFICIAL GARDENS IN BRAZIL

Cannabis sativa L. is a truly medicinal plant, but in the current context it is very important to reflect that, according to the definition and models of Living Pharmacy

presented, the inclusion of this species in your gardens would limit the spaces of action with other medicinal plants and herbal medicines. Therefore, it is known that there would be a whole legal rigor around the cultivation and use of *medical cannabis*.

In this intent, it would be an important legal strategy to implement Official *Cannabis sativa Gardens* in Brazil with the support of the Ministry of Health. The implementation of these Official Gardens aims to establish the requirements for compliance with good practices for the cultivation and collection of *Cannabis sativa* L. This garden may be instituted through a bill to be implemented one in each region of the country, for example, or in each state, according to climatic conditions to be established for the quality of the species and cannabinoid content.

The Official Garden to be implemented, in addition to the support of the Ministry of Health, must have the adhesion of the State Health Secretariats, and may have the surveillance of actions through the State Secretariats of Public Security.

MAIN TECHNICAL REQUIREMENTS:

-The site of implementation of the Official Cannabis *sativa* L Garden and its adjacent areas must have its perimeter protected, in order to prevent access to unauthorized persons and ensure the necessary controls to mitigate the risks of dissemination and diversion, provided with a video surveillance system at all entry points, with access restriction, security alarm system, without prejudice to other security measures that may be adopted.

- For the cultivation of *Cannabis sativa* L *in* the Official Garden, certified seeds or seedlings must be used, in accordance with Law No. 10,711, of August 5, 2003, or clones obtained through genetic improvement, from them. For greater safety, cultivation should be carried out in a greenhouse. A security plan should be organised.

- In the Official Garden, there must be the presence of a technical responsible, who will be in charge of ensuring the application of good agricultural practice techniques, as well as being responsible for controlling the levels of Δ9 –THC in *Cannabis sativa* L.

-In the Official Garden, there should be a Pharmaceutical Laboratory for the production of extracts as raw material for *Cannabis sativa* L. for the Pharmaceutical Workshops of Farmácia Vivas for the preparation of herbal medicines.

FARMÁCIA VIVA AS A UNIT FOR THE PREPARATION OF HERBAL MEDICINES BASED ON *CANNABIS SATIVA* L.

In this system, Farmácia Viva would receive the extracts prepared from the Official Cannabis *sativa Garden* of the region or state and, according to pharmaceutical techniques, would develop the appropriate dosage forms in small batches, for greater quality control of operations.

The distribution of these herbal medicines would be done by the Pharmaceutical Supply Center of the Farmácia Viva unit or the Pharmaceutical Assistance Coordination, through a standardized form, to the Health Posts and Centers.

For the development of this work system, the following steps can be taken into account:

- ✓ It has the advantage of making the herbal medicine available with a greater territorial coverage, thus reaching a greater number of users of health services;
- ✓ The service user can find the herbal medicines at the nearest and most convenient Health Posts and Centers for him, without the need for Habeas Corpus or judicial process;
- ✓ In this system, greater effort is required from Farmácia Viva to provide training of human resources in service, on a regular basis, for professionals at health posts and centers, as a way to minimize failures in dispensing and/or storage;
- ✓ Guide for the proper storage of herbal medicines and pharmaceutical ingredients based on Good Storage Practices;
- ✓ Provide guidance on the distribution system of herbal medicines in the Health Centers, SUS, following the criteria for programming the preparation of these herbal medicines, according to the availability of pharmaceutical inputs, analysis of monthly movement;
- ✓ Promote the quality control of herbal medicines produced in the municipalities, through sampling, in Specialized Laboratories;
- ✓ Greater effort is required from Farmácia Viva to monitor the correct storage and stocks, to avoid deterioration and/or breakage, compromise of the schedule;
- ✓ Provide guidance on the distribution system of herbal medicines in the Health Centers, SUS, following the criteria for programming the preparation of these herbal medicines, according to the availability of pharmaceutical inputs, analysis of monthly movement;
- ✓ Promote the quality control of herbal medicines produced in the municipalities, through sampling in specialized laboratories;

- ✓ The products made by Farmácias Vivas can only be dispensed after proof of tests that validate the levels of the main cannabinoids present in their formula, among them, minimally CBD and Δ9-THC;
- ✓ Establish phytoeconomic indicators for monitoring and evaluation.

