

## Diagnosis of Public Programs focused on Herbal Medicines in Brazil

[Diagnóstico de los programas de Fitoterapia, inscrita en el sistema de salud pública en Brasil]

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### Abstract

The present study is aimed to diagnose the current public programs focused on herbal medicine in Brazil where the following results can be observed. The main purpose of implementation of these programs was the demand of the users of medicinal plants and herbal medicines. The initiative of the implementation of these programs was related to the managers (58%). The difficulties in this implementation were due to lack of funding (90%) of the programs. In 80% of the programs, the physicians did not adhere to herbal medicine services due to lack of knowledge in the subject. Training courses were proposed (70%) to increase the adhesion of prescribers to the system. Some municipalities use information obtained from patients to assess the therapeutic efficiency of medicinal plants and herbal medicines. Of the programs underway, cultivation of medicinal plants was observed in 50%, and 67% of the programs adopted quality control. In most programs, this control is not performed in accordance with the legal requirements.

**Keywords:** Medicinal plants, herbal medicines, public health.

### Resumen

Este trabajo tiene como objetivo diagnosticar los programas de fitoterapia en actividad en Brasil, donde se pudo verificar los siguientes resultados. El motivo principal para la implantación de los programas fue la demanda de los usuarios de plantas medicinales y fitoterápicos. La iniciativa de la implantación de los programas está relacionada a los gestores (58%). Las dificultades en la implantación están relacionadas a la falta de recursos financieros (90%) de los programas. En 80% de los programas, los médicos no adhirieron a los servicios de fitoterapia por falta de conocimiento del asunto. Cursos de capacitación fueron propuestos (70%) para aumentar la concordancia de los prescriptores al sistema. Parte de los municipios utiliza informaciones de los pacientes para la evaluación de la eficiencia terapéutica de las plantas medicinales y fitoterápicos. De los programas en actividad, 50% cultivan plantas medicinales y 67% realizan control de calidad. En la mayoría de los programas ese control no atiende a la legislación vigente.

**Palabras Clave:** Las plantas medicinales, hierbas medicinales, la salud pública.

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## INTRODUCTION

The use of medicinal plants for therapeutic purposes (both the traditional and popular usage of these plants and their use based on scientific evidence) is a common practice nowadays. The use of natural plants to mitigate symptoms or cure diseases has been a very common practice for long, especially because the resources used in the production of drugs have not always been available according to the needs of the population, or else, because many of these drugs are being developed. These historical aspects of the use of medicinal plants clarify the importance of the interaction between local communities and their natural environment to the entire society in the present and in the future. At the same time, there is the urgent need to investigate the abundant biodiversity and, particularly, the medicinal flora, its proper and rational use, in order to find out how medicinal plants can be used by the population for medicinal purposes in an efficient and safe way (Alzugaray, 1988).

The public health system in Brazil does not count on a pharmaceutical care policy capable of meeting the medical needs of the population, and, thus, lower income people have difficult access to basic drugs and are more likely to get sick (Brasil, 2006; Malta *et al.*, 1999). With governmental decentralization, the Brazilian municipalities were allowed to implement their own health care programs (Ogawa, *et al.* 2003; Vianna, Dal Poz, 1998). Thus, some states and municipalities have been developing herbal medicine programs in order to deliver primary healthcare services to their communities (Matos, 1998; Michiles, 2004).

Since most primary healthcare services in Brazil are provided through the Family Health Program (FHP) delivered in Basic Care Units, many public healthcare programs based on herbal medicines are currently linked to the FHP. The current herbal medicine programs in Brazil were based on the Living Pharmacy Program, created by Professor Francisco José de Abreu Matos, of the Federal University of Ceará, about twenty years ago. This was the first social assistance program based on medicinal plants developed in Brazil, which was aimed to provide low-cost herbal medicines accessible to the poor (Matos, 1998; Michiles, 2004). After its establishment in the state of Ceará, the program has become a reference for the whole country (Cosendey *et al.*, 2000).

A previous study conducted by the Department of Pharmaceutical Services of the Department of Science and Technology and Strategic

Inputs of the Brazilian Ministry of Health (DAF/SCTIE/MS) identified several other programs delivered between the eighties and nineties in Brazil (Viana *et al.*, 2002). Some municipalities that implemented such programs include: Ipatinga in the state of Minas Gerais, Brasília, in the Distrito Federal, Cuiabá, in the state of Mato Grosso, Macapá, in the state of Amapá, Campinas, in the state of São Paulo, among others. Following the establishment of the National Policy on Complementary and Integrative Health and the National Policy on Medicinal Plants and Herbal Medicines, in the 2000s, several programs were implemented in the country.

