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Article

Normative framework related to the indication and prescription of herbal medicines by pharmacists in Brazil

Arcabouço normativo relacionado à indicação e prescrição de medicamentos fitoterápicos por farmacêuticos no Brasil

Marco normativo relacionado con la indicación y prescripción de medicamentos herbarios por parte de los farmacéuticos en Brasil

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Abstract

Objective: analyze the regulatory aspects associated with pharmaceutical prescription of herbal medicines in Brazil. **Methodology:** an integrative review, a gray literature search and a document analysis were carried out. The databases used for the integrative review were Medical Literature Analysis and Retrieval System Online, Latin American and Caribbean Literature on Health Sciences and Scientific Electronic Library Online, covering the period from January/2008 to December/2023. The gray literature search was undertaken on Google Academic. The document analysis was conducted on websites of institutions relevant to the pharmaceutical practice, such as the Federal Council of Pharmacy, the Brazilian Health Regulatory Agency and the Brazilian Ministry of Health. **Results:** the integrative review did not identify studies on pharmacists' prescription of herbal medicines, although two studies were found in the grey literature, mainly in the context of primary care. Professional insecurity was observed, associated with lack of preparation and gaps in academic training. Some studies highlighted the relevance of the pharmacist in phytotherapy, while others pointed to the absence of specific regulation. A divergence was found between the requirements established for prescription and the lack of requirements for dispensing. Official documents were identified, such as the National Policy on Integrative and Complementary Practices, the National Policy on Medicinal Plants and Phytotherapeutics, and Federal Council of Pharmacy resolutions, which provide regulatory support but are still considered insufficient. **Conclusion:** regulation has

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advanced in the integration of herbal medicines into pharmaceutical care, promoting evidence-based action for the pharmaceutical indication and prescription of herbal medicines.
Keywords: Pharmaceutical Prescription; Herbal Medicines; Regulation; Legislation; Clinical Pharmacy.

Resumo

Objetivo: analisar aspectos regulatórios relacionados à indicação e prescrição farmacêutica de medicamentos fitoterápicos no Brasil. **Metodologia:** realizou-se uma revisão integrativa da literatura científica e busca na literatura cinzenta, complementada por análise documental. A revisão integrativa abrangeu as bases , Literatura Latino-Americana e do Caribe em Ciências da Saúde e *Scientific Electronic Library Online*, com publicações entre janeiro/2008 e dezembro/2023. Na literatura cinzenta, as buscas foram realizadas no *Google* Acadêmico. A análise documental foi realizada em *sites* de instituições relevantes à prática farmacêutica como a Agência Nacional de Vigilância Sanitária, Conselho Federal de Farmácia e Ministério da Saúde. **Resultados:** não foram identificados estudos sobre a prescrição de fitoterápicos por farmacêuticos na revisão integrativa, porém na literatura cinzenta foram encontrados dois estudos, concentrados principalmente na atenção primária. Observou-se insegurança profissional associada à falta de preparo e lacunas na formação acadêmica. Parte dos trabalhos registrou a relevância do farmacêutico na fitoterapia, enquanto outros apontaram a ausência de regulamentação específica. Constatou-se divergência entre os requisitos estabelecidos para prescrição e a inexistência de exigências para dispensação. Foram localizados documentos oficiais, como a Política Nacional de Práticas Integrativas e Complementares, a Política Nacional de Plantas Medicinais e Fitoterápicos e resoluções do Conselho Federal de Farmácia, que oferecem respaldo normativo, porém ainda considerados insuficientes. **Conclusão:** a regulamentação tem avançado na integração dos medicamentos fitoterápicos ao cuidado farmacêutico, promovendo a atuação baseada em evidência para a indicação e prescrição farmacêutica de medicamentos fitoterápicos.
Palavras-chave: Prescrição Farmacêutica; Fitoterápicos; Regulamentação; Legislação; Farmácia Clínica.

