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Scientific production from 2010 to 2018 about the quality control of plant species included in the Brazilian National List of Essential Medicines

Produção científica de 2010 a 2018 sobre o controle de qualidade de espécies vegetais incluídas na Relação Nacional de Medicamentos Essenciais

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ABSTRACT

Introduction: The Brazilian Ministry of Health established the National List of Medicinal Plants of Interest to the Unified Health System (Rénisus) to encourage scientific research related to a list of 71 plant species with potential to generate new products for the public health system. However, only 12 of these species are contemplated by the Brazilian National List of Essential Medicines (Rename) and therefore have their respective phytomedicines offered at SUS. In addition, 3 of them are not contemplated in the Brazilian Pharmacopoeia. **Objective:** This work aims to indicate the possibility of using the available references to elaborate and include the missing monographs in the Brazilian Pharmacopoeia; as well as to assess whether the main government policy to encourage research in the area influenced Brazilian scientific production considering the studied profile. **Method:** A longitudinal retrospective study was carried out using the Web of Science and Scopus databases regarding the quality control of the 12 plant species contemplated in the Rename by different analytical techniques considering the pre and post-Rénisus periods (pre and post-2010). **Results:** All evaluated species presented scientific articles describing analytical methods to determine their constituents. Among the evaluated species, 67% had low individual nominal growth (≤ 8 articles) in the pre and post Rénisus periods, while the rest showed greater growth (≥ 19 articles). **Conclusions:** There are available references in the literature with potential analytical methods for the elaboration of the missing pharmacopoeial monographs in the Brazilian compendium. However, the incentive policies may not have had significantly influenced the studied fraction of the Brazilian scientific production.

KEYWORDS: Medicinal Plants; Phytomedicines; Bibliometric Analysis; Rename; Rénisus

RESUMO

Introdução: O Ministério da Saúde elaborou a Relação Nacional de Plantas Medicinais de Interesse ao Sistema Único de Saúde (Rénisus) para incentivar a pesquisa científica de 71 espécies vegetais com potencial para gerar produtos para o Sistema Único de Saúde. Destas, 12 constam na Relação Nacional de Medicamentos Essenciais (Rename) e, portanto, têm seus respectivos fitoterápicos ofertados no sistema público. Entretanto, três ainda não apresentam monografias na Farmacopeia Brasileira. **Objetivo:** Avaliar quantitativamente a produção científica sobre o controle de qualidade das 12 espécies da Rename, demonstrar a possibilidade de utilização das referências já disponíveis na elaboração e inclusão das monografias ainda não contempladas no compêndio nacional e avaliar se a principal política governamental de incentivo da área influenciou a produção científica brasileira considerando o recorte estudado. **Método:** O levantamento dos dados foi realizado a partir de um estudo longitudinal retrospectivo, considerando o controle de qualidade das 12 espécies vegetais da Rename por diferentes técnicas analíticas nos

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períodos pré e pós-Renise (pré e pós-2010), utilizando as bases de dados *Web of Science* e Scopus. **Resultados:** Todas as espécies avaliadas apresentaram artigos científicos descrevendo métodos analíticos para a determinação de seus constituintes. Considerando a produção científica brasileira, 67% das espécies vegetais apresentaram baixo crescimento nominal individual ($\leq$ oito artigos) no período posterior à promulgação da Renise, enquanto o restante apresentou maior crescimento ($\geq$ 19 artigos). **Conclusões:** As espécies ainda não contempladas na Farmacopeia Brasileira apresentaram referências na literatura com potenciais métodos analíticos para elaboração de futuras monografias farmacopeicas. Entretanto, as políticas de incentivo podem não ter influenciado significativamente a fração estudada da produção científica brasileira.

PALAVRAS-CHAVE: Plantas Medicinais; Fitoterápicos; Análise Bibliométrica; Renise; Renise

INTRODUCTION

Scientific and technological progress over the years is expected to increase scientific production, which, in turn, generates the need to monitor the evolution of the various domains of knowledge as research areas. Bibliometric analysis is a widely used tool in information sciences, especially in the area of scientometrics, for the specific study of scientific and technological production and dissemination.¹ Thus, both the scientific merit of what is produced and the levels of productivity can be represented by several bibliometric indicators. Governments and companies see these tools as an opportunity to ascertain whether their research investments have yielded results,² and researchers see them as an opportunity for the investigation of knowledge gaps.