Thus, the present study is aimed to diagnose the herbal medicine programs in Brazil, assessing the general situation and assisting the creation of a mechanism that regulates these programs in the country.

## METHODOLOGY

Data were obtained from questionnaires sent to 124 municipalities, which, according to the Department of Pharmaceutical Assistance of the Ministry of Health – DAF/MS already counted on healthcare programs based on herbal medicine. The questionnaires containing closed and open questions were divided into nine axes, and concerned information on the municipal health department, human resources involved, training courses and continuing education, patients using medicinal plants and/or herbal medicines, selection of the program's medicinal plants and herbal medicines, cultivation and processing of medicinal plants, purchase of raw material and intermediate extracts, herbal medicine production or handling and closing remarks.

Based on the information obtained, 9 municipalities that had ongoing herbal medicine programs, were randomly selected for *in loco* visits, with the purpose of confirming the performance of these programs regarding the topics contained in the forms.

The qualitative and quantitative data obtained were analyzed for estimation of the percentages in relation to the answers to the questions of the questionnaires.

## RESULTS

Of all the forms sent, 44 were returned, ie approximately 36%, and of these, in 24 (55%) respondents reported the existence of herbal medicine programs and 20 (45%) reported the lack of herbal

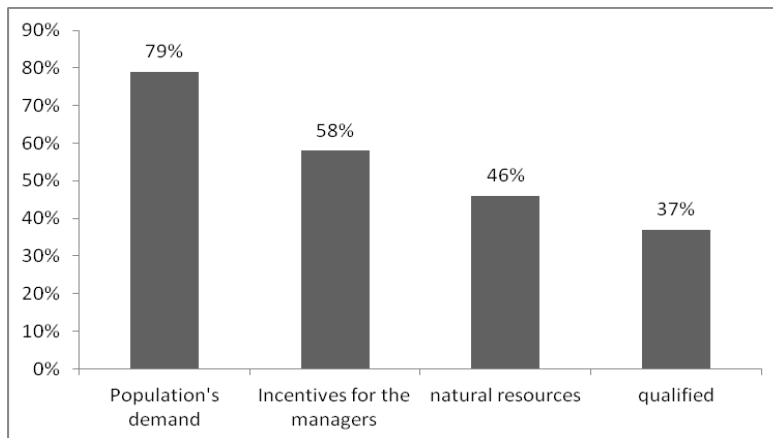
medicine programs. 3 (15%) of the municipalities that did not implement herbal medicine programs had in fact implemented such programs, which were later discontinued, though. However, 17 (85%) have never implemented such programs. This situation was observed in municipalities that did not create political mechanisms to ensure the continuity of the programs and also as a consequence of the extinction of the Medicines Center (CEME). The exact number of active herbal medicine programs in Brazil is not currently known because many of them are not registered at the DAF/MS.

Regarding program activities, it has been found that 22 (92%) have medicinal plant gardens for cultivation of the species used in the city and 2 (8%)

have no gardens for the cultivation of these plants. The latter purchase plants and supplies from third parties to meet the needs of the local population.

The reasons provided by the municipalities to implement herbal medicine programs were as follows: in 11 (46%) they were explained by the abundance of natural resources in the region, in 19 (79%) they were created to meet the demand of the population for medicinal plants or herbal medicines, in 9 (37%) because of the existence of skilled professionals involved and in 14 (58%) due to the incentives provided by the local authorities (figure 1). There were many multiple-choice questions, and, thus, the respondents provided more than one answer to complex questions.

