

# The global strategy on public health, innovation and intellectual property: establishment of a priority order for research and development needs in Brazil

A estratégia global sobre saúde pública, inovação e propriedade intelectual: estabelecimento de uma ordem de prioridade das necessidades de pesquisa e desenvolvimento no Brasil

 **Jordão Lima<sup>a</sup>**

<https://orcid.org/0000-0001-8828-7947>

E-mail: jordaohoracio@hotmail.com

 **Sueli Dallari<sup>a</sup>**

<https://orcid.org/0000-0002-6999-4854>

E-mail: sdallari@usp.br

<sup>a</sup>Universidade de São Paulo. Faculdade de Saúde Pública. São Paulo, SP, Brasil.

## Abstract

The adoption of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) within the framework of the World Health Organization (WHO) is based on the need to improve the access conditions of developing countries to medicine and other products that meet their specific public health needs. This study verifies the implementation of the first GSPOA Element in Brazil, which refers to the establishment of an order of priority for research and development needs. This qualitative case study was based on a critical perspective and established theoretical frameworks, seeking to place GSPOA in a transnational health context in an era of globalization, and to discuss the challenges to more fully implement a right to health that transcends the use of medicines and individual requirements. We concluded that, from 2008 to 2015, Brazil was successful in developing methodologies and mechanisms to identify and disseminate the gaps in the research of diseases of greatest incidence in the country and their consequences on public health, guiding the development of feasible and affordable therapeutically products.

**Keywords:** Global Strategy on Public Health; Innovation and Intellectual Property; World Health Organization Research and Development.

## Correspondence

Jordão Lima

Av. Dr. Arnaldo, 715. São Paulo, SP, Brazil. CEP: 01255-000

## Resumo

A aprovação da Estratégia Global e do Plano de Ação sobre Saúde Pública, Inovação e Propriedade Intelectual (GSPOA, do inglês Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property), no âmbito da Organização Mundial da Saúde (OMS), está baseada na percepção da necessidade de melhoria nas condições de acesso dos países em desenvolvimento a medicamentos e outros produtos que atendam às suas necessidades específicas de saúde pública. Nesse contexto, o escopo desta consiste em perscrutar a implementação, no Brasil, do primeiro elemento da GSPOA, que se refere ao estabelecimento de uma ordem de prioridade das necessidades de pesquisa e desenvolvimento. Trata-se de estudo de caso, enquanto método de investigação qualitativa. Partindo de uma perspectiva crítica e de marcos teóricos consagrados, buscou-se situar a GSPOA num contexto de saúde transnacional em uma era de globalização e pontuar os desafios para implementar mais completamente um direito à saúde que transcenda os medicamentos e as exigências individuais. Conclui-se que, para o período de 2008 a 2015, o Brasil logrou êxito em desenvolver metodologias e mecanismos para identificar e divulgar as lacunas nas pesquisas de doenças de maior incidência no país e suas consequências na saúde pública, orientando o desenvolvimento de produtos terapêuticamente viáveis e a preços acessíveis.

**Palavras-chave:** Estratégia Global Sobre Saúde Pública; Inovação e Propriedade Intelectual; Organização Mundial da Saúde; Pesquisa e Desenvolvimento.

## Introduction

The impact of the provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) on access to medicines has caused the World Health Organization (WHO) to initiate, slowly and gradually, a process of invoking competence to discuss the subject of intellectual property and its impact on public health as a whole. This fact has always aroused strong opposition from developed countries, claiming that this issue should be debated in the World Trade Organization (WTO), a forum with a mercantile aspect and in which the economic weight of the actors is decisive.

Notably, the establishment of the WTO has changed the global patent landscape. For the first time in the course of the historical process, all countries wishing to belong to this organization would be required to bring the protection of intellectual property rights to a minimum common level, guaranteed by the TRIPS Agreement. It is currently the most representative set of guidelines on intellectual property and, by internationalizing minimum levels of protection for this property, it brings profound changes in nationally sensitive issues, such as the registration of pharmaceutical products, which become mandatory object of patentability.

Even though defenders of intellectual property protection justify that this legal support is necessary to ensure that investments in research and development (R&D) return to the inventor, causing a positive cyclical process - in which greater investments in the area would be promoted in the face of the concession of the temporary exploitation monopoly of the invention -, in the scope of public health, there was an intensification of inequities, especially in relation to access to medicines and technologies related to diseases that disproportionately affect developing countries and those with less relative development (Buss; Chamas, 2012).

In 2003, the 56th World Health Assembly (WHA) determined the creation of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) (WHO, 2003), which sought to find evidence of the possibility of achieving a balance between innovation and intellectual property

rights and public health interests (Alcazar, 2008 apud Almeida, 2014). The commission's work ended in 2006, highlighting, in 60 recommendations, the access problems caused by the current international system of intellectual property and the lack of innovation, especially for diseases that affect the most intensely the developing and least developed countries.