In February 2009, the Brazilian Ministry of Health published the National List of Medicinal Plants of Interest to the Unified Health System (SUS), Renise, containing 71 plant species that have the potential to generate products of interest to the system. The purpose of the list is to guide research that can support the development of phytomedicines to be made available to the population with safety and efficacy for the treatment of a particular disease.³ Phytomedicines are medicines “obtained with the exclusive use of active vegetable raw materials, whose safety and efficacy are based on clinical evidence and which are characterized by the constancy of their quality.”⁴ Treatments are usually based on the use of a single species of medicinal plant or a group of plants with complementary properties.⁵

Through Ordinance n. 533, of March 28, 2012,⁶ the Ministry of Health established the list of medicines and supplies of the National List of Essential Medicines (Renise) under the SUS, including 12 phytomedicines from the following plant species: *Espinheira-santa* (*Maytenus ilicifolia*); Guaco (*Mikania glomerata*); Artichoke (*Cynara scolymus*); Brazilian peppertree (*Schinus terebinthifolius*); Cascara buckthorn (*Rhamnus purshiana*); Devil's claw (*Harpagophytum procumbens*); Soybean (*Glycine max*); Cat's claw (*Uncaria tomentosa*); Peppermint (*Mentha piperita*); Aloe (*Aloe vera*); Willow (*Salix alba*); and Desert Indian wheat (*Plantago ovata*). According to the 2020 Renise,⁷ these phytomedicines remain included in the SUS. According to Normative Instruction n. 02, of May 13, 2014,⁸ only *A. vera* and *S. terebinthifolius* are not on the list of phytomedicines that can have simplified application processes. Among

those on the list, *H. procumbens*, *M. ilicifolia*, *M. glomerata* and *U. tomentosa* are classified as Traditional Phytotherapeutic Products,⁸ as their use is “supported by a long history of human use, demonstrated in technical-scientific documentation, without known or reported evidence of risk to the user's health.”⁴

Although it is often grounded on traditional use, phytomedicine as a science can be evaluated by quantitative and qualitative bibliometric tools. Marmitt et al.⁹ used these tools in a review involving Renise, from 2010 to 2013, to confirm the therapeutic activity of the listed species. Similarly, the objective of this study was to use bibliometrics as a quantitative analysis tool in the Web of Science and Scopus databases to verify whether public policies positively influenced research on the quality control of plant species already covered in Renise by Renise. In addition, the investigation may demonstrate the availability of articles about analytical methods for species available as phytomedicines in Renise and not yet included in monographs in the Brazilian Pharmacopoeia (*G. max*, *M. glomerata*, *U. tomentosa*).¹⁰

METHOD

The methodological approach consisted of evaluating the scientific production referring only to the 12 plant species currently offered as phytomedicines by the SUS. For this, the Web of Science (WoS) (Clarivate Analytics) and Scopus (Elsevier) databases were used to search the scientific literature. The researched terms initially included the scientific names adopted by Renise without the use of synonyms, together with the common names in Portuguese, Spanish and English (whenever possible), using the “OR” operator. Table 1 shows the keywords of the first stage of the bibliographic research.

Scientific articles that mention analytical techniques commonly used in quality control were searched quantitatively through the filters shown in Table 2. Scientific production was organized according to the periods before and after the publication of Renise, that is, before and after 2010 (the year following the publication of the list). For this, the results from the searches were stored after applying filters 3 and 4 in the Scopus database and filters 5 and 6 in the WoS database. The search in both databases was carried out on January 9, 2019. The values of synonymous or duplicate entries were added so we could have only one



Table 1. Names used as keywords in the first stage of the bibliographic research in the Web of Science and Scopus databases.