**Figure 1**



**Factors allocated to the municipalities for the implementation of herbal medicine programs.**

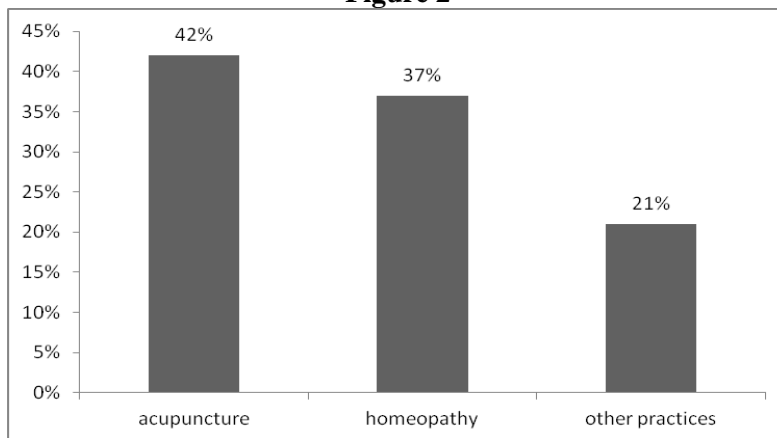
As it can be seen in the responses to the questionnaires, the initiative for the creation of the programs stemmed from several people. Regarding the total program activities, 14 (58%) respondents affirmed the programs were developed thanks to the encouragement of the local authorities, 11 (46%) affirmed the programs were created by professionals of the local health departments, 9 (38%) affirmed the programs were an initiative of the executive authority of the municipality and for 4 (16%) respondents they were an initiative of the local population.

The herbal medicine programs are not always integrated into the local pharmaceutical assistance

programs. Therefore, it was observed that 75% of herbal medicine program activities in Brazil are developed within the scope of the local pharmaceutical care plan.

Considering the herbal medicine program as an activity introduced by the National policy on Integrative and Complementary Practices in the Health System, other municipal activities can be cited. It has been found that 42% of the herbal medicine programs also provided acupuncture services for the local population, 37% offer homeopathic treatment and 21% do not have other complementary and integrative practices (Figure 2).

**Figure 2**



**Complementary and integrative practices offered in the municipalities and herbal medicine services.**

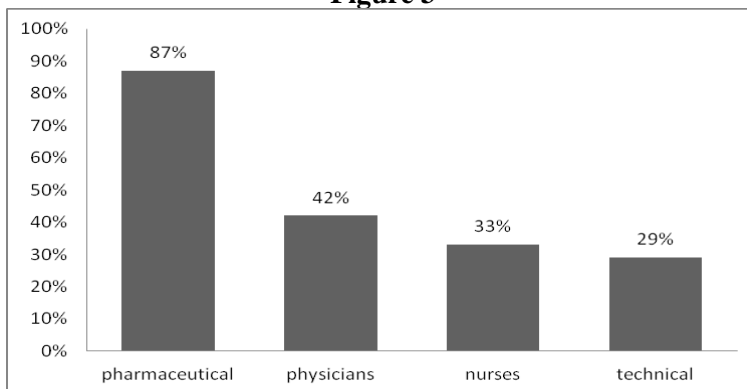
Regarding the implementation of herbal medicine programs in the municipalities, it has been found that 92% reported lack of financial resources to maintain the services as the main cause of these difficulties. But this is not an isolated fact because 30% have mentioned lack of skilled professionals, 58% reported non-adherence of prescribers to herbal medicine practices and 62% reported the unavailability of facilities to develop herbal medicine programs.

Concerning the funding for the implementation of herbal medicine programs, it has been found that one municipality received support from the federal government, six obtained assistance from the state governments and 92% used their own

funds. According to the respondents, the most organized and structured programs were not always the programs funded by the federal and state governments.

Only doctors and dentists can prescribe drugs to humans. However, concerning the program activities, 79% reported lack of adherence of doctors to these programs because they lacked knowledge on the issue; 8% said that the doctors argued that herbal medicines are ineffective and 29% said that patients were not interested in herbal medicines. Therefore, it has been found that in 87% of the herbal medicine programs the drugs are prepared by pharmacists, in 29%, by technicians, in 33%, by nurses and in 42%, by physicians (Figure 3).

**Figure 3**



**Percentage of professionals involved in prescribing herbal programs in herbal medicine.**

Regarding the prescription and dispensing of medicinal plants and herbal medicines, which requires

properly trained professionals, it has been found that 71% of the programs delivered courses in herbalism

for professional training and 29% did not deliver any training courses allegedly because of lack of funding, facilities and proper adherence of the professionals.

With respect to informing the local people about the use of medicinal plants and herbal medicines, we found that 88% of the program activities involved lectures, distribution of booklets and leaflets and 13% did not provide any information on the subject to the community. However, many respondents were already developing information material to be handed over to the population.