The CIPIH studies have found, in practice, no evidence that the implementation of the TRIPS Agreement in developing countries has significantly boosted pharmaceutical research and development. For the commission, the main reason for this would be the lack of market incentives. In the same year, the 59th WHA passed a resolution requesting the creation of an intergovernmental working group - the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), with the mandate of preparing a global strategy and action plan to address these issues in the circumstances that greatly affect developing countries (WHO, 2006).

The Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property (GSPOA) was approved in 2008 by the 61st WHA, promoting the full involvement of WHO in the binomial public health and intellectual property (WHO, 2008). The main elements of the GSPOA focus on the recognition that the ongoing initiatives to increase access to pharmaceutical products are insufficient and the mechanisms that encourage intellectual property rights are unable to benefit people living in markets with low consumer potential.

While still recognizing the role of intellectual property in the innovation process, the strategy also recognizes that the price of drugs is one of the factors that can prevent access to treatment. It also recognizes that international intellectual property agreements could contain flexibilities that would facilitate access to pharmaceutical

products by developing countries. However, these States face obstacles when using such flexibilities, with emphasis on those with insufficient or no production capacity, which limits the effective use of the compulsory license, in addition to the increase in patents on marginal or trivial advances (sometimes called evergreening patents), that block or delay generic competition (Velásquez, 2011).

The GSPOA is divided into eight main elements and 25 sub-items, spread over 108 action points, which aim to increase efficiency in promoting innovation within countries through institutional development, and investment and coordination of areas relevant to health innovation. These points communicate with each other and are divided into eight macro areas: (1) prioritizing research and development needs; (2) promoting R&D activities; (3) building and improving innovation capacity; (4) transfer of technology; (5) application and management of the intellectual property regime to contribute to innovation and promote public health; (6) improving distribution and access; (7) promoting sustainable financing mechanisms; and (8) establishing monitoring and reporting systems (WHO, 2008).

This study aims to carry out a careful investigation based on a survey of specific data from established theoretical references, seeking to adequately elucidate how the national scenario has adjusted to the provisions within the scope of the GSPOA. More precisely, we address its first element, which guides the prioritization of research and development needs. By advancing the scientific research concerning the implementation of this element by the Brazilian government, we emphasize that the identification of gaps and challenges is essential so that we can reach, as a sovereign nation, adequate parameters in research and development, as well as in access to medicines, especially in relation to the problems that affect Brazil disproportionately.<sup>1</sup>

---

<sup>1</sup> In this context, it is worth mentioning initiatives such as the installation of the antiretroviral and other medicines factory in Mozambique, called Mozambican Medicines Society (SMM), in partnership with the Oswaldo Cruz Foundation (FIOCRUZ). In addition, the presence of the Brazilian government in international consortia for the development of a pediatric medicine for the treatment of schistosomiasis, praziquantel, and for the development of combined therapies (FDC) for the treatment of malaria is highlighted. We also mention the Partnerships for Productive Development (PDP). All these initiatives are industrial policy mechanisms used in healthcare and will not be addressed in this investigation. These are projects related to other GSPOA devices that are not included in our object of study.

## Theoretical and methodological aspects

The need to align investments in R&D in health with the health demands of developing countries is one of the most complex global public health challenges today. At this moment, our challenge is to understand the hermetic scenario in which the addressing of inequities related to access to medicines is situated, in a context of transnational health in an era of globalization (Brown; Cueto; Fee, 2006). For Biehl (2011), the “magic bullet” approaches are more becoming more and more frequently the standard procedure in global health. They are defined by the delivery of health technologies (usually new drugs or devices) aimed at a specific disease, despite the myriad of other societal, political and economic factors that influence health issues. Thus, this scenario requires the extrapolation of limits of the vertical-technical-instant-solution approach in global health, that overcomes the challenges of more fully implementing a right to health that transcends medications and individual requirements, ensuring that primary health care and prevention are sufficiently robust to reduce vulnerability.

From this perspective, the reconsideration of the systemic relationship between pharmaceutical research, commercial interest and public health care is brought under discussion. A more sustainable solution must be considered for the obstacles posed by patentability and commercial control over basic science and medical care. GSPOA appears precisely in this context, by promoting a new reflection about innovation and the access to medicines, as well as proposing “[...] a medium-term framework to guarantee a solid and sustainable basis for health R&D, guided by needs and centered on diseases that disproportionately affect developing countries” (WHO, 2008, p. 4-5).

Here we emphasize that, when analyzing the challenges for the implementation of an

international policy based on the action of a specific actor (the Brazilian government), we consider the following assumptions: (1) the internal, external and international policies make up a continuum of decision-making; and (2) foreign policy is no different from other public policies. These assumptions support each other in order to allow the conception of the foreign policy decision-making process within the framework of policy analysis (Sanchez et al., 2006). Currently, there is a growing connection between domestic and international policies, which requires that national decision-making processes start to consider, more explicitly, international trends and dimensions - internal policies are becoming increasingly internationalized while international politics is progressively internalized<sup>2</sup> (Silva; Spécie; Vitale, 2010).

