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Análise dos rótulos de chás medicinais provenientes do comércio formal e notas sobre a falta de preocupação com a nomenclatura botânica

Analysis of labels of medicinal teas from formal trade and notes on the lack of concern for botanical nomenclature

Análisis de las etiquetas de tés medicinales del comercio legal en Brasil y notas sobre la falta de preocupación con la nomenclatura botánica

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Resumo

Este estudo analisou rótulos de chás medicinais provenientes do comércio formal, de acordo com a legislação específica. Rótulos de trinta amostras de chás medicinais incluídos no Formulário de Fitoterápicos da Farmacopeia Brasileira foram fotografados em

estabelecimentos comerciais no estado do Rio de Janeiro, Brasil, e analisados de acordo com a Resolução Anvisa RDC 26/2014 e o referido Formulário. Informações relacionadas à nomenclatura botânica, parte da planta, orientações para o preparo, advertências, alegações de uso e modo de usar apresentaram-se inconsistentes com os padrões oficiais em diversas amostras, e 77% foram vendidas como produtos alimentícios, embora as espécies estudadas não estejam regulamentadas para a comercialização na área de alimentos. O consumo de chás medicinais em desacordo com as recomendações oficiais pode causar efeitos tóxicos ou a ausência dos benefícios esperados. As irregularidades identificadas sugerem a ausência ou falhas no controle de qualidade e a falta de preocupação com a nomenclatura botânica científica, expondo ao risco a saúde pública.

Palavras-chave: Adulteração; Controle da qualidade; Embalagem; Plantas medicinais.

Abstract

This work analyzed the labels of medicinal teas from formal trade, according to the specific legislation. Thirty samples of herbal drugs included in the Form of Phytotherapeutics of the Brazilian Pharmacopeia were photographed in commercial establishments in Rio de Janeiro state, Brazil, and analyzed according to the Resolution of Anvisa RDC 26/2014 and the Form. Information related to the botanical nomenclature, plant part, guidelines for preparation, warnings, claims, and orientations for use was inconsistent with the official standards in most samples, and 77% were marketed as food products, although the studied species are not regulated for the commercialization in the food area. The consumption of herbal products in disagreement with the official recommendations may cause toxic effects or lack of the expected benefits. The irregularities identified suggest the absence or failure in quality control and a lack of concern for the scientific botanical nomenclature, exposing the public health to risks.

Keywords: Adulteration; Quality control; Package; Medicinal plants.

Resumen

Este estudio analizó las etiquetas de tés medicinales del comercio legal, de acuerdo con la legislación específica. Etiquetas de treinta muestras de drogas vegetales incluidas en el Formulario de Fitoterápicos de la Farmacopea Brasileña se fotografiaron en establecimientos comerciales en el estado de Río de Janeiro, Brasil, y se analizaron de acuerdo con la Resolución Anvisa RDC 26/2014 y del mismo Formulario. Información relacionada con la nomenclatura botánica, partes vegetales, advertencias, reclamos, modo de preparación y uso

eran inconsistentes con los estándares oficiales. Además, el 77% se vendió como alimento, aunque las especies estudiadas no están reguladas para su comercialización en este área. El consumo de tés medicinales en infracción a las recomendaciones oficiales puede causar efectos tóxicos o la ausencia de los beneficios esperados. Las irregularidades identificadas sugieren la ausencia o fallas del control de calidad y la falta de preocupación con la nomenclatura botánica científica, exponiendo la salud pública al riesgo.

Palabras clave: Adulteración; Control de calidad; Embalage; Plantas medicinales.

1. Introduction

The adulteration of products intended for therapeutic or medicinal purposes in Brazil, including information on packages, is considered a crime against public health (Brazil, 1940). Given the relevance, this issue integrates the Law of Heinous Crimes (Brazil, 1990). The standardization regarding medicinal plants commercialized in the country is established by official documents such as the Resolution of the Collegiate Board of Directors (RDC) of the Brazilian Surveillance Agency (Anvisa) n. 26, of May 13, 2014 (Brazil, 2014); the Form of Phytotherapeutics of the Brazilian Pharmacopeia (Brazil, 2011); and the monographs of the 6th edition of the Brazilian Pharmacopeia (Brazil, 2019), which contain parameters for quality evaluation.