NOTE: Talk about associations and Living Pharmacies

https://agenciabrasil.ebc.com.br/politica/noticia/2021-06/comissao-da-camara-aprova-projeto-que-autoriza-plantio-de-cannabis

It is necessary to be aware that the insertion of *Cannabis sativa* in the SUS should come concomitantly with the acquisition of knowledge that guarantees a quality practice for the health care of patients. It is also urgent to implement Permanent Education in Health on the subject, which articulates management to guarantee spaces for education in service to health professionals.; professionals who are committed to a practice of popular health education, sharing knowledge and actions in the search for the collective good and users being co-responsible for the care of their health and that of the community, through social participation.

OFFICIAL LABORATORY FOR THE PRODUCTION OF HERBAL MEDICINES BASED ON *CANNABIS SATIVA* L. FOR THE SUS

In Brazil there is a current need to regulate marijuana (*Cannabis sativa* L.) for medicinal purposes and the production of herbal medicines, mainly motivated by the high costs of importation, bureaucracy and urgency for the treatment of pathologies by the administration of cannabinoids (epilepsy, sclerosis, anorexia, neuropathic pain, fibromyalgia, etc.).

The story of the first attempt to produce marijuana-based medicines in Brazil was through the Pharmaceutical Laboratory of the State of Pernambuco Governador Miguel Arraes (LAFEPE). This Laboratory was created in 1965 to produce quality medicines at low cost, being a mixed capital company, with administrative and financial autonomy, linked to the State Health Department. Classified as one of the three largest public laboratories in Brazil, it develops, produces and sells medicines and glasses, meeting public health policies.

It is important to note that LAFEPE stood out in the production of antiretroviral drugs and was the first institution in the country to prepare a formal request for the production of a drug derived from marijuana for the treatment of patients with AIDS, cancer and epilepsy, 20 years before the approval of the first drug authorized by the National Health Surveillance Agency (Anvisa). The request was denied.

What LAFEPE intended in this claim was to isolate cannabinoids (including THC), mentioning dronabinol. Currently, instead of isolating cannabinoids as phytopharmaceuticals, there are several attempts underway in which it is possible to prepare marijuana extracts enriched with cannabidiol, the cannabinoid, that is, herbal medicines, preferred in clinical medicine.

Thus, in the expectation of organizing Official Laboratories, it is appropriate to seek the LAFEPE model in the production of quality and low-cost medicines for the possible and necessary production of medicines based on *Cannabis sativa* L, integrated with the Official Gardens for the production of raw material of the aforementioned species, already described.

LOCAL PRODUCTIVE ARRANGEMENTS (APLs) WITH MEDICINAL PLANTS

Medicinal plants are part of a production chain in which they can originate industrialized or manipulated herbal medicines, from plant drugs or the plant *in natura*, and also participate in the production of foodstuffs, veterinary, phytosanitary and cosmetics. Active ingredients, the so-called phytopharmaceuticals, used by the pharmaceutical industry, can also be isolated from medicinal plants or their derivatives.

For the production of herbal medicines by the Living Pharmacy model III, it is necessary to produce raw materials, that is, medicinal plants. In this way, the production of herbal medicines can be compromised if the Medicinal Plants Garden of the municipality is not able to produce adequately and in sufficient quantity.

In view of this reality, the Local Productive Arrangements (LPAs) of medicinal plants and herbal medicines are an alternative to increase the production of this raw material and ensure the satisfactory production of herbal medicines through the participatory association of farmers who can produce medicinal plants in cooperatives with a view to the production of herbal medicines or for the pharmaceutical industry.