In this context, we propose a rigorous investigation of the legal or non-legal provisions and public policies implemented by the Brazilian government, as well as thematic programs, specific actions or international cooperation that may include the elements envisaged by the GSPOA. By crossing information between the actions carried out by Brazil and the provisions of Resolution WHA61.21, we expect to confront situations that hinder the implementation in Brazil of a new thinking about innovation and access to medicines, with the purpose of contributing to the debate related to the triad of public health, innovation and intellectual property. Therefore, we hope to foster discussions related to access problems caused by the current international intellectual property system and the lack of innovation, especially for diseases that disproportionately affect developing and relatively less developed countries.

The time frame positivated initially in the GSPOA, which ranged from 2008 to 2015, was considered. However, due to the systematic

---

<sup>2</sup> A theoretical basis that advanced in this diagnosis was made by Helen Milner (1997). In her work named “Interest, Institutions and Information” took advantage of a theoretical approach addressing the relationship between internal, external and international policies and, based on the methodology of Robert Putnam’s two-level game theory, sought to incorporate into this model the role of actors other than states. From this review, Helen Milner suggests that decision-making processes, structured as polyarchies, form a continuum - from national to international and vice versa.

dynamics that encompasses the development of policies, whether its internal, external or international, one must consider that certain elements posited within the scope of the GSPOA were already practiced internally by Brazil before the advent of Resolution WHA61.21. Other elements, in turn, even though they have already been included in the national political and normative structure in the proposed time frame, had considerable developments beyond the specified interstice and, eventually, were appreciated with due scientific robustness. To improve the quality of this investigation, we took into account this dynamism that characterizes the scenario of public policies, while never losing sight of the considered time frame.

Thus, this investigation is considered a case study that, as a method for qualitative research, is applied when the researcher seeks an extensive understanding that is more focused on objectivity and conceptual validity rather than a statistical validity about the worldview of popular sectors. There is also interest in the perspectives that point to a civilization project that is identified with the history of these groups, as well as the product of their dreams and utopias (Rocha, 2008).

Regarding the methodological steps for the case study - or how to do a case study -, André (2008), quoting Nisbett and Watts (1978), states that, as a rule, three distinct phases must be fulfilled: (1) exploratory phase; (2) data collection phase; and (3) data analysis phase. In the exploratory and data collection phases, we selected qualitative research approaches from primary and secondary sources, gathering as much information as possible about the triad of public health, innovation and intellectual property, notably in relation to the texts of the international agreements, information, data, and reports extracted from Brazilian government agencies - Ministry of Health (MS); Ministry of Science, Technology and Innovation (MCTI); Ministry of Development, Industry, and Foreign Trade (MDIC); Ministry of Foreign Affairs (MRE); National Health Surveillance Agency (ANVISA); Brazilian Cooperation Agency (ABC); FIOCRUZ;

and National Institute of Industrial Property (INPI) - and international organizations, such as WHO, WTO and World Intellectual Property Organization (WIPO). We also examined Brazilian public policies related to health R&D, innovation and production of health products, application and management of intellectual property in health, and the promotion of innovative and sustainable mechanisms in R&D.

For the analysis of selected documents, the method of content analysis used by Bardin (2009) was adopted in the methodological stage for two fundamental reasons: (1) its procedures allow an analysis based on inferences extracted from the contents of the document, starting from a controlled interpretation by variables or indicators that provide greater freedom to the analyst, without losing the objectivity of the investigation; and (2) because the analysis is based on specific policies and actions by Brazilian implementers, in addition to official documents from national and international government agencies, whose form are homogeneous. Thus, the choice of a method aimed primarily at content is the most appropriate practice for research whose documents analyzed have a high degree of homogeneity in terms of form (Guimarães; Sales, 2010).

The first element of GSPOA determines the establishment of an order of priority for R&D needs. It reinforces the need to develop methodologies and mechanisms to identify the gaps in research on diseases with a higher incidence in developing or relatively less developed countries. From this point, it is necessary to disclose these gaps and evaluate their consequences on public health, guiding the development of therapeutically viable products at affordable prices. To accomplish that, there is a subdivision of this element in three sub-items, which in turn result in 13 action points. The sub-element 1.1, points A, B and C, and the sub-element 1.2, point D, have the World Health Organization as the responsible its implementation, with the governments supporting its action (WHO, 2008). Therefore, for the purpose of delimiting this investigation, the analysis will focus on the

nine action points that place governments as protagonists for the achievement of the goals.<sup>3</sup>

## Results and discussion

Sub-element 1.2-A of the GSPOA refers to the definition of research priorities, in order to meet public health demands and implement policies in this area based on needs assessments in an appropriate and regular manner. In this context, the National Agenda for Health Research Priorities (ANPPS) deserves mention. Published in 2006, it was revised in 2010 and its premise is “to respect national and regional health needs and increase selective induction for the production of knowledge and material and procedural goods in the priority areas for the development of social policies” (Brasil, 2015a, p. 13).