Scientific name	Common name (Portuguese)	Common name (Spanish)	Common name (English)
<i>Aloe vera</i>	Aloe	<i>Ságuila</i>	-
<i>Cynara scolymus</i>	Artichoke	<i>Alcachofera</i>	Artichoke
<i>Glycine max</i>	Isoflavona-de-soja	<i>Soja</i>	Soybean
<i>Harpagophytum procumbens</i>	Garra-do-diabo	<i>Garra del diablo</i>	Devil's claw
<i>Maytenus ilicifolia</i>	Espinheira-santa	<i>Congorosa</i>	-
<i>Mentha x piperita</i>	Hortelã-pimenta	<i>Menta piperita</i>	Peppermint
<i>Mikania glomerata</i>	Guaco	<i>Guaco</i>	-
<i>Plantago ovata</i>	Plantago	<i>Llantén de la india</i>	Desert indian wheat
<i>Rhamnus purshiana</i>	Cáscara-sagrada	<i>Cáscara sagrada</i>	Cascara buckthorn
<i>Salix alba</i>	Salgueiro	<i>Salguero</i>	Willow
<i>Schinus terebinthifolius</i>	Aroeira-vermelha	<i>Pimentero brasileño</i>	Brazilian peppertree
<i>Uncaria tomentosa</i>	Unha-de-gato	<i>Uña de gato</i>	Cat's claw

Source: Renisus/Rename, 2020.

Table 2. Identification of filters used in the Web of Science and Scopus databases to search the number of publications involving analytical methods for quality control of plant species dispensed as phytomedicines by the Unified Health System.

Filters	Web of Science (all bases)	Scopus
Filter 1	Scientific technology	Article
Filter 2	Main collection	Chemistry
Filter 3	Article	Analytical methodologies*
Filter 4	Chemistry	Period 2010-2018**
Filter 5	Analytical methodologies*	-
Filter 6	Period 2010-2018**	-

* Includes the terms: "HPLC" or "High Performance Liquid Chromatography"; "GC" or "Gas Chromatography"; "CE" or "Capillary electrophoresis"; "MS" or "Mass Spectrometry"; "ICP" - encompassing Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP-AES), where Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES) is synonymous with the latter -; "Spectrophotometry" or "Spectrophotometric"; "Spectrofluorimetry" or "Spectrofluorimetric"; "Potentiometric" or "Potentiometric"; "Voltammetry" or "Voltammetric".

** The first year available until 2009 was considered as the "pre-Renisus" period and the period from 2010 to 2018 as the "post-Renisus" period. Source: Prepared by the authors, 2020.

entry. Data like type of institution (public or private), state and region of Brazilian affiliations were collected from the official websites of the institutions.

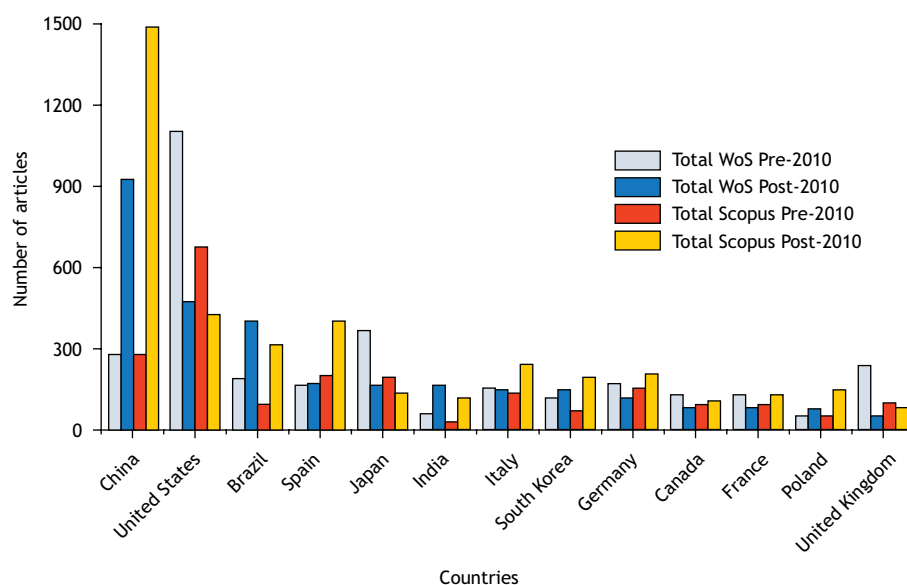
All data files were manually grouped, and the relevant results were summarized and grouped by plant species and country.

RESULTS AND DISCUSSION

Over the years and the consequent scientific and technological progress, it is expected that the world scientific production will increase as a whole, but when countries are evaluated separately, not all perform the same way. Figure 1 shows the variation in the number of articles related to analytical methods for quality control of plant species available in the SUS that were indexed in the WoS and Scopus databases in the pre- and post-Renisus periods (before and after 2010) in the 13 countries with the highest number of publications on the subject. China, Brazil and India presented the biggest positive variations: +231%, +114% and +172%, respectively, in WoS; and +449%, +247% and

+350%, respectively, in Scopus. These countries are considered emerging countries and have a significant population in rural areas with limited access to medicines and frequent use of medicinal plants. This culture of traditional medicine, therefore, plays an important role in these countries, also enabled by their great biodiversity and favorable climate. In addition, these countries' own development process also favors an increase in scientific production in the evaluated periods.