Medicinal teas are herbal drugs with medicinal purposes, to be prepared by infusion, decoction or maceration in water by the consumer (Brazil, 2014), and are listed in the Form (Brazil, 2011). Differently, food teas are prepared with the plant species and respective parts listed in the Technical Regulation of Plant Species for the Preparation of Teas, and are excluded from this definition the species with therapeutic or medicinal purposes (Brazil, 2005a, 2005b, 2006).

Medicinal teas consisting of dry leaves of “assa-peixe” (*Vernonanthura polyanthes* (Sprengel) Vega & Dematteis) (Asteraceae), “chapéu-de-couro” (*Echinodorus macrophyllus* (Kunth) Micheli) (Alismataceae), “espinheira-santa” (*Monteverdia ilicifolia* (Martius *ex* Reissek) Biral) (Celastraceae), “guaco” (*Mikania glomerata* Spreng. and *Mikania laevigata* Schultz Bip. *ex* Baker) (Asteraceae) and “quebra-pedra” (*Phyllanthus niruri* Linnaeus) (Phyllanthaceae) are largely commercialized and consumed in Brazil (Nascimento et al., 2005; Vega & Dematteis, 2010; Bochner et al., 2012; Biral et al., 2017; Leal-Costa et al., 2018).

These species are included in the Form of Phytotherapeutics of the Brazilian Pharmacopeia and its first supplement, containing specific standardized information regarding scientific and vernacular botanical nomenclature, plant part, guidelines for the preparation, warnings, therapeutic indications and orientations for use (Brazil, 2011, 2018). Medicinal teas integrating this document may be exempted from product registration and notified to Anvisa in the category of traditional phytotherapeutic product (Brazil, 2014).

Accurate consumer information on labels has equal importance as the medicinal plant quality (Kunle et al., 2012), including the scientific botanical nomenclature, which allows unambiguous communication in many disciplines such as biology, chemistry, medicine, pharmacology, and pharmacy (Bennett & Balick, 2014). An analysis of herbal product packages from the formal trade in Rio Grande do Sul, Brazil, verified several problems related to labeling quality and highlighted the interest in which such studies would comprehend other populations (Colet et al., 2015). As a contribution to quality control, this work aimed to analyze the labels of herbal drugs from the formal trade in Rio de Janeiro state, according to the specific legislation.

2. Methodology

Thirty samples of medicinal teas marketed with the vernacular names “assa-peixe”, “chapéu-de-couro”, “espinheira-santa”, “guaco” and “quebra-pedra”, from 11 different companies, were photographed in herbal shops, supermarkets and newsstands in Rio de Janeiro state, Brazil, between 2016 and 2017. Samples were considered from the formal trade, since the companies had a Brazilian Register of Legal Entity - CNPJ (“Cadastro Nacional de Pessoa Jurídica”). This research employed a descriptive, quali-quantitative approach (Pereira et al., 2018).

The labels were analyzed according to RDC 26/2014 (Brazil, 2014) and the Form of Phytotherapeutics of the Brazilian Pharmacopeia on pages 32, 40, 43, 50 and 64, (Brazil, 2011) considering standardized specific information related to the botanical nomenclature (scientific and vernacular), plant part, guidelines for preparation, warnings, claims for use, orientations for use, and the presence of an informative leaflet. The scientific botanical nomenclature was considered complete when comprising the genus name, specific epithet and author of the taxon, whereas the use of italics was disregarded. Samples were considered marketed as a food product when the label mentioned food-related expressions such as "alimentar", "alimentos" or "alimentícios", or references to any legislation pertinent to the

food area.

3. Results

The analyzed samples were stored in transparent plastic packages and 67% (20), from seven companies, were stapled, not sealed. No sample included an informative leaflet or indicated a product notification or registration. According to information on the labels, 77% (23) of the samples, from three companies, were marketed as food products.

Other parameters, such as the scientific and vernacular names, plant part, guidelines for preparation, warnings, claims and orientations for use, were verified on the labels as absent or different from those standardized in official documents, and are synthetized in Tables 1 and 2.

Table 1. Parameters on the labels of 30 samples of medicinal teas from 11 different companies obtained from the formal trade in Rio de Janeiro state between 2016 and 2017, analyzed according to the Form of Phytotherapeutics of the Brazilian Pharmacopeia (Brazil, 2011).