ANPPS is comprised of 24 health research sub-agendas: (1) health of indigenous peoples; (2) mental health; (3) violence, accidents and traumas; (4) health of the black population; (5) non-communicable diseases; (6) health of older adults; (7) child and adolescent health; (8) women’s health; (9) health of people with special needs; (10) food and nutrition; (11) bioethics and ethics in research; (12) clinical research; (13) health production complex; (14) technology assessment and health economics; (15) epidemiology; (16) demography and health; (17) oral health; (18) health promotion; (19) communicable diseases; (20) health communication and information; (21) work management and health education; (22) health systems and policies; (23) health, environment, work and biosafety; and (24) pharmaceutical assistance. The agenda also has several lines of research related

to neglected diseases, mainly in the sub-agenda of communicable diseases (Brasil, 2015a).

As for the research topics, the following criteria were adopted to define priorities: (1) disease burden, measured in terms of DALY (Disability Adjusted Life Years) or other indicators; (2) analysis of the determinants of disease burden according to the different levels of intervention: individual, family, community; health ministry, system and health services; research institutions; government policies; and other sectors with an impact on health; (3) state of the art of available scientific and technological knowledge; (4) cost-effectiveness of possible interventions and the possibility of success; (5) effect on equity and social justice; (6) ethical, political, social and cultural acceptability; (7) possibility of finding solutions; (8) scientific quality of the proposed research; and (9) feasibility of human and financial resources (Brasil, 2015a).

Through epidemiological, demographic and disease impact data, seven priorities for action that make up the program in neglected diseases were defined among the diseases considered as neglected: (1) dengue; (2) Chagas disease; (3) leishmaniasis; (4) leprosy; (5) malaria; (6) schistosomiasis; and (7) tuberculosis (Brasil, 2015a).

On the other hand, the sub-element 1.2-B of the GSPOA determines that appropriate research should be conducted for places with few resources, as well as studies on technologically suitable products, according to public health needs, to combat diseases in developing countries. Thus, regarding this action point, it is worth mentioning the Research Program for the Brazilian Unified Health System (PPSUS), which is an initiative to promote health research in the federative units

3 Subelement 1.2-A: set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments. Subelement 1.2-B: conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries. Subelement 1.2-C: include research and development needs on health systems in a prioritized strategy. Subelement 1.2-D: urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for research and development to address public health needs. Subelement 1.2-E: increase overall research and development efforts on diseases that disproportionately affect developing countries, leading to the development of quality products that address public health needs, and that are user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability). Subelement 1.3-A: set research priorities in traditional medicine. Subelement 1.3-B: support developing countries to build their capacity in research and development in traditional medicine. Subelement 1.3-C: promote international cooperation and the ethical conduct of research. Subelement 1.3-D: support South-South cooperation in information exchange and research activities. Subelement 1.3-E: support early-stage drug research and development in traditional medicine systems in developing countries (WHO, 2008).

(FU), promoting scientific and technological development, aiming to meet the peculiarities and specificities of each Brazilian state and contribute to the reduction of regional inequalities. The objectives of PPSUS are: (1) financing research on priority topics for the health of the Brazilian population; (2) promoting the approximation of local health, science and technology systems; (3) reducing regional inequalities in science, technology and innovation in health; and (4) promoting equity (BRASIL, 2014a).

Sub-element 1.2-C of the GSPOA encourages WHO Member States to include research and development needs in health systems in a priority strategy. In this context, the Ministry of Health has been implementing, over the last few years, a results-oriented management model that aims to ensure the expansion of quality access to health services. This has been a challenging endeavor, based on planning, monitoring and evaluation strategies, in a context in which health is an integral part of the country's development. Thus, the Strategic Planning of the Ministry of Health was prepared for the period from 2011 to 2015. At the time, 16 strategic objectives were defined and validated, which then became institutional guidelines and configured a new framework of strategic guidelines for the institution (Brasil, 2014b).

Regarding Strategy No. 7, the Result No. 2 consisted of the elaboration of a plan for technological development and the production of drugs for neglected diseases, under the responsibility of FIOCRUZ (Brasil, 2014c).

It should also be noted that for scientific and technological research activities to contribute to the improvement of actions to promote, protect and recover the health of the population, they must have as a reference the priorities defined by the health policy. Aware of this condition, the Ministry of Health made an effort to map demands and to identify priority research topics.

This mobilization process, which involved all departments of the ministry, ANVISA, the National Supplementary Health Agency (ANS) and FIOCRUZ, resulted in the elaboration of a document composed of research priorities converging with the current needs of national health policy, called

Strategic Research for the Health System (PESS). This dialogue between the strategic planning of the Ministry of Health, which is guided by the national health policy, and the R&D needs aims to align the priorities of the federal government in the area of health with scientific and technological research activities, involving the Health Network Formation and Quality Improvement Project (QualiSUS) and the Institutional Development Program of the Brazilian National Health System (Proadi-SUS) (Brasil, 2011a).