With this in mind, in 2006 the National Policy on Medicinal Plants and Herbal Medicines, brings as one of its guidelines the promotion of the inclusion of family farming in the chains and productive arrangements of medicinal plants, inputs and herbal medicines.

In this Policy, Local Productive Arrangements are conceptualized as territorial agglomerations of economic, political and social agents, focusing on a specific set of economic activities, which may present links and interdependence. Generally, they involve the participation and interaction of companies, which can range from producers of final goods and services to suppliers of inputs and equipment, consulting and service providers, traders, customers, among others – and their various forms of representation and

association. They may include several other public and private institutions focused on training and training human resources, such as technical schools and universities, research, development and engineering; policy, promotion and financing.

The National Policy on Medicinal Plants and Herbal Medicines was the basis for the construction of the National Program on Medicinal Plants and Herbal Medicines, which has the following principles: the need to expand therapeutic options and improve health care for SUS users through the use of phytotherapy; the sustainable use of the country's biodiversity; the appreciation and preservation of the knowledge of traditional communities and peoples; the strengthening of family farming; economic growth with job and income generation; technological and industrial development; social inclusion and reduction of social inequalities, in addition to encouraging popular participation and social control.

The APLs of medicinal plants and herbal medicines are potential spaces for the innovation of services and products, as a competitive strategy and market opportunity for the pharmaceutical industry of herbal medicines, encourage technological and economic development with job and income generation, strengthen family farming, generate the sustainable use of biodiversity and, above all, stimulate the production and use of medicinal plants and herbal medicines by SUS users. In this way, they respect the principles of the National Program of Medicinal Plants and Herbal Medicines and enable its effective implementation.

In addition to increasing the production of raw material, measures for the formation of LPAs aimed at the agricultural and commercial exploitation of medicinal plants and herbal medicines, can help reduce regional disparities in income concentration in Brazil, with emphasis on regions with fewer economic and social opportunities, as is the case of the Northeast, notably the backlands of Ceará.

The APLs bring to the region where they are inserted satisfactory results in terms of the generation of employment and income and improvement in the quality of life of the population, as it strengthens a local productive activity and the potential of each territory.

The Ministry of Health has the function of articulating and integrating social actors and enterprises in the area of cultivation, production, service, teaching and research, in medicinal plants and herbal medicines, in the public and private sectors, especially within the scope of the SUS. From this articulation, it will be possible that medicinal plants cultivated by family farming, in urban or rural areas, can be used as raw material for the production of herbal medicines. Users assisted in the Basic Family Health Units, of Primary Health Care, could then have access to services and products with quality, safety and efficacy throughout the country.

With this in mind, the Ministry of Health presented proposals to encourage the development of LPAs throughout the country. One of these initiatives was public notice No. 01, of May 24, 2013, which dealt with the public selection of projects for the local productive arrangement of medicinal plants and herbal medicines within the scope of the SUS. The main objective of this notice was to encourage the structuring, consolidation and strengthening of Local Productive Arrangements within the scope of the Unified Health System, according to the National Program of Medicinal Plants and Herbal Medicines and the National Program of Medicinal Plants and Herbal Medicines, with the purpose of strengthening pharmaceutical assistance and the production chain in medicinal plants and herbal medicines in the states and municipalities, assisting in actions to modify the socioeconomic and health situation of the local population.

In view of the above, it is clear that, for the elaboration of a Bill that inserts "family farming" for the cultivation of *Cannabis sativa* L. It would be of fundamental importance to make "real" and "achievable" reflections on the possible flexibility and monitoring of this activity to obtain the raw material, through the organization of Local Productive Arrangements of small producers.

The importance of including the Ministry of Agriculture, Livestock and Supply (MAPP) in the Bill to support the projects is highlighted, with the distribution of selected seed breeds and cultivation of the species, among others.

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