Resumen

Objetivo: analizar los aspectos regulatorios asociados a la prescripción farmacéutica de fitoterápicos en Brasil. **Metodología:** se realizó una revisión integradora de la literatura científica y búsqueda de literatura gris, complementada con análisis documental. La revisión integradora abarcó las bases de datos *Medical Literature Analysis and Retrieval System Online*, Literatura Latinoamericana y del Caribe en Ciencias de la Salud y *Scientific Electronic Library Online*, con publicaciones entre enero/2008 y diciembre/2023. En la literatura gris las búsquedas se realizaron en *Google Scholar*. El análisis de documentos se realizó en sitios web de instituciones relevantes para la práctica farmacéutica, como la Agencia Nacional de Vigilancia Sanitaria, el Consejo Federal de Farmacia y el Ministerio de Salud. **Resultados:** se identificaron pocos estudios sobre la prescripción de fitoterápicos por parte de farmacéuticos, concentrados principalmente en la atención primaria. Se observó inseguridad profesional asociada a la falta de preparación y a vacíos en la formación académica. Parte de los trabajos registró la relevancia del farmacéutico en la fitoterapia, mientras que otros señalaron la ausencia de una reglamentación específica. Se constató una divergencia entre los requisitos establecidos para la prescripción y la inexistencia de exigencias para la dispensación. Se localizaron documentos oficiales, como la Política Nacional de Prácticas Integrativas y Complementarias, la Política Nacional de Plantas Medicinales y Fitoterapéuticos y resoluciones del Consejo Federal de Farmacia, que ofrecen respaldo normativo, aunque todavía se consideran insuficientes. **Conclusión:** la regulación ha avanzado en la integración de los medicamentos herbarios en la atención farmacéutica, promoviendo acciones basadas en evidencia para la indicación farmacéutica y prescripción de medicamentos herbarios.

Palabras clave: Prescripción Farmacéutica; Medicamentos Herbarios; Regulación; Legislación; Farmacia Clinica.

Introduction

In 1978, the Alma-Ata Declaration[1] marked an important historical moment by officially recognizing the use of medicinal plants and herbal medicines for preventive, therapeutic, and palliative purposes. From that date on, the World Health Organization (WHO) began to recognize the use of medicinal plants and the practice of phytotherapy[2]. At the end of the 1970s, the same entity created the Traditional Medicine Program,recommending[1] that member states formulate public policies to facilitate the integration of complementary and alternative medicine into national health care systems, as well as its rational use.

In 1987, the World Health Assembly reiterated the recommendations made by the Alma-Ata Conference, also indicating the organization of broad projects related to the identification, evaluation, preparation, cultivation, and conservation of plants used in traditional medicine, as well as in relation to ensuring the quality of drugs derived from traditional medicines extracted from plants[1].

The Brazilian population has long used plant-based products in their daily health care. It is estimated that approximately 82% of Brazilians have used these products, either for aesthetic purposes or for the management of chronic or self-limiting health problems[3]. Thus, valuing the use of medicinal plants and herbal medicines, standards and rules were established to ensure access to traditional medicine in a safer and more rational manner. Herbal medicine was officially incorporated into the Unified Health System (SUS) with the creation of the National Policy on Integrative and Complementary Practices (PNPIC) in 2006[4]. This initiative aimed to revive the tradition of using medicinal plants among the population, expand access to these resources, prevent disease, promote and maintain health, and contribute to patient recovery, reinforcing the fundamental principles of the SUS[5,6,7].

