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A critical examination of labeling practices in herbal medicinal products

Abstract

The present work proposed to research the labels of some industrialized and compounded herbal medicines, authorized for commercialization by ANVISA. It assessed the agreement with the rules recommended in the current national legislation. 150 labels of herbal medicines composed of 42 medicinal plants, acquired in the months of August and September 2017 in Belo Horizonte, were analyzed. The analysis was made as to the presence of items according to the Resolution of the Collegiate Board nº26, of May 13, 2014. The result confirmed that many labels were in disagreement with the legislation. Of the 150 samples, 58 were inadequately packaged and only 21 samples presented important information as contraindications. None of the phytotherapics analyzed in this work had, on their labels, information about the adverse effects of medicines. When making a comparison with the previous studies, it appears that there has been an improvement in the labeling of herbal medicines. However, they still require regulatory actions, as they fail to provide important information about the correct and safe use of these medicinal plants.

Keywords: medicinal plants, vegetable drugs, teas, medications

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Introduction

Phytotherapy is the study of medicinal plants and their applications in the prophylaxis and cure of diseases. In Brazil, the Indians made use of medicinal plants even before the arrival of the Portuguese. Nowadays, herbal medicines are widely used in Brazil and in the world. The packaging of a herbal medicine has undergone many modifications over the years and, today, in addition to its protective and transport properties, the packaging and label are responsible for arousing the interest of the product to the consumer. ANVISA is the body responsible for regulating, controlling and inspecting all products and services that involve public health risks, including packaging, labels and herbal medicines.

In Brazil, there is a national policy on medicinal plants and herbal medicines that aims to guarantee the population safe access and the rational use of these products. The legislation that establishes the norms about phytotherapies was created based on the analysis of international laws such as Australia, Canada and the European Community.

The objective of this work was to analyze the packaging and labels of herbal medicines available in drugstores and pharmacies in the city of Belo Horizonte, Minas Gerais. Specifically, analyze whether the basic information required for the legitimate manufacture and registration of labels is fulfilled in herbal medicines available in the city, evaluate the quality of the labels in relation to the information they bring and compare the data obtained in this study with those of previous studies.[1]

Material and methods

During the months of July and August 2017, a descriptive study of labels for herbal medicines or traditional herbal products was carried out in the Belo Horizonte trade. In order to carry out a study that covered a better profile of the city of Belo Horizonte, 24 drugstores and 10 pharmacies were visited in the south, east, west, north and central areas. Of which: a pharmacy on the east side, two on the south side, one on the west side and 6 in the city center. As for drugstores, they were visited: five in the south, six in the east, seven in the north, four in the west and two in the central region. Regarding drugstores, 17 were large and the other seven were small drugstores, while pharmacies were all medium-sized. 120 samples were collected in pharmacies and 30 in drugstores. All samples had only one species of the plant drug, so samples that were associations of two or more plant drugs were excluded from the research.

Being a pharmacy the establishment of manipulation of masterful formulas, of trade in drugs, medications, pharmaceutical inputs and related items; and drugstore: establishment of dispensing trade in drugs, medications, pharmaceutical supplies and related products in their original packaging.[2]

Products that had only one species of the plant drug were analyzed and presentations of the same plant drug of the same brand were excluded from this research when found in more than one commercial establishment.

In all samples, the integrity of the packaging and the product's packaging were analyzed, being evaluated the presence of a safety seal and some type of protection against light and moisture.

For data collection, an Analysis Form (Appendix A) was prepared and applied in all drugstores and pharmacies. This form was made based on other research and studies done and that are parameters that are in the RDC n. 26, of May 13, 2014,[3] which establishes the rules for the labeling of medicines. RDC nº 278 of December 22, 2005,[4] which "Approves the categories of Food and Packaging Dispensed and with Registration Requirement" was also used as a source of consultation. RDC No. 71 of December 22, 2009,[5] which "Establishes rules for the labeling of medicines", was also used for consultation.

Appendix A Analysis form

File 001

Name of the establishment:

Address:

CNPJ:

Required information according to RDC 26, 2014	Absent	Contained
Popular Nomenclature		
Botanical Nomenclature		
Technical manager		
Registration number		
Batch		
Indications for use		
Contraindications		
Adverse effects		
Additional Information		
Protection from light effect		
Security seal		

Comments:

Results and discussion

150 packages were analyzed; the data were organized and presented in two tables. Following is their analysis and discussions on the subject. Table 1 shows the medicinal plants found most frequently in pharmaceutical establishments in Belo Horizonte. In the line "others", in that table, those plants found less frequently were included, which represent 71 plant drugs from 32 different plants.