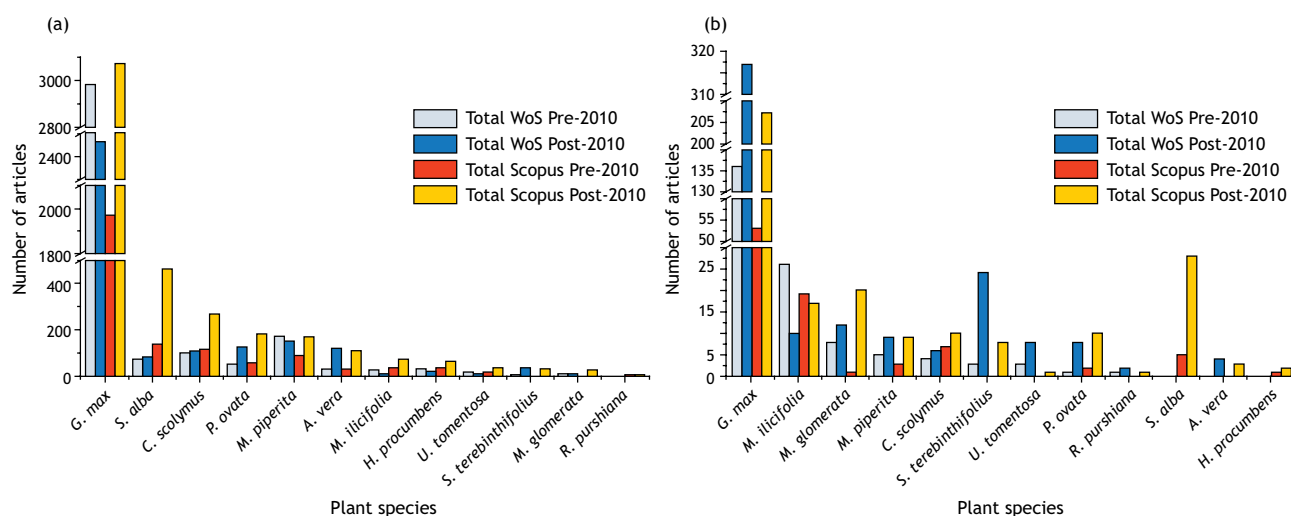
Figure 2 shows the substantial difference between *G. max* (soybean) and the other species studied. Soybean stands out for being present in a plethora of food products around the world, in addition to being consumed fresh by humans and livestock. It is one of the most grown and most profitable species in the world. Moreover, the production of grains and oilseeds like soybean has recently gained momentum to meet the demand generated by the increase in income and urbanization, with the population consuming more animal protein, which heavily depends on feed made of soybean. There has also been an increase in the demand for renewable energy sources, such as



Source: Web of Science and Scopus, 2020.

*The 10 countries with the highest number of publications were counted in the Web of Science and Scopus databases and totaled 13.

Figure 1. Comparison between the pre- and post-Reniscus periods (before and after 2010) in relation to the number of indexed articles (Web of Science and Scopus) involving analytical methods for quality control of the 12 plant species dispensed as phytomedicines by the Unified Health Service, by country.*