According to Resolution No. 26/2014 of the Collegiate Board of Directors (RDC) of the Brazilian Health Regulatory Agency (Anvisa), herbal medicines consist of products obtained from active plant raw materials, excluding isolated substances, used for prophylactic, curative, or palliative purposes. The term herbal medicine encompasses both herbal medicines and traditional herbal products, thus being a broader concept. For this study, the target of study is herbal medicines, defined by the same resolution as industrialized ph l products obtained exclusively from active plant raw materials whose safety and efficacy are based on clinical evidence and which are characterized by consistent quality[8]. Since this study addresses the indication and prescription made by the pharmacist, it is important to highlight the inclusion of herbal medicines in the List of Over-the-counter Medicines (LMIP). The LMIP is periodically updated by Anvisa and, according to Normative Instruction (IN) No. 285, of March 7, 2024[9] ,a herbal medicine will be exempt from prescription if the product contains the same species, part used, and therapeutic indication(s) based on each line of the LMIP. The presence of these drugs on the list reflects their importance to public health as well as the need for special attention by pharmacists, both in the context of indication, prescription, and dispensing. The complexity of herbal medicines, which require in-depth knowledge of their properties, potential drug interactions, and possible adverse effects, highlights the importance of adequate educational training. Technical expertise in areas such as preparation for therapeutic purposes, indications, precautions, dosage, and understanding the relationship between health and

disease is essential for professionals to make accurate prescriptions. As some of these products do not require a prescription, pharmaceutical guidance is essential to ensure the rational and safe use of herbal medicines[10].

In this sense, the constant need for a comprehensive analysis of the regulations and legislation associated with the prescription of herbal medicines highlights the importance of providing a more up-to-date understanding of their regulatory aspects. The National Policy on Medicinal Plants and Herbal Medicines[2] establishes guidelines to ensure safe access to and rational use of these products, covering everything from the regulation of production and distribution to professional qualification and research incentives. In view of this, the regulation of pharmaceutical services and the act of prescribing or recommending herbal medicines is based on this policy, ensuring that the practice is carried out with technical and regulatory support.

Thus, the present study aimed to analyze regulatory aspects related to the indication and pharmaceutical prescription of herbal medicines in Brazil.

Methodology

An integrative review[11] was conducted on the regulatory aspects associated with the indication and pharmaceutical prescription of herbal medicines, complemented by a survey and analysis of the gray literature and a documentary analysis related to legislation for the indication and pharmaceutical prescription of herbal medicines. The integrative review was conducted on the regulatory aspects of the pharmaceutical prescription of herbal medicines in Brazil. At this stage, the objective was to acquire a contextualization of what is available in the literature on herbal medicine legislation in the context of pharmaceutical prescription. The following electronic databases were used: Medline (Medical Literature Analysis and Retrieval System Online), SciELO (Scientific Electronic Library Online), and Lilacs (Latin American and Caribbean Health Sciences Literature). Free descriptors and others present in DeCS/MESH were used to search for articles , using the search strategies described in Box 1.