Sub-element 1.2-E of the GSPOA recommends increasing global R&D efforts for diseases that disproportionately affect developing countries, leading to the development of quality products that meet public health needs and are easy to use (in terms of use, prescription, and management) and accessible (in terms of availability and accessibility).

Regarding the participation of Brazil in global R&D efforts for these diseases, and considering the availability and accessibility of products that meet the needs of health systems, it is worth mentioning the partnership within the scope of Therapeutics for Rare and Neglected Diseases (TRND). It is an initiative embodied by the National Institutes of Health (NIH). Located in the United States of America, it comprises 27 research centers.

NIH's cooperation with Brazilian scientists is supported by cooperation instruments, such as: (1) Memorandum of Understanding in Health and Medical Sciences between the United States Department of Health and Human Services (HHS) and the Ministry of Health of Brazil, signed in September 2015 (Brasil, 2015b); and (2) Letter of Intent between the National Institutes of Health (NIH), the Ministry of Health (MS) and the Ministry of Science, Technology and Innovation (MCTI), signed in June 2014 (BRASIL, 2014d).

Another initiative that is worth mentioning is the Global Network for Neglected Tropical Diseases, an initiative of the Sabin Vaccine Institute. The network seeks to overcome logistical and financial barriers to offer treatments against neglected diseases to people who have high level needs, as stated on its website. One of the Brazilian government's partnerships with this initiative is realized through the development of the vaccine against human hookworms, using the

Na-GST-1 antigen, whose clinical trial (phase 1) was carried out in 2012 by FIOCRUZ.

Brazil is also a partner of the Special Program for Research and Training in Tropical Diseases, a global scientific collaboration initiative established in 1975. Its focus is to improve health and well-being of people burdened by neglected infectious diseases through research and innovation. TDR is hosted by WHO and is sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Program (UNDP), the World Bank and WHO itself. Another relevant initiative is the United to Combat Neglected Tropical Diseases initiative, also called the London Declaration on Neglected Tropical Diseases. It is made up of a group of international partners - governments, the pharmaceutical industry and non-governmental organizations (NGOs) - led by the Bill & Melinda Gates' Foundation, in order to accelerate progress towards eliminating or controlling 10 neglected tropical diseases (NTDs) by 2020.

The sub-element 1.3-A of the GSPOA determines the definition of research priorities in traditional medicine. Sub-element 1.3-B, in turn, reinforces the need to support developing countries in building their R&D capacity in traditional medicine. Sub-element 1.3-C encourages the promotion of international cooperation and ethical conduct in research involving traditional medicine. Sub-element 1.3-D encourages South-South cooperation in the exchange of information and research activities. Finally, sub-element 1.3-E reinforces support for research and development of drugs that are in an early stage in traditional medicine systems in developing countries.

In this context, the aforementioned ANPPS contemplates, in item 22.4.4, "Studies on natural medicine and complementary health practices in SUS, such as: homeopathy, acupuncture, traditional Chinese medicine, anthroposophical medicine, phytotherapy and body practices" (Brasil, 2015a, p. 58).

Likewise, the document that provides the PESS reinforces the priority of research in traditional medicine. In this case, it addresses the need to promote "Studies that fill the gaps in the development of herbal medicines from medicinal plants from the Brazilian flora, prioritizing species

that generate products for SUS" (BRASIL, 2011a, p. 72). Such prioritization includes the Strategic Planning mandates of the Ministry of Health from 2011 to 2015, as well as the planned initiatives of the 2012-2015 Pluriannual Plan (PPA) in relation to the strategic objective No. 12, especially regarding the item "(19) Production of drugs, medicines and herbal medicines" (BRASIL, 2011a).

As for international cooperation, according to the Management Report 2006/2010 of the National Coordination of Integrative and Complementary Practices, in the period from 2008 to 2010 Brazilian experts participated in international missions in Argentina, Peru, China, Republic of Congo, Democratic Republic of Congo, Burkina Faso and Mozambique. A cooperation agreement was signed with the latter in relation to the training of health professionals in community therapy (Brasil, 2011b). It is also noteworthy that the Brazil-China Joint Action Plan in Health, formalized in 2011. This plan includes, among other areas, cooperation in the field of traditional Chinese medicine.

Regarding the II BRICS Health Ministers Meeting, the final document, also known as Delhi Communiqué, stated that:

The Ministers acknowledged the value and importance of traditional medicine and need of experience and knowledge-sharing for securing public health needs. They urged for cooperation amongst the BRICS countries through visits of experts, organization of symposia to encourage the use of traditional medicine, in all spheres of health. (BRICS..., 2013)

In addition, there is cooperation within the scope of the Community of Portuguese Speaking Countries (CPLP), as noted in the CPLP Strategic Health Cooperation Plan (Pecs/CPLP), for the period from 2009 to 2012. In its Strategic Axis No. 7, "Health Promotion and Protection", it is provided the objective of the "Promotion of the exchange of innovative experiences in the field of health promotion." The structuring project, in this context, is guided by: "7.2 Implementation of a program to raise awareness among healers, witches and other traditional doctors and midwives for the recognition

and derivation of specific pathologies to the health system” (CPLP, 2009, p. 12).