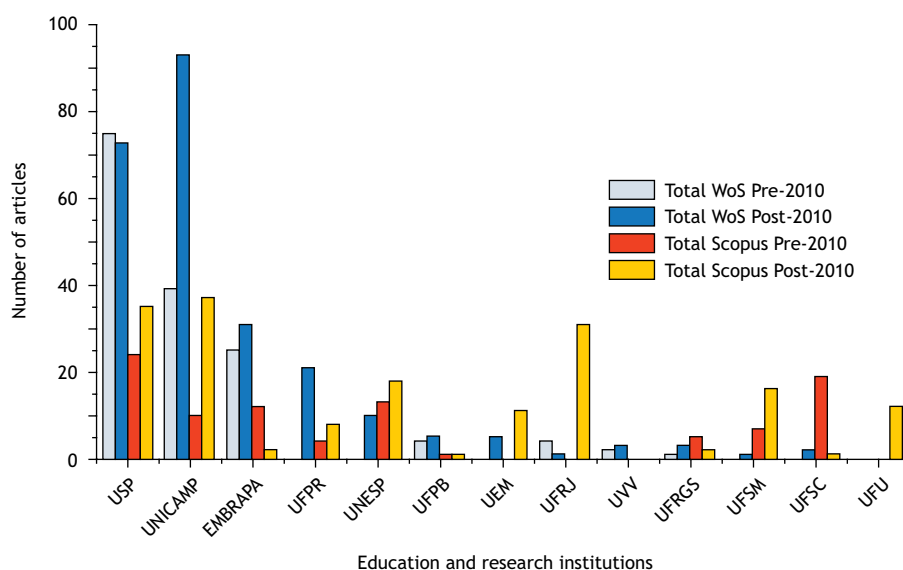
Source: Web of Science and Scopus, 2020.

Figure 2. Comparison between the pre- and post-Reniscus periods (before and after 2010) in relation to the number of indexed articles (WoS and Scopus) involving analytical methods for quality control of each of the 12 plant species dispensed as phytomedicines by the Unified Health Service, worldwide (a) and in Brazil (b).

biofuels.¹¹ Soybean is therefore a strategic cash crop for many countries, which justifies the search for publications on this topic by researchers, which, in turn, may explain the huge difference we observed.

In Brazil, *G. max* is also far ahead of the other studied species (Figure 2B). However, more common species in the Brazilian territory began to appear soon after. When we arbitrarily consider a nominal growth close to 20 articles as “satisfactory”, in the pre- and post-Reniscus period, four species stand out: *G. max*

(+181 [WoS], +154 [Scopus]); *M. glomerata* (+4 [WoS], +19 [Scopus]); *S. alba* (0 [WoS], +23 [Scopus]); and *S. terebinthifolius* (+21 [WoS], 0 [Scopus]). This growth may not be the result of Brazilian public incentive policies: it may be a natural evolution process resulting from time and scientific and technological progress, as well as market trends. Furthermore, the landscape for the other eight of the 12 species studied did not change significantly. About these species, we can notice the low Brazilian productivity (individual nominal growth ≤ 8 articles) considering the results of both databases.



Source: Web of Science and Scopus, 2020.

USP: University of São Paulo; Unicamp: University of Campinas; Embrapa: Brazilian Agricultural Research Corporation; UFPR: Federal University of Paraná; Unesp: São Paulo State University; UFPB: Federal University of Paraíba; UEM: State University of Maringá; UFRJ: Federal University of Rio de Janeiro; UVV: Vila Velha University; UFRGS: Federal University of Rio Grande do Sul; UFSM: Federal University of Santa Maria; UFSC: Federal University of Santa Catarina; UFU: Federal University of Uberlândia

*The ten affiliations with the highest number of publications were counted in the Web of Science and Scopus databases and totaled 13.

Figure 3. Comparison between the pre- and post-Reniseq periods (before and after 2010) between Brazil's main affiliations in relation to the number of indexed articles (Web of Science and Scopus) involving analytical methods for quality control of the 12 plant species dispensed as phytomedicines by the Unified Health Service.

It is noteworthy that *G. max*, *M. glomerata* and *U. tomentosa* are included in Reniseq but do not have monographs available in the Brazilian Pharmacopoeia¹⁰. Although Resolution n. 37, of July 6, 2009,¹² deals with the possibility of using the content of certain foreign compendia in addition to the national compendium, the inclusion of monographs is a matter of national sovereignty, as well as a matter of accessibility, since the Brazilian Pharmacopoeia is widely distributed online and free of charge by the National Health Surveillance Agency (Anvisa). The number of scientific articles referring to quality control methods applied to these plant species can encourage the preparation and inclusion of their monographs in the national compendium. Furthermore, bibliometric tools can also be applied to other Reniseq species with the same purpose, since their inclusion in Reniseq can be facilitated after their monograph is available in the Brazilian Pharmacopoeia. In this study, we found that *G. max* has much consultable material (5,446 total articles in WoS; 5,039 total articles in Scopus), whereas *M. glomerata* (24 total articles in WoS; 32 total articles in Scopus) and *U. tomentosa* (31 total articles in WoS; 58 total articles in Scopus) may still have gaps to be filled. Be that as it may, the possibility of qualitative evaluation of these materials for the elaboration of their monographs stands out.