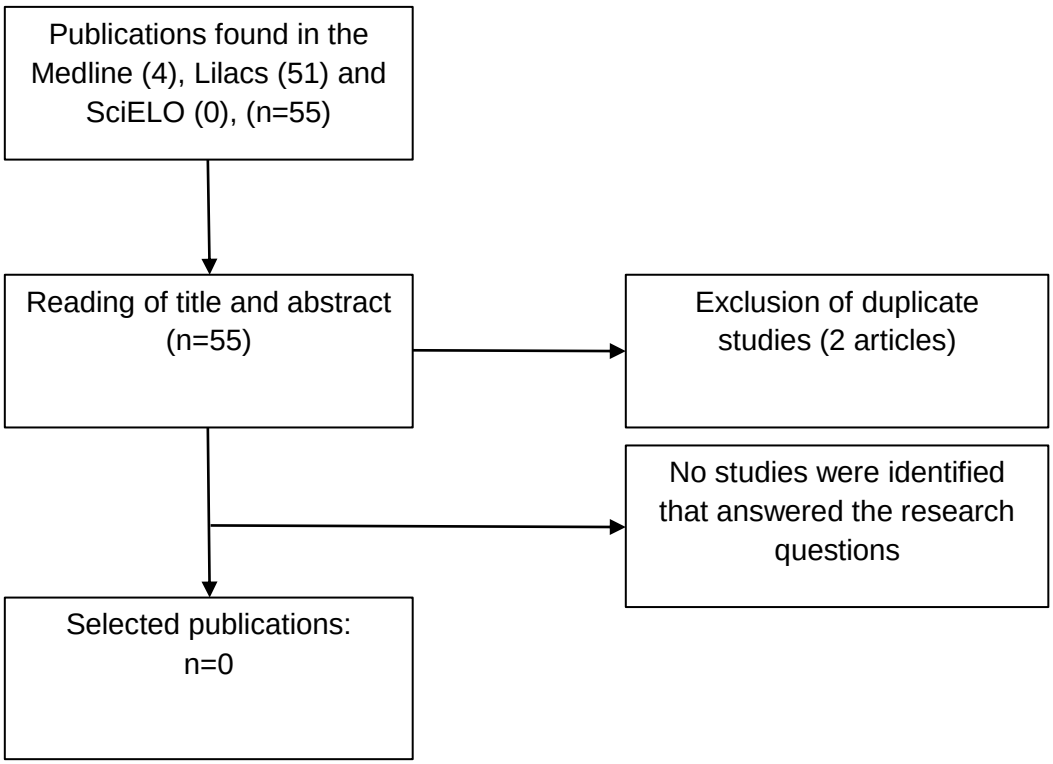
Box 1. Search strategy for the integrative review conducted on the regulatory aspects of the pharmaceutical prescription of herbal medicines

Language	Search Strategy
Portuguese	((prescrições) OR (indicação terapêutica) OR (prescrição de medicamentos)) AND (farmacêuticos) AND ((legislação) OR (legislação de medicamentos)) AND ((medicamento fitoterápico) OR (fitomedicamentos) OR (fitoterapia))
English	((prescriptions) OR (therapeutic indication) OR (drug prescriptions)) AND (pharmacists) AND ((legislation, drug) OR (legislation)) AND ((phytotherapeutic drugs) OR (phytomedicines) OR (phytotherapy))
Spanish	((prescripciones) OR (indicación terapéutica) OR (prescripciones de medicamentos)) AND (farmacéuticos) AND ((legislación, droga) OR (legislación)) AND ((medicamentos fitoterápicos) OR (fitomedicamentos) OR (fitoterapia))

Source: Prepared by authors.

A total of 55 studies were found in the databases searched: Lilacs (45 studies in Spanish); Lilacs (six studies in Portuguese) and Medline (four studies in English).

Figure 1. Flowchart of identification and selection of articles for the integrative review



Source: Prepared by the authors.

To complement the integrative review, a search was conducted in the gray literature to expand and retrieve national studies and articles related to the topic in question, using Google Scholar.

For the integrative review and gray literature, the same selection criteria were applied in order to achieve the research objectives: 1) publication in article format; 2) publication in the last 15 years (2008-2023); 3) articles in Portuguese, Spanish, or English; 4) availability of the full text in one of the databases used, via access to the researcher's institutional network. The following exclusion criteria were established for the integrative review and gray literature: 1) duplicate articles and 2) articles that did not fit the intended scope.

The strategy adopted involved searching for articles that contained all relevant keywords in their titles, aiming to establish associations and increase the probability of finding significant results. The same descriptors listed in Table 1 were selected; however, despite the numerous possibilities explored, results were only obtained when using the keywords “prescription,” “pharmaceutical,” and “herbal medicines,” resulting in the selection of 13 articles. No studies coinciding with those found in the integrative review were identified, but 11 studies were excluded because they did not comply with the research criteria, leaving two selected publications.