Parameter	Correct		Incorrect		Absent	
	N	%	N	%	N	%
Scientific name	4	13	15	50	11	37
Vernacular name	29	97	1	3	0	0
Plant part	3	10	9	30	18	60
Guidelines for preparation	0	0	25	83	5	17
Warnings	0	0	12	40	18	60
Claims for use	0	0	5	17	25	83
Orientations for use	0	0	15	50	15	50

N = Number of samples. Source: Authors (2020).

Table 2. Information on the labels of 30 samples of medicinal teas commercialized as “assa-peixe” (A), “chapéu-de-couro” (C), “espinheira-santa” (E), “guaco” (G), “guaco-da-horta” (GH) and “quebra-pedra” (Q) obtained from the formal trade in Rio de Janeiro state between 2016 and 2017, analyzed according to the Form of Phytotherapeutics of the Brazilian Pharmacopeia (Brazil, 2011).

Company	Sample identification	Scientific name	Vernacular name	Plant part	Guidelines for preparation	Warnings	Claims for use	Orientations for use
I	A, C, E	+*	+	-	+*	-	-	+*
	GH	+	+*	-	+*	-	-	+*
	Q	+	+	-	+*	-	-	+*
II	A, C, G	+*	+	+*	+*	-	-	-
III	A, C, G, Q	-	+	-	+*	+*	+*	+*
IV	G	-	+	-	+*	-	-	-
V	A, Q	+*	+	+	-	-	-	-
	C	+*	+	+*	-	-	-	-
	G	+	+	+*	-	-	-	-
	E	+*	+	+*	-	-	-	-
VI	C, E	+*	+	-	+*	+*	-	-
VII	A	+*	+	+*	+*	-	-	-
	G	+	+	+*	+*	-	-	-

VIII	A, C, G, Q	-	+	-	+*	+*	-	+*
	E	-	+	-	+*	+*	-	+*
IX	E	-	+	-	+*	-	-	+*
X	E	+*	+	+*	+*	-	-	-
XI	E	+*	+	+	+*	+*	+*	-

+ = Present, correct; +* = Present, incorrect; - = Absent. Source: Authors (2020).

According to Table 1, the scientific name was absent in 37% (11) of samples and correct in only 13% (4), while the vernacular name was present in all samples and correct in 97% (29). The plant part was absent in 60% (18) of samples and correct in only 10% (3). Other parameters (guidelines for preparation, warnings, claims for use and orientations for use) were incorrect or absent in all samples. In Table 2, it is possible to observe these information detailed per company and vernacular name used in the samples commercialization.

The analysis of the scientific botanical nomenclature revealed that no sample mentioned the family name, in addition to several other inconsistencies with official standards, as shown in Table 3.

Table 3. Scientific botanical nomenclature on the labels of medicinal teas of "assa-peixe" (A), "chapéu-de-couro" (C), "espinheira-santa" (E), "guaco"(G) and "quebra-pedra" (Q) obtained from the formal trade in Rio de Janeiro state between 2016 and 2017; standardized scientific nomenclature in the Form of Phytotherapeutics of the Brazilian Pharmacopeia (Brazil, 2011) and the correspondent accepted names.

Vernacular name	Company	Scientific name on the label	Author name on the label	Scientific name in the Form of Phytotherapeutics of the Brazilian Pharmacopeia (Brazil, 2011)	Accepted name	References
A	I	Vernonia Polyanthes	-	*Vernonia polyanthes* Less	*Vernonanthura polyanthes* (Sprengel) Vega & Dematteis	Vega & Dematteis (2010).
	II	VERNONIA SPP	-			
	V	*Boehmeria arborescens*	-			
	VII	Vernonia ssp.	-			
C	I	Echinodrus Macrophyllus	Kun	*Echinodorus macrophyllus* (Kunth) Micheli	As in Brazil (2011).	Micheli (1881); Lehtonen (2008).
	II	ECHINODORUS MACROPHYLLUS	-			
	V	*Echinodorus macrophyllus*	-			
	VI	ECHINODORUS MACROPHYLLUS	-			
G	I*	Mikania glomerata	Spreng	*Mikania glomerata* Sprengel /	As in Brazil (2011).	Sprengel (1826);