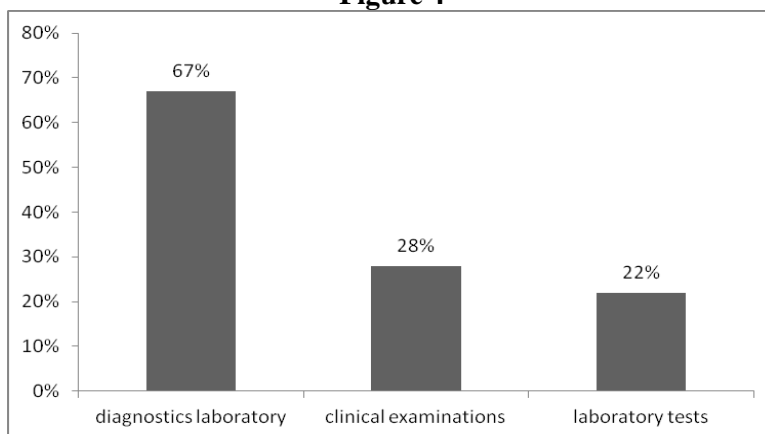
Regarding the monitoring of patients using medicinal plants and herbal medicines, we found that 75% of the programs conduct monitoring and 25% did not do any patient monitoring. However, concerning the programs that include follow-up of patients using herbal medicines, it was found that in 78% of them monitoring is done through medical

consultations, in 5% through the family assistance program, in 17% through pharmacovigilance units within the municipal health system, in 56% through the Family Health Program and in 33% through the support of the family health nucleus.

The guidance on the use of herbal medicines in all programs conducted in Brazil is provided as follows: concerning dosage (92%), side effects (71%), preparation of forms at home (87%), conservation (75%) and adherence to treatment (58%).

According to the responses to the questionnaires, 18 programs were reported to be able to assess the efficacy of medicinal plants and herbal medicines. In 67% of these programs such assessment was made by clinical examination of patients, 22% used laboratory tests, but the 18 programs used information provided by the patients to assess the efficacy of herbal medicines (Figure 4).

**Figure 4**



**Events held by the herbal medicine programs to evaluate the therapeutic efficacy of herbal medicines.**

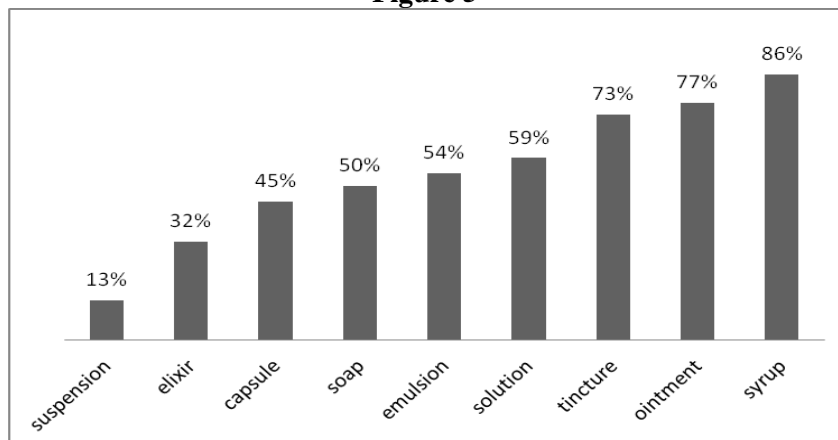
The mass production and handling of herbal medicines in drugstores occurred in 22 of all the programs that implemented herbal medicine. Only pharmacists can handle and dispense medications. However, it has been found that one of the programs was not supervised by a pharmacist, which is contrary to the current legislation.

According to resolution No 477/2008 of the Federal Council of Pharmacy, the expression pharmaceutical workshop was adopted to describe the places where herbal medicines are produced. Of all the programs on herbal medicines, only one reported the use of an industrial laboratory. All the

others were conducted in pharmaceutical workshops. Also, it has been found that of all the programs that produce herbal medicines, 45% meet the legislation requirements and one of them provided a certificate of good manufacturing practices, required for pharmaceuticals, according to the resolution DRC 10/2010 of ANVISA – *Agência Nacional de Vigilância Sanitária* (Brazilian Sanitary Surveillance Agency).

The dosage forms produced in the programs that count on this activity are shown in figure 5, as well as their respective percentages.