Regarding the documentary analysis, the search and review of the legislation were carried out to decide on its inclusion or exclusion in the study. First, a pre-analysis was conducted, involving an initial and exploratory reading of the legislation to determine its relevance to the study. The choice of

agencies and institutions consulted during the research was based on their relevance to the topic investigated, established according to the normative, legal, and technical-scientific authority of each. The Federal Council of Pharmacy (CFF) was included because it is the regulatory body for the pharmaceutical profession and responsible for issuing resolutions that guide professional practice. The Agência Nacional de Vigilância Sanitária (Anvisa) was considered because of its legal competence in health regulation, covering the registration, control, and regulation of medicines, including herbal medicines. The Ministry of Health was consulted because it is the body responsible for formulating and implementing national policies, such as the National Policy on Integrative and Complementary Practices (PNPIC)[2] which covers herbal medicine within the scope of the Política Nacional de Práticas Integrativas e Complementares (PNPIC)[2] which covers herbal medicine within the scope of the Unified Health System (SUS). National Association of Compounding Pharmacists (Anfarmag) was selected for its technical and professional relevance, acting as a reference in the field of drug compounding and in the provision of legislation applicable to the practice.

The following websites were consulted to access the respective legislation: the website of the Nacional dos Farmacêuticos Magistrais (Anfarmag), in the legislation section (http://www.anfarmag.org.br/legislacao), the Anvisa (https://antigo.anvisa.gov.br/legislacao#), the Ministry of Health https://www.gov.br/saude/pt-br/composicao/sectics/daf/pnpmf/publicacoes), and the CFF (http://www.cff.org.br/).

The regulations in force were identified in each source consulted, taking into account those specifically related to the prescription of herbal medicines by pharmacists. Specific research was conducted in each source, including analysis of the Brazilian Pharmacopoeia's Herbal Medicine Formulary and other policies related to the prescription of herbal medicines. The selected legislation was thoroughly analyzed, and relevant information was documented for further evaluation and organized in a table to facilitate understanding and analysis of the results.

Results and discussion

The recommendation and prescription of herbal medicines by pharmacists are practices that require a solid and comprehensive regulatory framework to ensure their safety and efficacy. During the integrative review, a significant gap in the scientific literature was noted in relation to regulatory aspects, since none of the 55 scientific articles found directly addressed this specific issue. Regarding the gray literature, with the application of the search strategies described, two articles related to the research were identified (Box 2).

Box 2. General distribution of articles selected on Google Scholar

Article Tittle	Authors	Year of publication	Main points	Place of publication
Pharmaceutical Indications for Herbal Medicines: An Analysis of Legal Concepts in Relation to Professional	SCREMIN F,M,*et al.*[12]	2016	The study investigated current legislation on prescription and pharmaceutical indication, using official documents from the Federal Pharmacy Council and Anvisa. The results show that this legislation defines the responsibilities of pharmacists in	Revista Ciência & Cidadania

Practice			prescribing and indicating medications, including herbal medicines and medicinal plants, with a view to rational dispensing. These duties are regulated by the Federal Pharmacy Council and and Brazilian Health Regulatory Agency, but new laws are suggested to make the legislation more comprehensible.	
Pharmaceutical prescription of medicinal plants and herbal medicines.	SILVA T O.[13]	2019	The study analyzed the current legislation on the prescription of medicinal plants and herbal medicines by pharmacists, highlighting their role in the rational dispensing of these products. Regulation is carried out by both the Federal Pharmacy Council and and Brazilian Health Regulatory Agency. Despite this, there is an identified need for legislative updates to facilitate the work of professionals in this context.	Final Course Project (Bachelor of Pharmacy), Centro de Educação e Saúde, Universidade Federal de Campina Grande, Cuité, PB

Source: Prepared by the authors.

The articles[12,13] address the prescription of herbal medicines, prioritizing other aspects of practice, such as clinical practice, and only three emphasize regulatory aspects. This observation highlights the need for a more comprehensive and integrated approach to the indication and pharmaceutical prescription of herbal medicines, taking into account not only clinical aspects, but also legal and regulatory aspects that directly impact this practice.