They are: *Illicium verum* (star anise), *Melissa officinalis* (melissa), *Cymbopogan citratus* (lemongrass), Bancha (national green tea), *Cynara scolymus* (artichoke), *Calendula officinalis* (marigold), *Maytenus ilicifolia* (holy thorn), *Mikania glomerata* (guaco), *Sida cordifolia* (mauve), *Passiflora alata* (passion fruit), *Zingiber officinale* (ginger), *Vernonia polyanthes* (fish-bake), *Stryphnodendron adstringens* (barbatimão), *Rhamnus purshiana* (sacred cascara), Aesculus hippocanum), *Echinodorus macrophyllus* (leather hat), *Taraxacum officinale* (dandelion), *Cordia verbenácea* (whaling herb), *Cymbopogom citratus* (lemongrass), *Hamamelis virginiana* (hamamelis), *Achyrocline satureoides* (macela), *Mentha piperita* (mint) *Achillea millefolium* (thousand leaves), *Phyllanthus niruri* (stone breaking), *Sambucus nigra* (elderberry), *Salvia officinalis* (salvia), *Plantago major* (plantain), *Plectranthus barbatus* (national boldo), *Symphytum officinale* (comfrey), *Citrus aurantium* (bitter orange), *Foeniculum vulgare* (fennel) and *Punica granatum* (pomegranate).

Table 1 The main packages of medicinal plants evaluated in pharmacies and drugstores in Belo Horizonte, Minas Gerais

Popular Nomenclature	Therapeutic indications	Botanical Nomenclature	Number of Samples	% referring to the total	Samples Non-conforming
Green Tea	Stimulant	*Camellia sinensis*	12	8%	(5) Lack of adverse effects information; Absence of contraindications; Incorrect botanical nomenclature on some samples
Guarana	Stimulant	*Paullinia cupana*	10	7%	(4) Missing technical manager information; Incomplete storage instructions; No registration number
Chamomile	Anxiolytic	*Chamomilla Matricaria*	10	7%	(4) Absence of adverse effects and contraindications; Missing batch number on some packages; No light protection for storage
Fennel	Antidispeptic	*Pimpinella anisum*	9	6%	(3) Lack of contraindications; No technical manager information; Insufficient light protection
Boldo From Chile	Antidispeptic	*Peumus boldus*	7	5%	(3) Absence of security seal; Missing adverse effects information; No registration number
Carqueja	Antidispeptic	*Baccharis genistelloides*	7	5%	(3) Missing contraindications; Absence of batch number; No protective packaging against moisture
Hibiscus	Diuretic	*Hibiscus sabdariffa*	7	5%	(2) Lack of adverse effects; No contraindications for pregnant women; Missing CRF number
Sene	Laxative	*Cassia angustifolia*	7	5%	(3) Absence of technical manager; No security seal; Lack of storage protection
Mint	Antispasmodic	*Mentha piperita*	6	4%	(2) Missing registration number; Incomplete batch information; Lack of adverse effects
Rosemary	Anti-inflammatory	*Rosmarinus officinalis*	4	3%	(1) Missing contraindications; No light protection
Others			71	48%	(28) Various non-conformities including absence of adverse effects, incorrect packaging, lack of registration numbers
Total			150	100%	58

Of the 150 packages analyzed, it is observed that 20% of them had active vegetable pharmaceutical ingredients (IFAV) that are not listed in the latest edition of the Brazilian Pharmacopoeia Formulation Form (FFFB)[6] and that, therefore, do not have specific quality control monograph published in the Brazilian Pharmacopoeia.

Green tea was the most commonly found plant in the trade, with 8% of the total number of samples. It is a plant rich in caffeine that appeared in China and India, but that has gained the world due to its medicinal properties. Its high demand in pharmaceutical establishments is probably related to its use in diets for weight reduction and a healthier lifestyle, much exposed by the media. In addition, Green Tea also has anti-inflammatory, antioxidant and energizing actions.[7]

Among the 10 most frequent samples in the Belo Horizonte market, three of them, including the most found, Green Tea, are not listed in the FFFB. This means that 30% of the most commonly found medicinal plants, which are likely also the best-selling, do not have a

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specific quality control monograph in the Brazilian Pharmacopoeia. As a result, consumers are more susceptible to encountering medicinal plants that may be sold incorrectly, whether it is the wrong part of the plant containing the active ingredient or a different plant with similar visual characteristics.