	II	Mikania Guaco	-	*Mikania laevigata* Schultz Bip.		Baker (1876);
	V	*Mikania glomerata*	*Sprengel*	ex Baker		Flora do Brasil
	VII	Mikania glomerata	Sprengel			(2020).
E	I	Maytenus ilicifolia	Martius	*Maytenus ilicifolia* (Schrad.)	*Monteverdia truncata*	Biral & Lombardi
	V	*Maytenus ilicifolia*	-	Planch.	(Nees) Biral**	(2012); Biral et al.
	VI	MAYTENUS, SP	-			(2017).
	X	Maytenus ilicifolia	-			
	XI	*Maytenus Ilicifolia*	-			
Q	I	Phyllanthus niruri	L	*Phyllanthus niruri* L.	As in Brazil (2011).	Linnaeus (1753);
	V	*Phyllantus niruri*	-			Bouman et al.
						(2018).

- = Absent information; * = Vernacular name as “guaco-da-horta” on the label; ** = *Monteverdia ilicifolia* (Mart. *ex* Reiss.) Biral is the “espinheira-santa” included in the 6th edition of the Brazilian Pharmacopeia (Brazil, 2019), referred as the basionym *Maytenus ilicifolia* Mart. *ex* Reiss., the most commonly used and studied species within the genus (Niero et al., 2011). Source: Authors (2020).

According to Table 3, the scientific names on labels include spelling errors, inconsistent use of italics and capitalization, inaccuracy or absence of author names of the taxa, identification of a species only at the generic level ("sp."), indication of the presence of more than one species per sample, non-identified at the species level ("spp."), and provision of solely the genus name.

4. Discussion

The packaging in the analyzed samples did not provide adequate protection against effects of light and did not guarantee the product inviolability, exposing the material to humidity and contaminations (Brazil, 2014), especially by excessive microbial growth, possibly pathogenic (Kunle et al., 2012; Zhang et al., 2012).

Regarding the labels, absent information or in disagreement with the standards in official documents (Brazil, 2011, 2014) were verified for all the analyzed parameters. Orientations and warnings on the labels are relevant to reduce the risk of herbal drug misuses and adverse effects (Shaw et al., 2012), which may be exemplified by the warnings for "espinheira-santa" and "quebra-pedra", not recommended for pregnant women (Brazil, 2011). The correct indication of the plant part is also fundamental since the active constituents may differ between plant organs (Kunle et al., 2012).

In concern of the scientific botanical nomenclature, several inconsistencies with the official standards were verified. Accurate botanical nomenclature follows the rules of the International Code of Nomenclature for Algae, Fungi, and Plants (Turland et al., 2018). The complete and correct scientific name is of paramount importance to prevent misidentifications of herbs that show similarity in appearance and share the same common names, but lack the known active constituents or exhibit toxic effects (Zhao, 2006), whereas author names have paramount importance to differentiate homonyms, *i.e.*, equally spelled names based on distinct types (Nesbitt et al., 2010; Turland et al., 2018).

The relevance of the author names of taxa is evident in the following issue: a sample of "espinheira-santa" identified on the label as "Maytenus ilicifolia Martius", from company I, diverges from the nomenclatural standards of the official documents (Brazil, 2011, 2018), which also show a number of inconsistencies. In the first supplement of the Form of Phytotherapeutics of the Brazilian Pharmacopeia (Brazil, 2018) and in the 6th edition of the Brazilian Pharmacopeia (Brazil, 2019), the vernacular name "espinheira-santa" is associated to *Maytenus ilicifolia* Mart. *ex* Reissek, a basionym for *Monteverdia ilicifolia* (Mart. *ex*

Reiss.) Biral (Biral et al., 2017), the most commonly used and studied species within the genus (Niero et al., 2011). Differently, in the Form (Brazil, 2011), the scientific name for "espinheira-santa" appears as *Maytenus ilicifolia* (Schrad.) Planch., a synonym for *Monteverdia truncata* (Nees) Biral (Biral & Lombardi, 2012; Biral et al., 2017). The transfer of some *Maytenus* species to the genus *Monteverdia* (Biral et al., 2017) was published before the supplement (Brazil, 2018) and the 6th edition of the Brazilian Pharmacopeia (Brazil, 2019), but the problem is not limited to an outdated terminology. It is important to highlight that *Maytenus ilicifolia* Mart. *ex* Reiss. and *Maytenus ilicifolia* (Schrad.) Planch. are homonyms, thus *Monteverdia ilicifolia* and *Monteverdia truncata* are accepted names for different species and not synonyms.