Regarding the document analysis, the research results indicated a variety of regulations and policies related to the prescription of herbal medicines by pharmacists, from the sources consulted. Fifteen legal norms were found that directly or indirectly regulate the indication and pharmaceutical prescription of herbal medicines, including one federal law, one Ministry of Health ordinance, five CFF resolutions, five Anvisa Collegiate Board Resolutions (RDC), and three Normative Instructions (Box 3). No more specific guidelines were found in the professional associations or pharmaceutical associations consulted.

Box 3. Legislation and regulations related to pharmaceutical prescriptions in chronological order [4]

Legislation and regulation	Responsible for publication	Provision	Specific information related to indication/prescription
GM/MS Ordinance Nº 971, dated May 3, 2006(4)	Ministry of Health	Approves the National Policy on Integrative and Complementary Practices (PNPIC) in the Unified Health System.	Recommends the adoption of measures that enable the education of university-level health professionals on aspects of the prescription of medicinal plants and herbal medicines
Resolution Nº. 459 of February 28, 2007(14)	Federal Pharmacy Council	Provides for the duties of pharmacists in the field of medicinal plants, , and herbal medicines, and makes other provisions.	Describes the role of pharmacists as a resource for health professionals responsible for prescribing.
Resolution Nº. 477 of May 28, 2008(15)	Federal Pharmacy Council	Provides for the duties of pharmacists in the field of medicinal plants and herbal medicines and other measures.	Describes the role of pharmacists as support for healthcare professionals responsible for prescribing and cites the need for pharmaceutical advice when filling a prescription or engaging in responsible self-medication
Ordinary Law Nº. 16,703 / 2009(16)	Legislative Assembly of	Establishes the State Policy on Integrative and Complementary	It mentions the provision of access to homeopathic and herbal medicines, ensuring the specificities of pharmaceutical care
Resolution Nº. 546 of July 21, 2011(17)	Federal Pharmacy Council	Provides for the pharmaceutical indication of over the counter medicinal plants and over the counter herbal medicines.	Establishes and describes the pharmaceutical indication of over the counter medicinal plants and herbal medicines
CFF Resolution Nº. 585, of August 29, 2013(18)	Federal Pharmacy Council	Regulates the clinical duties of pharmacists.	Cites the analysis of prescriptions as a duty of pharmacists
Resolution Nº. 586, August 29, 2013(19)	Federal Pharmacy Council	Regulates pharmaceutical prescriptions and provides other measures.	Establishes and describes pharmaceutical prescriptions
IN Nº. 02, of May 13, 2014(20)	National Health Surveillance Agency	Publishes the "List of with simplified registration" and the "List of traditional herbal products with simplified registration"	Lists of simplified registration herbal medicines and traditional herbal products
Law No. 13,021, of August 8, 2014(21)	Presidency of the Republic	Provides for the exercise and supervision of pharmaceutical activities.	Cites the analysis of prescriptions as a responsibility of pharmacists

[4] Legend: GM: Office of the Minister, MS: Health Ministry, CFF: Federal Council of Pharmacy, IN: Normative Instruction, RDC: Collegiate Board Resolution, * : Revoked.