Just like Green Tea, Hibiscus is not listed on the Brazilian Pharmacopoeia's Phytotherapic Form, this plant has been used indiscriminately by consumers and needs even greater attention, as it has vasodilating activity, causing dizziness and weakness.[8] In addition, there are no studies with pregnant women, so, as a precaution, it is not recommended that they make use of this medicinal plant. This information, which should come on the label of these products, but which, in none of the Hibiscus samples, was found any reference to pregnant women. Therefore, it is extremely important that the pharmacist is present when dispensing this type of product, so that the consumer has as much information as possible about such a medicinal plant.

Table 2 lists some of the information that is required by RDC No. 26 of 2014 and was chosen because it is the most analyzed criteria in other studies.[3]

Table 2 Information on packaging and labels of products collected according to RDC 26 May 2014 for medicinal plants

Necessary information according to the RDC	Absent	%	Contained	%
Popular Nomenclature	0	0%	150	100%
Botanical Nomenclature	14	9%	136	91%
Technical manager	93	62%	57	38%
Registration number	148	99%	2	1%
Batch	4	2%	146	98%
Indication of Use	3	2%	147	98%
Contraindications	129	86%	21	14%
Adverse effects	150	100%	0	0%
Additional Information	46	31%	104	69%
Light Effect Protection	57	38%	93	62%
Security seal	1	1%	149	99%

According to RDC, the popular name and botanical nomenclature must be present in the packaging of products based on medicinal plants, since in Brazil there are a variety of these plants that for their identification are classified by species, with botanical name, according to their characteristics. In this research, the popular nomenclature was present on all labels, but in botany 9% were at variance, one with an incorrect nomenclature and the others absent.

As for technical responsibility, the name of the responsible pharmacist and the number of the Regional Pharmacy Council (CRF) must appear on the packaging. In the samples collected, 62% did not have these data, and of those that did, seven of them were incomplete, lacking the CRF number. This is a worrying fact, since there is no responsible technical professional, it is understood that there is no one who makes the assessments of physical-chemical and microbiological quality and thus, the consumer may be purchasing a low-quality product and, therefore, compromise some treatment and health.

Regarding the registration number, only two samples were registered. This is because, according to RDC No. 278 of 2005, teas are products that are exempt from registration, so these samples can be classified as teas. This is another worrying fact, since teas are now widely used not only as food, but their use extends as a medicine, and therefore regularization and inspection should be more rigid.[4]

Regarding the expiration date, all packages were within the period established by the manufacturer. Although 112 samples had a validity of more than one year, and, according to RDC 26 of 2014, "when the traditional herbal product to be notified is a medicinal tea, that product is exempt from the presentation of stability tests, as long as the deadline established for the product is up to 1 (one) year". There is no way of knowing whether these tests recommended by the RDC actually took place. On a positive note, almost 100% of the packages had the batch number, that is, if it was necessary to ascertain contamination in production, it would be possible, in most companies, to trace the suspicious batch and thus not allow a quality product doubtful reach the consumer.[3]

Information about how to prepare or use the analyzed products was present in 98% of the packages, making it transparent how to make correct use of the medicinal plant. On the other hand, none of the packaging had adverse effects, which is a matter of concern, since it is known that medicinal plants have adverse effects and that a consumer, when making compulsive and irrational use of these plant species, which can culminate in intoxications.[9] In 86% of the labels, there was no contraindication, such as use by pregnant women, children and the elderly. Information that is indispensable to these risk groups.

Similarly, in the study by Pereira,[10] which carried out an analysis of the label of herbal products based on Allium sativum oil, all 10 samples collected did not have information regarding contraindications, mechanism of action, drug interactions, qualitative and quantitative description and generic name of the active ingredients, conduct in case of overdose and results of effectiveness. This shows that since 2012, and even after the creation of Regulation nº26 of May 2014, there is still a lack of important information established in order to guarantee quality products to users of herbal medicines, which can lead to misuse and a consequent inefficiency. of it or the appearance of undesirable effects.

In the analysis of the samples, additional information, such as the nutritional table, was present in 69% of the labels. This shows that companies are concerned with selling a product that has low calories, showing the consumer that its use will not bring weight gain. It also makes clear the lack of awareness that these companies have with respect to consumer health. Adverse effects and contraindications should be the concern of those who are directly dealing with people's health.

In the study by Premoli et al.,[11] in which an analysis was made of five products of plant origin indicated for the elimination of abdominal fat, all were at odds with the current legislation, as companies were concerned with producing a label that instigated the consumer, and thus, linked therapeutic indication by means of illustrative figure and persuasive commercial name.