Figure 5



**Pharmaceutical dosage forms produced in pharmaceutical workshops in herbal medicine programs.**

Quality control is considered essential in the marketing of pharmaceuticals, supplies, herbal drugs, among others and should comprise all the stages from the cultivation of plant species to the dispensing of herbal medication. It has been found that of the 24 ongoing programs, 16 perform quality control and 8 do not carry out any quality control activities. It has been found that 81% adopted macroscopic control in plant species and 25% performed microscopic control. As shown in the physical-chemical tests, 12.5% of the programs provided the identification and determination of the main markers of the vegetable species used, 44% assessed pH, 19% informed total ash and insoluble ash indexes for medicinal plants, 31% measured the densities of liquid forms, 19% carried out viscosity tests for semi-solids and liquids and 19% performed tests to assess the solubility in water of the compounds.

The results obtained show the status of programs of distribution of medicinal plants and herbal medicines. These programs are usually irregular and do not comply with the pertinent legislation.

## DISCUSSION

Most herbal programs in Brazil were based on popular knowledge, which was passed down from generation to generation until today. Also, they count on the support of the local authorities in some municipalities. It must be said, however, that herbal medicine is not recognized as a complementary medicine by prescribers in general.

Regarding the implementation of these programs, despite the fact that the National Policy on Medicinal Plants and Herbal Medicines was approved in 2006, most programs were not regulated by state

laws or municipal regulations that ensure the continuity of their services. Nevertheless, several groups attempted to regulate the sector. All the same, the communities and professional societies have been actively promoting the implementation of these programs by holding forums, seminars and conferences.

The results of the questionnaires highlight the difficulties faced by the herbal medicine sector in Brazil, which is not regulated and does not provide guidance to the municipalities regarding the sustainable development of the programs. The adoption of herbal medicine as a complementary practice in public schools is hindered by the lack of strategies to provide the resources required to ensure the implementation of the referred practice.

On the other hand, the lack of public policies in the cities, associated to the decentralization of SUS, has led many municipalities to implement the program without the observation of quality standards, which generates mutual distrust between the professionals involved and the local population. This practice dates back to the early colonization of Brazil, but at that time there was little or no concern with the quality of products for human consumption.

Regarding the production of herbal medicines in the pharmaceutical workshops, it has been found that 91.7% of the ongoing programs produced herbal remedies, but do not meet the legal requirements. There are many factors together that corroborate this situation, particularly the lack of financial resources and the difficulty of obtaining skilled labor.

Regarding the dosage forms produced in the programs, a relationship can be detected between the factors indicated in the preceding paragraph and the

local need, which prevents the standardization of herbal medicines. Also, it is important to mention that the herbal medicines under the SUS are not all industrialized, which makes them less accessible.

Most Brazilian herbal medicines do not carry out tests to assess the safety and efficacy of herbal products. This discussion has been quite exhausted at the ANVISA, which has been attempting to find a way to implement a resolution in order to meet the sector requirements.

Obviously, the current legislation on the production and control of herbal medicines should not be different for governmental programs. The funding of these programs, however, deserves further consideration because they should be sustainable and meet the legal requirements. This might ensure the delivery of high quality and reliable services, which would certainly be endorsed by the involved professionals and the population.

The current public policy for the distribution of medicinal plants and herbal medicines at the SUS does not allow regulation of the sector. However, the passing of a bill in the Brazilian congress could ensure the regulation of these programs. This is observed in the state of Ceará where after the publication of Act No 12951 of 07/10/1999, the existing herbal medicine programs have made attempts to meet the legal requirements.

Finally, the results of this study show that herbal medicine programs have been discussed in many events across the country. Also, given the percentage of municipalities that have discontinued these programs following the extinction of CEME, the number of municipalities that have implemented the programs after the introduction of the PNPIC and PNPMF is remarkable. This indicates that herbal medicine is important because it may ensure the access of the population to primary care.

Many other related issues can be discussed in further studies, such as the dissemination of programs for the distribution of medicinal plants and herbal medicines under the SUS, in an attempt to discuss the level of information provided to users of herbal medicine services, as recommended by the World Health Organization.

## CONCLUSION

The medicinal plants and herbal medicine programs implemented in Brazil are impacted by chronic infrastructure, management, operational capability and self-sustaining difficulties. The direct consequence of these facts is the lack of a national policy for

medicinal plants and herbal medicines that regulates the segment.

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