IN Nº. 11, of September 29, 2016*[22]	National Health Surveillance Agency	Provides for the list of prescription-free medicines.	List of over the counter herbal medicines
Resolution N. 84, dated June 17, 2016[23]	National Health Surveillance Agency	Approves the Herbal Medicine Memento of the Brazilian Pharmacopoeia and makes other provisions.	Presents monographs on medicinal plants and herbal medicines.
RDC Nº. 463 of January 27, 2021[24]	National Health Surveillance Agency	Provides for the approval of the Brazilian Pharmacopoeia Herbal Medicine Formulary, 2nd edition.	Compilation of monographs organized by plant species, describing preparation, indications, use, and warnings.
IN No. 120 of March 9, 2022*[25]	National Health Surveillance Agency	Defines the List of Over the Counter Medicines	Presents the List of Over the Counter Medicines, including herbal medicines, which can be prescribed by a pharmacist specializing in the area.
RDC No. 678 of 04/29/2022[26]	National Health Surveillance Agency	Updates the Brazilian Pharmacopoeia Herbal Medicine Formulary, 2nd edition, referred to in Collegiate Board Resolution - RDC No. 463, dated January 27, 2021.	Update of the Brazilian Pharmacopoeia Herbal Medicine Formulary, which contains guidelines on the indication of herbal medicines
RDC No. 785 of April 13, 2023[27]	National Health Surveillance Agency	Updates the Brazilian Pharmacopoeia Herbal Medicine Formulary, 2nd edition, addressed by Collegiate Board Resolution - RDC No. 463, dated January 27, 2021.	Update of the Brazilian Pharmacopoeia Herbal Medicine Form, which contains guidelines on the indication of herbal medicines
IN nº 285, of March 7, 2024[9]	National Health Surveillance Agency	Defines the List of Over-the Counter Medicines.	Update of the MIP list

Source: Prepared by the authors.

Considering that the use of medicinal plants in healing has origins dating back to the dawn of humanity and is associated with popular tradition, Ordinance Nº 971 of 2006 from the Ministry of Health[4] of 2006, responsible for approving the PNPIC in the SUS, was an important starting point for expanding access to herbal medicines and their rational use.

Resolution Nº 459 of 2007 of the CFF directly clarified the role of pharmacists in the field of medicinal plants and herbal medicines, initially supporting the work of professionals in this area[14]. Resolution Nº 477 of 2008 of the CFF[15], which updates the role of professionals in the field, establishes the principle of what would be the pharmaceutical prescription of herbal medicines. In Article 9 of the same standard, the first paragraph determines that responsible self-medication for

over-the-counter herbal medicines should only occur with the guidance and monitoring of a pharmacist. By updating the responsibilities of professionals, this regulatory framework not only strengthens their role, but also ensures that herbal medicines are used more safely and effectively, protecting patient health[15].

In 2011, Resolution Nº 546 of the CFF[17] established the pharmaceutical indication of herbal medicines. This resolution defines the requirements for professionals to be considered qualified to prescribe these medicines. Thus, in order to perform this service, it is established that the pharmacist must have completed a course in herbal medicine with a minimum of 60 hours, supplemented by an internship in the handling and/or dispensing of medicinal plants and herbal medicines of at least 120 hours, or must present a specialist title or specialization course in herbal medicine.

In 2013, with CFF Resolutions Nº. 585 and No. 586 of August 29, pharmaceutical recommendation was expanded to pharmaceutical prescription, establishing the role of the professional as a prescriber within specific contexts, such as herbal medicines[18,19]. Although the resolutions contribute significantly to strengthening the role of pharmacists in the area, it is important to raise questions about the established requirements. In November 2024, the Federal Court of the Federal District declared Resolution CFF No. 586/2013[19] unconstitutional and illegal, which authorized the prescription of medicines by pharmacists. The decision was handed down in a public civil action filed by the Federal Council of Medicine (CFM), which argued that the rule violated the Medical Act Law (Law No. 12,842/2013) and the Federal Constitution by assigning to pharmacists competencies that are exclusive to medicine. Despite the decision, the Federal Pharmacy Council (CFF) appealed the ruling and, in March 2025, published CFF Resolution Nº. 5/2025[20] with content similar to that of the suspended resolution. In response, the CFM filed a new public civil action, questioning the legality of the new rule, which is still being reviewed by the Judiciary. To date, CFF Resolution Nº 586/2013 remains ineffective, and CFF Resolution No. 5/2025 is under judicial review. CFF Resolution Nº 546/2011, which deals with the pharmaceutical indication of herbal medicines, remains in force and has not been affected by these decisions.