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It is known that several plant drugs lose their physicochemical properties due to exposure to light, temperature and humidity variation.[12] In the analyzed samples, 38% of the packages were at odds with what is recommended by RDC 26 of 2014, for storage of these plants. Of the 57 samples, all of them had transparent packaging, which may not provide adequate protection from light, and 14 were stored in irregular places (exposure to the sun). This puts the consumer at risk once again, by being able to purchase a plant drug that no longer has its active ingredients suitable for our use. Of all the packages analyzed, only one did not have a seal or security seal.

In the study by Colet et al.,[13] which aimed to analyze the packaging of medicinal plants sold in Rio Grande do Sul, 44 packages of medicinal plants were evaluated, of which 71% were irregular regarding the therapeutic indication and the method of preparation, considering what is recommended by the RDC in force at the time, RDC 10, of March 9, 2010 and in addition 16% of the products were not safe in terms of packaging, being exposed directly to the sun or in places with high humidity.

The market and use of herbal medicines and traditional herbal medicines deserves greater attention from the population and the authorities responsible for inspecting these products. As we have seen, it is a very large market in our country and if these products are used inappropriately, they can harm consumers' health and even compromise their treatment.

Based on the data obtained and applying what is recommended by RDC nº 26, of May 13, 2014, there are 99% of the failed samples, which corresponds to 148 samples, as they do not present the registration number, but it is worth mentioning that there is a law, created in 1973 that "Provides on the Sanitary Control of the Trade of Drugs, Medicines, Pharmaceutical and Related Supplies and Other Providences" that the great majority of the producers of herbal medicines follow.

According to Law No. 5991 of 1973,[2] if a medicinal plant is marketed without indications or therapeutic claims, it may be classified as trade in medicinal plants. In this case, this trade must be limited to the dispensation of the medicinal plant properly packaged, with information on its correct botanical classification and without any reference to possible indications or therapeutic claims. In this situation, it is not necessary to register or notify medicinal plants and, therefore, that contained in RDC No. 26, 2014, is not applicable.[14]

Then, applying what is recommended by Law nº 5991 of 1973,[2] this study has 48% of failed samples, which represents 72 products. Of this number, about 19%, 14 samples, failed because they were in disagreement with the botanical nomenclature, three of them had a wrong nomenclature and the other 11 did not have a nomenclature. Of the total of 72 failed samples, 81% of them, 58 samples, failed because they were not properly packaged, of these ones did not have a seal or safety seal and the other 57 were exposed directly to the sun and had a transparent packaging, which may be that do not do the correct protection from light.

Although we know that many doctors of different specialties prescribe herbal medicines, on average, at least one of each specialty, but few said that they have a constant habit,[15] concluding that many of these medicines are acquired and the patient has only the guidance of the pharmacist, which is often not requested, reinforcing the need for the information on the label.

Still, it is worth reflecting on Anvisa's requirements for this trade in medicinal plants, as the Article 7 of Law 5991 has never been regulated, so there is no specific provision on what should appear on product labels. Thus, information that is essential to any product, such as adverse effects, is not available in these packages, of products that are widely used by the Brazilian population.

Conclusion

The results showed that many of the pharmacies and drugstores in Belo Horizonte sell medicinal plant products that still show difficulties in complying with the current sanitary standards. There is still a lack of establishments to better store packaging so that vegetable drugs do not have their physical-chemical properties compromised and as for labels, these should bring more important information to the consumer, such as adverse effects and contraindications.

Much time has passed since the trade in medicinal plants exists, and there are still many irregularities regarding compliance with the rules. It is necessary to evolve and improve. The presence of several regulations leaves confusing and unclear about the regulation of herbal products and traditional herbal products for commercialization. There are laws that should be revised because they were created a long time ago and this damages and makes room for low quality products to reach the market.

The 2005 resolution, which exempts teas from registration, and the 1973 law, should be revised, given that medicinal teas are now widely used in the prophylaxis and treatment of diseases and therefore should have greater control over the its manufacture and trade. It is of fundamental importance that the inspection agencies are more active and present so that the consumer can purchase products with quality and safety, preserving the greatest good: health.

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Author contributions

B. G. F. F. and R. A. L. participated in the design of the study. B. G. F. F. performed the statistical analysis, data interpretation, and writing of the manuscript; R. A. L. provided theoretical and statistical expertise. All authors revised and approved the final manuscript.

Conflicts of interest

There are no conflicts of interest.

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