As for the promotion of ethical conduct in research involving traditional medicine, it should be noted that there is a close relationship between traditional medicine and the indigenous peoples. The National Policy on Health Care for Indigenous Peoples, made official by the Ministry of Health through Ordinance No. 254, of January 31, 2002, has among its guidelines the “promotion of ethics in research and in health care actions involving indigenous communities,” further stipulating that the body responsible for carrying out health care actions for indigenous peoples, together with the official indigenous body, will adopt and promote compliance with Resolution No. 196/1996 of the National Health Council (CNS), which regulates the conduct of research involving human beings, and Resolution No. 304/2000, which concerns the special theme of research involving indigenous populations (Brasil, 2002).

CNS’s Resolution No. 466, of December 12, 2012, on the other hand, asserted that research involving human beings in any area of knowledge must observe, among other requirements, the proof, the commitments (in the case of research conducted abroad or with foreign cooperation), and the advantages for the research participants and for Brazil, that resulted from its realization (Brasil, 2013). Furthermore, in research with foreign cooperation conceived at an international level, the term of free and informed consent must be adapted, by the responsible researcher, to the ethical norms and local culture. It must always be written with clear and accessible language, specially to research participants, taking special care of making it easily readable and understandable.

The devices related to research ethics, including international cooperation, especially when it comes to traditional medicine and indigenous peoples, find support in national legislation, both ordinary and non-legal.

Regarding support for the research and development of medicines within the scope of traditional medicine systems, it should be noted that Brazil instituted, through Presidential Decree No. 5,813, of June 22, 2006, the National Policy on

Medicinal Plants and Herbal Medicines. This was a multisectoral initiative, involving the ministries of Health, Environment and Social and Economic Development, aimed at improving the population’s access to medicinal and herbal plants, to social and regional inclusion, to industrial and technological development and to the promotion of food and nutritional security, in addition to the sustainable use of Brazilian biodiversity and the appreciation and preservation of traditional knowledge associated with traditional communities and peoples. Already within the time frame proposed for this study, the Interministerial Ordinance No. 2,960, of December 9, 2008, approved the National Program for Medicinal Plants and Herbal Medicines (PNPMF) and created the National Committee for Medicinal Plants and Herbal Medicines (Brasil, 2009).

Such initiatives are essential to promote support for research and the development of potential drugs that are linked to the institute of traditional medicine and that are still in the initial phase of studies. In February 2009, the National List of Medicinal Plants of Interest to SUS (ReniSUS) was released. Phytotherapies were included in the list of strategic products for SUS, according to Ordinance of the Minister’s Office (GM)/MS No. 3.089/2013. And, still in 2009, the Seminar “Industrial Complex of Health and Phytotherapies” was held to promote integration between the academic, productive, and service sectors and the Ministry of Health and, thus, identify the potential for phytotherapeutic production.

Among other initiatives undertaken by the Brazilian government regarding research, technological development and innovation that involves medicinal plants and herbal medicines, we mention the Public Consultation of the Secretariat of Science, Technology and Strategic Inputs (SCTIE) No. 28/2014. It includes nine monographs on medicinal plants of interest to SUS: *Alpinia* sp., *Calendula officinalis*, *Lippia* sp., *Plantago major*, *Plantago ovata*, *Polygonum* sp., *Schinus terebinthifolius*, *Stryphnodendron adstringens* and *Vernonia condensata*. In the second half of 2013, the Foundation for Technological and Scientific Development in Health (FIOTEC)/FIOCRUZ opened a selective process for hiring 26 scholars

to produce monographs about the plant species listed in ReniSUS.

In 2014 and 2015, the Ministry of Health (MS) published the Public Notices No. 1 and No. 2 from its Secretariat of Science, Technology and Strategic Inputs (SCTIE/MS), which established the selection process of projects to support pharmaceutical assistance in medicinal and herbal plants and the local productive arrangement of medicinal and herbal plants within the scope of SUS, in addition to the development and sanitary registration of herbal medicines by the National List of Essential Medicines (RENAME), through public laboratories. Such initiatives seek to support the structuring, consolidation and strengthening of local productive arrangements within the scope of the PNPMF, with the purpose of invigorating pharmaceutical assistance and the production complex in medicinal and herbal plants in municipalities and states, contributing to transformative actions in the context of health, the environment and living conditions of the population.

The Brazilian government edited Law No. 13,123, of May 20, 2015, which provides for access to genetic heritage, the protection and access to associated traditional knowledge and the sharing of benefits for conservation and sustainable use of biodiversity. This legal act was later regulated by Decree No 8,772, of May 11, 2016. Both reveal the economic importance of traditional medicine and the concern about issues involving intellectual property and professional regulation. This is due to the fact that, as traditional medicine is becoming more popular, it is important to balance the need to protect rights and recognize the traditional knowledge of indigenous peoples and traditional populations and communities, ensuring a fair sharing of benefits.