Regarding the training of pharmaceutical professionals, there is an inconsistency between what is established by the National Curriculum Guidelines (DCN) for undergraduate Pharmacy courses and the reality of pharmacist training. Herbal medicine is included in the DCN, as a result of an update following the publication of Ordinance No. 971/2006, which established the PNPIC[4], however, there is a critical gap between what is recommended by the DCN and the reality of the training of pharmacy professionals, reflected in the insecurity demonstrated in the application of phytotherapy and the lack of theoretical and practical knowledge.

To draw a parallel, in a study conducted by Mota et al. in 2019[29], the most commonly dispensed MIPs in community pharmacies in the metropolitan region of Belo Horizonte were identified, and pharmacists' knowledge of the legal categorization of these drugs was assessed. The results showed that the most commonly dispensed MIP drugs include drugs with analgesic and/or anti-inflammatory effects, but 35.2% of pharmacists mentioned at least one drug that is not exempt from prescription.

The prescription of conventional MIPs does not require specific training beyond the knowledge acquired during undergraduate pharmacy studies. In contrast, the prescription of herbal medicines requires that the pharmacist have taken a specific number of hours of herbal medicine courses during their undergraduate pharmacy studies, in addition to completing an internship in the handling and/or

dispensing of medicinal plants and herbal medicines for at least 120 hours in higher education institutions, pharmacies, or herbal medicine distribution programs in the SUS in partnership with educational institutions[17].

The complexity of these medicines requires robust training and knowledge to ensure that pharmacists provide a safe and effective service, in addition to strengthening their performance in phytotherapy. In this sense, it is essential that professionals be trained for such guidance, since herbal medicines have their own complexity and may interact with other medicines[30]. Given this context, there is a need to ensure that pharmacists are trained to dispense MIP herbal medicines.

The requirement for specific training in the prescription of herbal medicines represents an additional challenge for pharmacists, considering the already intense curriculum of Pharmacy courses. One solution would be to integrate the principles and concepts of Integrative and Complementary Practices (ICP), including herbal medicine, into existing compulsory subjects, offering a general introduction to their relevance and related policies.

To deepen knowledge without overloading the curriculum, specific subjects, such as herbal medicine, could be offered as electives. This flexible approach would meet the interests of students who wish to explore the area in greater depth, without compromising the basic training of others. However, the intrinsic complexity of herbal medicines, which requires detailed knowledge of their properties, pharmacological interactions, and potential adverse effects, supports the need for adequate educational preparation. Robust training in herbal medicine not only enables professionals to practice safely and effectively, but also reinforces the credibility of the pharmaceutical profession in the context of integrative and complementary health practices, aligning with the guidelines of the PNPIC[1].

Final Considerations

The analysis of regulatory aspects related to the indication and prescription of herbal medicines allowed for a deeper understanding of the regulations that guide the pharmacist's role in this context in Brazil. It was possible to identify technical products, regulations, and legislation that support and validate this evidence-based practice, demonstrating robust regulatory support. These products also highlight the importance of the pharmacist's role in the context of the indication and prescription of herbal medicines, given the complexity of these medicines. Thus, improving the pharmacist's performance in this context is essential to ensure quality service. In this way, the study contributes to the recognition of the practice of recommending and prescribing herbal medicines by pharmacists as an essential and regulated service. Furthermore, it highlights the need for further studies and research in this area to fill this knowledge gap.

Conflict of interest

The authors declare that there is no conflict of interest.

Contribution of the authors

Parreira APG contributed to the conception/design of the article, analysis and interpretation of data, and writing of the article. Silva LIF contributed to the conception/design of the article, analysis and interpretation of data, and writing of the article. Dewulf NLS contributed to the conception/design of the article, analysis and interpretation of data, writing of the article, critical review of its content, and approval of the final version.

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