Still on the scientific production referring to Reniseq species, the Brazilian affiliations that are most attributed to the authors (Figure 3) are: University of São Paulo (USP), University of Campinas (Unicamp), Brazilian Agricultural Research Corporation (Embrapa), Federal University of Paraná (UFPR), São Paulo State University (Unesp), Federal University of Paraíba (UFPB),

Maringá State University (UEM), Federal University of Rio de Janeiro (UFRJ), Vila Velha University (UVV), Federal University of Rio Grande do Sul (UFRGS), Federal University of Santa Maria (UFSM), Federal University of Santa Catarina (UFSC) and Federal University of Uberlândia (UFU).

The only private institution present on the list is UVV, with only two affiliations attributed in the pre-Reniseq period and three in the post-Reniseq period, in scientific journals indexed by WoS. There is good representation of state universities from São Paulo (USP, Unicamp and Unesp). USP has more affiliations than all the others, except for the post-Reniseq period of the WoS platform, where it is behind Unicamp.

With the exception of Embrapa and UVV, all institutions in Figure 3 are ranked among the 31 best Higher Education Institutions (HEI) in Brazil. USP ranks first (it is also considered the best in Latin America and the seventy-seventh in the world),¹³ followed by Unicamp in second, UFRJ in third, UFRGS in fifth, Unesp in sixth, UFSC in seventh, UFPR in eighth, UFSM in 21st, UEM in 24th, UFU in 25th and UFPB in 31st.¹⁴

Among the HEIs with publications on the subject indexed in Scopus (63 in total), 46% are in the Southeast, 27% in the South, 16% in the Northeast, 8% in the Center-West, and 3% in the North. In this percentage, the states of São Paulo and Rio de Janeiro stand out, with ten and nine HEIs, respectively, followed by Minas Gerais, Paraná and Rio Grande do Sul, with seven. When evaluating the 31 best Brazilian universities,¹⁴ a similar distribution is found: 48% are located in the Southeast, 26% in the South, 16%



in the Northeast, 7% in the Center-West and 3% in the North. The demographic density concentrated on the Brazilian coast,¹⁵ as well as the fact that the states that most contribute to the country's gross domestic product (GDP) are located in the Southeast and South,¹⁶ may explain this phenomenon.

CONCLUSIONS

By comparing the defined periods, we found that the vast majority of Brazilian research on the subject was carried out by Public Institutions of Higher Education (82%), especially those in the Southeast region (46%), with emphasis on two state universities of São Paulo, which together have more affiliations than the sum of the others: USP and Unicamp.

The variation in Brazilian scientific production about analytical methods for quality control of the 12 plant species dispensed by the SUS as phytomedicines, of +114% and +247% in the WoS and Scopus bases, respectively, may suggest the success of Brazilian public policies in encouraging production in this area of science. However, these numbers summarize the scenario of scientific

production for all species studied together at the national level. In other words, they do not reveal the actual individual situation of each species. Among the 12 species, eight have shown low individual nominal growth ($\leq$ eight articles) when we compare the periods before and after Renisus. The productions referring to the species *G. max*, *M. glomerata*, *S. alba* and *S. terebinthifolius* had a relevant nominal growth in the post-Renisus period ($\geq$ 19 articles).

Finally, it is noteworthy that this study was limited to 12 species currently included in Renisus and that public policies encourage scientific production for all 71 species present in Renisus. Therefore, the continuity of this work requires other bibliometric studies on other species. As for the three species (*G. max*, *M. glomerata* and *U. tomentosa*) included in Renisus, but not in the Brazilian Pharmacopoeia, the work quantitatively demonstrated the availability of studies that can be considered and used as references in the preparation of monographs, as is the case of *G. max*, in view of the large amount of material available (5,446 total articles [WoS]; 5,039 total articles [Scopus]).

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Authors' Contribution

Rodrigues LO - Conception, planning (study design), data acquisition, analysis and interpretation and writing of the manuscript. Mourão SC - Analysis, interpretation of data and review of the manuscript. Gouvêa MM - Conception, planning (study design), analysis, interpretation of data and review of the manuscript. All authors approved the final draft of the manuscript.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.



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