In May 2014, ANVISA's collegiate board approved two regulations on phytotherapeutic products. The agency updated the registration of phytotherapeutic medicines and created the registration and notification of traditional phytotherapeutic products. The Resolution of the Collegiate Board (RDC) No. 26/2014 defines how the registration or notification of traditional products should be carried out. The document is followed by the Normative Instruction No. 2/2014, which lists phytotherapeutic medicines

and traditional products that can have simplified registration in ANVISA. RDC n° 38/2014 provides for the execution of post-registration petitions for phytotherapeutic medicines and traditional phytotherapeutic products and establishes other measures on the matter.

Hasenclever et al. (2017) analyzed the development of the medicinal plant and herbal medicine industry in Brazil between 2009 and 2015 - therefore, in a period close to the time frame of this study. The authors' research pointed to a setback both in productive activities with phytotherapeutic medicines and in research activities with medicinal plants in the period. This was observed due to the slow implementation of public policies aimed at the industry, thus impacting research, due to the delay in the regulation of the law on access to genetic heritage and production, due to the lack of harmonization of regulation in the entire production chain of the medicinal plant and phytotherapeutic medicine industry.

The authors note that the aforementioned legislation is sometimes complex and corroborates a weak institutional framework and a legal uncertainty in R&D involving biodiversity. The relationship between the most diverse actors in the production chain, from basic research to production, involving government control organizations (Genetic Heritage Management Council - CGEN, ANVISA, Science and Technology Institutes - ICT, Incorporation and Transfer Centers of Technology - NIT and the pharmaceutical industry), is hampered by the difficulty of coordinating so many bureaucratic instances that interfere in the phytotherapeutic production chain. Researchers who study the impact of medicinal plants and phytotherapeutic medicines in treating neglected diseases, such as leishmania and malaria, in many cases do not have interaction with CGEN, the organization responsible for monitoring and standardizing guidelines for access to genetic heritage and the associated traditional knowledge. Therefore, there is no coordinated coordination between the organizations that act in the regulation of the various stages of its production chain (Hasenclever et al., 2017).

However, in the context of this study, it is noticed that the Brazilian government's effort

to standardize, regulate and foster research and development of drugs that are in the initial stage, in traditional medicine systems, finds sustainability regarding the establishment of an order of priority of R&D needs, as proposed by element 1 of the GSPOA. Thus, the edition of the PNPMF and the National Committee for Medicinal and Phytotherapeutic Plants, as well as the publication of public notices and cooperation terms involving R&D of medicinal and phytotherapeutic plants, the divulgation of ReniSUS, the inclusion of phytotherapeutic medicines in the list of strategic products for the SUS and the enactment of Law No. 13,123/2015 and RDC/ANVISA No. 26/2014 and No. 38/2014 are properly aligned with the assumptions made in the GSPOA policy.

## Final considerations

The approval of GSPOA, within the scope of WHO, is part of a broad context of perception of the need to improve the conditions of access of developing countries to medicines and other products that meet their specific public health needs.

This study analyzed the implementation of the first element of the GSPOA, which determines the establishment of an order of priority for research and development needs. We observed that the development of mechanisms to identify the gaps in the research of diseases of higher incidence occurred in Brazil. Likewise, these gaps were publicized, allowing to assess their consequences on public health and guiding the development of therapeutically viable and affordable products.

ANPPS, PPSUS, and PESS encompass some of the policies implemented in the period. It must be considered that in order to contribute to the improvement of actions of promotion, protection and recovery of the health of the population, scientific and technological research activities should have the priorities defined by the health policy as a reference. Aware of this condition, the MS promoted an effort to map demands and identify priority research topics.

Based on the principle that innovation should be seen in the perspective of expanding the effectiveness of health services, we concluded that

it is up to research and accumulated scientific production to contribute to assess the potential for inclusion of SUS and the realization of the right to health. However, it is axiomatic in Brazil challenges for the implementation of a solid and sustainable basis for health R&D within the framework recommended by GSPOA still exists, despite the establishment of priority elements for research and development in the health sector. Therefore, it is essential that the development of the productive forces does not generate social relations that are exclusive and disconnected from social needs.

In future investigations, it is necessary to examine the other elements in the GSPOA, which addresses the promotion of R&D activities, technology transfer, application and management of the intellectual property regime and the promotion of sustainable financing mechanisms, in order to identify the gaps that limit the formulation of strategies and that place the universal health system in a central position within the scope of State policies, promoting the reconsideration of the systemic relationship between pharmaceutical research, commercial interest and public health assistance.