Still regarding the official standards for herbal drugs, nomenclatural issues concerning "chapéu-de-couro" and "assa-peixe" were verified as well. "Chapéu-de-couro" is cited in the Form of Phytotherapeutics of the Brazilian Pharmacopeia (Brazil, 2011) as *Echinodorus macrophyllus* (Kunth) Micheli, but the 6th edition of the Brazilian Pharmacopeia (Brazil, 2019) relates the same vernacular name to another species, *Echinodorus grandiflorus* (Cham. & Schltdl.) Micheli (Matias, 2020). "Assa-peixe" is cited in the Form (Brazil, 2011) as "*Vernonia polyanthes* Less", but due to a genus transfer, the accepted name is *Vernonanthura polyanthes* (Sprengel) Vega & Dematteis (Vega & Dematteis, 2010) since before the document publication by Anvisa.

The imprecision of a vernacular name is demonstrated by analyzing the label of a sample of "assa-peixe" from company V, on which the scientific name is provided as "Boehmeria arborescens", a synonym for *Boehmeria caudata* Swartz (Urticaceae), known in Brazil's southeastern region as the vernacular name (Gaglioti & Araújo, 2020), but not regulated in the country for the commercialization as a medicinal tea (Brazil, 2011, 2018). Additionally, a sample of "guaco" from company I was identified as "guaco-da-horta", but the vernacular name standardized in the Form of Phytotherapeutics of the Brazilian Pharmacopeia (Brazil, 2011) for the species indicated on the label, *Mikania glomerata*, is only "guaco". Vernacular names are not substitutes for scientific names, since unrelated species may share similar or the same vernacular name, whereas one species may have different local names (Farah et al., 2006; Zhao et al., 2006; Nesbitt et al., 2010). Thus, scientific nomenclature is the basic language and only universal system that allows unambiguous communication in biology, so its use is recommended as mandatory to avoid such confusion (Bennett & Balick, 2014; Peruzzi, 2020).

Nomenclatural errors and misprints are not restricted to labels of medicinal plants from trade or standards from official documents. A broad study conducted by Peruzzi (2020) showed a non-negligible incidence of such problems regarding plant scientific literature. A widespread lack of attention to botanical nomenclature is attributed to a number of reasons such as ignorance, apathy and a phenomenon described as “plant blindness”, an inability to notice plants and recognize their importance in different contexts (Bennett & Balick, 2014). According to Zhao et al. (2006), the confusion around standardization and authentication of medicinal plants can be reduced by the promotion of education and training of professionals in taxonomy, a solution also indicated by Peruzzi (2020).

Furthermore, though a majority of the analyzed samples were marketed as food products, none of the species included in this study integrate the lists of plant species for the preparation of teas in the food area (Brazil, 2005a, 2006), for which the labeling is regulated by RDC 259/2002 (Brazil, 2002), with different requirements in relation to RDC 26/2014 (Brazil, 2014). The registration or notification in the appropriate category is fundamental because it allows the implementation of specific quality control measures, such as the report of herbal drug analysis to Anvisa and the mandatory presence of an informative leaflet accompanying the traditional phytotherapeutic product, with relevant information about composition and utilization to instruct the consumer (Brazil, 2014).

The quality of the consumer information about the product in Brazil is a responsibility of the company that produces medicinal teas (Brazil, 2014). According to Kunle et al. (2012), currently, no international organization or government body certifies herbal products as correctly labeled, which represents a source of frustration for consumers.

5. Final Considerations

The labels of medicinal teas analyzed in this work were verified as inconsistent with the specific legislation and standards from official documents in several parameters. The consumption of herbal products in disagreement with these recommendations may cause toxic effects to the organism or lack of the expected benefits. The irregularities identified in labels of medicinal teas from the formal trade suggest absence or failure in quality control, exposing to risk the public health, and a lack of concern for the scientific botanical nomenclature, evidencing the need to promote education in taxonomy and the effective involvement of professionals from this field in the elaboration of quality parameters and their application in authenticity evaluation of herbal drugs.

These findings highlight the promising potential for future studies comprising a greater number of plant species, with an emphasis on nomenclatural analyses.

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