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Original article

Systematic organization of medicinal plant information: a monograph template proposal

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ABSTRACT

The use of medicinal plants in Brazil is widespread and is supported by public policies; it has the objective of providing the population with safe and effective herbal medicines of adequate quality. An action in these policies is to develop medicinal plant monographs to gather published information and decide which medicinal plants should be financed by the Brazilian government and distributed by the public health system. Currently, the monographs published worldwide do not present unified information regarding medicinal plants, and generally, they do not cover enough requirements for herbal medicine registration. The aim of this study is to develop a monograph model with standardized information not only about botany, agronomy, quality control, safety, and efficacy but also about relating regulatory aspects that support herbal medicine regulation. The development of standardized monographs favors the fast authorization and distribution of herbal medicines in the public system. The model also points out the lacking studies that should be carried out to supplement the necessary regulatory information of medicinal plants.

Introduction

Brazil is one of the countries with the largest biodiversity of the world; however, most of it remains unexploited (Gonçalves et al., 2010). Brazil is also considered to house a large number of researchers. Nevertheless, knowledge generated by these studies is generally not applied for launching new products to the market, resulting in few herbal medicines made of Brazilian medicinal plants (Carvalho et al., 2008; SBPC, 2005).

In 2006, the Brazilian government published the National Policy of Integrative and Complementary Therapies, which includes phytotherapy in the public health system (*Sistema Único de Saúde*, SUS) (MS, 2006). In addition, in 2006, the National Policy of Medicinal Plants and Herbal medicines was published establishing the major actions to ensure the rational use of herbal medicines according to national legislation and international recommendations (Brasil, 2006).

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In 2009, the Brazilian Ministry of Health published the List of medicinal plants of interest for SUS (Renisus), which included those considered as potentially valuable for the generation of herbal medicines. Researchers have been encouraged to make use of this list as a guide to select species to study. The resulting information regarding the species can then be used to prepare the national lists of herbal medicines and medicinal plants, and promote development and innovation in the field of medicinal plants (MS, 2009).

Several monographs have been published worldwide, some of which are used as sources of information by many countries, such as the WHO Monographs on Selected Medicinal Plants (Veiga Junior and Mello, 2008; WHO, 1999, 2003, 2004, 2007, 2009)

The two kinds of official monographs in Brazil are the Brazilian Pharmacopoeia, which includes quality control tests for synthetics and herbal medicines, and the *Formulário de Fitoterápicos da Farmacopeia Brasileira*, which includes safety of herbal formulations for pharmaceutical compounding. Along with these official Brazilian references, some selected foreign pharmacopoeias are officially used in Brazil, such as the United States Pharmacopoeia (USP) and USP National Formulary, the International Pharmacopoeia (from the World Health Organization - WHO), and Germanic, Argentinean, British, European, French, Japanese, Mexican and Portuguese pharmacopoeias (Anvisa, 2009b), as well as other unofficial monographs: *Monografias de plantas medicinais brasileiras e aclimatadas* (Gilbert et al., 2005); *Farmácias Vivas* (Matos, 2000), and books including monographs of medicinal plants published for Brazilian phytotherapy public services. Scientific journals and articles are used also to gather information about medicinal plants. However, usually, each monograph or paper presents different approaches and do not face all the important requirements needed for a thorough documentation about medicinal plants, such as botanical authentication, cultivation, quality criteria, safety, efficacy, market, and regulatory issues (Veiga Junior and Mello, 2008).

Thus, a monograph template, including mandatory aspects as determined by Anvisa (Agência Nacional de Vigilância Sanitária) as well as international regulations, was developed. The objective is to systematize the available information on medicinal plants of interest to the Brazilian public health system.

The monograph template includes information considered relevant for the use of medicinal plants, based on a review of the scientific literature and databases to compile all previously published information on specific medicinal plants. This model's intent is to allow for remaining non-fulfilled items in the monograph be used to guide future research and financing by the Brazilian government.

Thus, after fulfilling this model with pre-published data on the plant species included in the Renisus (Relação Nacional de Plantas Medicinais de Interesse ao SUS), it will be possible to identify which are the more studied medicinal plants having sufficient data on their safety and efficacy, to be subsequently financed by SUS, and gradually included in the list of herbal medicines with simplified registration by Anvisa (2008a). The products included in this list must follow a strict set of standardization so the registration process is easier and faster than usual registration. For the less studied medicinal plants it would be possible to indicate which studies are needed to validate its use.

The monograph template presented herein is intended to be used by researchers funded by the Brazilian Ministry of Health to evaluate the plant species included in the Renisus. Following their completion, monographs will be reviewed by experts in the areas of interest and will be initially published as a public consultation to allow all stakeholders to contribute to the final monograph. It is also envisaged that the monograph template will guide the research and inclusion of important information for the publication of medicinal plant data. Thus, articles and books published under this model may be quickly recognized by Anvisa, among their reference lists, for evidence of safety, efficacy, and quality of herbal medicines.

Material and methods

Building the template

To support the template proposal, a comparative and exploratory study was performed by a comparison and consideration of the set of information presented in the monographs listed by Anvisa Normative Instruction 05/10 (Anvisa, 2010e): WHO Monographs on selected medicinal plants, tomes 1-4 (WHO, 1999, 2004, 2007, 2009); European scientific cooperative on phytotherapy - Monographs on the medicinal uses of plant drugs (ESCOP, 1996); American Herbal Pharmacopoeia (Upton and Petrone, 1999); *Monografias de plantas medicinais brasileiras e aclimatadas* (Gilbert et al., 2005), British Herbal Compendium (Bradley, 2006); Expanded Commission E monographs (Blumenthal, 1999; Blumenthal et al., 2000); and *Vademécum nacional de plantas medicinales* (Cáceres, 2006). This data is available at Carvalho, 2011.

The next step was the evaluation of regulation requirements for herbal medicine registration and for plant notification at Anvisa, as well as requirements on regulations for herbal medicines from other agencies such as: European Medicines Agency (EMA), Health Canada (HC-SC), *Comisión Federal para la Protección contra Riesgos Sanitarios* (Cofepris), *Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* (ANMAT), and the Paraguayan Health Ministry (Anmat, 1998, 1999a, b; Cofepris, 1998a, b, 2000, 2001, 2006, 2013; EMA, 2006a, b, c, d, 2007, 2008a, b, 2010a, b, c, d; HC-SC, 2003, 2006, 2007, 2010a, b; Paraguai, 1997). A preliminary template was created to verify if all the requirements were present, after which the template was submitted to peer review evaluation of the members of the Anvisa Herbal Medicine Technical Chamber (CATEF) and the Support Committee of Medicinal Plants and Herbal Medicines Policy from Brazilian Pharmacopoeia (CTT-APF) (Anvisa, 2010b; CATEF, 2010). The new template, with the reviewer-suggested modifications included, was tested at the preparation of the *Maytenus officinalis* Mabb., Celastraceae, monograph (unpublished results).