## References

- ALMEIDA, C. Saúde, política externa e cooperação Sul-Sul em saúde: elementos para a reflexão sobre o caso do Brasil. In: FUNDAÇÃO OSWALDO CRUZ. *A saúde do Brasil em 2030*. Rio de Janeiro, 2014. p. 233-327. v. 1.
- ANDRÉ, M. E. D. A. *Estudo de caso em pesquisa e avaliação educacional*. Brasília, DF: Liber Livros, 2008.
- BARDIN, L. *Análise de conteúdo*. Lisboa: LDA, 2009.
- BIEHL, J. Antropologia no campo da saúde global. *Horizontes Antropológicos*, Porto Alegre, v. 17, n. 35, p. 227-256, 2011.
- BRASIL. Ministério da Saúde. Portaria nº 254, de 31 de janeiro de 2002. *Diário Oficial da União*, Brasília, DF, 31 jan. 2002. Disponível em: <<https://bit.ly/3aVkaVf>>. Acesso em: 5 abr. 2020.

- BRASIL. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Assistência Farmacêutica e Insumos Estratégicos. *Programa Nacional de Plantas Medicinais e Fitoterápicos*. Brasília, DF, 2009.
- BRASIL. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Ciência e Tecnologia. *Pesquisas estratégicas para o sistema de saúde: PESS*. Brasília, DF, 2011a.
- BRASIL. Ministério da Saúde. Secretaria de Atenção à Saúde. Departamento de Atenção Básica. Coordenação Nacional de Práticas Integrativas e Complementares. *Relatório de gestão 2006/2010: práticas integrativas e complementares no SUS*. Brasília, DF, 2011b.
- BRASIL. Ministério da Saúde. Conselho Nacional de Saúde. Resolução nº 466, de 12 de dezembro de 2012. *Diário Oficial da União*, Brasília, DF, seção 1, p. 59, 13 jun. 2013. Disponível em: <<https://bit.ly/2VcDkzi>>. Acesso em: 5 abr. 2020.
- BRASIL. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Ciência e Tecnologia. *Encontro Nacional do PPSUS: iniciativas inovadoras de pesquisa em saúde - Programa Pesquisa para o SUS: gestão compartilhada em saúde - PPSUS*. Brasília, DF, 2014a.
- BRASIL. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Ciência e Tecnologia. *Programa de Pesquisa para o SUS: gestão compartilhada em saúde - Diretrizes técnicas*. 5. ed. Brasília, DF, 2014b.
- BRASIL. Ministério da Saúde. Secretaria-Executiva. Departamento de Monitoramento e Avaliação do SUS. *Planejamento estratégico do Ministério da Saúde: 2011-2015 - resultados e perspectivas*. 3. ed. Brasília, DF, 2014c.
- BRASIL. *Carta de intenções entre o National Institutes of Health (NIH), o Ministério da Saúde (MS) e o Ministério de Ciência, Tecnologia e Inovação (MCTI)*. Brasília, DF, 2014d.
- BRASIL. Ministério da Saúde. *Agenda nacional de prioridades de pesquisa em saúde*: Brasil. 2. ed. 4. reimp. Brasília, DF, 2015a.
- BRASIL. *Memorando de entendimento em saúde e ciências médicas entre o Departamento de Saúde e Serviços Humanos dos Estados Unidos da América (HHS) e o Ministério da Saúde do Brasil (MS)*. Brasília, DF, 2015b.
- BRICS Health Ministers' Communiqué. *BRICS Information Centre*, Deli, 11 jan. 2013. Disponível em: <https://bit.ly/2zfdFi8>. Acesso em: 5 maio 2019.
- BROWN, T. M.; CUETO, M.; FEE, E. A transição de saúde pública “internacional” para “global” e a Organização Mundial da Saúde. *História, Ciências, Saúde - Manguinhos*, Rio de Janeiro, v. 13, n. 3, p. 623-647, 2006.
- BUSS, P.; CHAMAS, C. Um novo modelo para a pesquisa em saúde global. *Valor Econômico*, São Paulo, 31 ago. 2012. Disponível em: <<https://glo.bo/39UfihF>>. Acesso em: 5 abr. 2020.
- CPLP - COMUNIDADE DOS PAÍSES DE LÍNGUA PORTUGUESA. *Plano estratégico de cooperação em saúde da CPLP (Pecs/CPLP) 2009-2012*. Lisboa, maio 2009. Disponível em: <https://bit.ly/2L8uFsR>. Acesso em: 5 maio 2019.
- GUIMARÃES, J. A. C.; SALES, R. *Análise documental: concepções do universo acadêmico brasileiro em Ciência da Informação*. São Paulo: Unesp, 2010.
- HASENCLEVER, L. et al. A indústria de fitoterápicos brasileira: desafios e oportunidades. *Ciência e Saúde Coletiva*, Rio de Janeiro, v. 22, n. 8, p. 2559-2569, 2017.
- MILNER, H. *Interest, institutions and information: domestic politics and international relations*. Princenton: Princeton University, 1997.
- ROCHA, J. C. *A reinvenção solidária e participativa da universidade: um estudo sobre redes de extensão universitária*. Salvador: Edueb, 2008.
- SANCHEZ, M. R. et al. Política externa como política pública: uma análise pela

regulamentação constitucional brasileira (1967-1988). *Revista de Sociologia e Política*, Curitiba, n. 27, p. 125-143, 2006.

SILVA, E. C. G.; SPÉCIE, P.; VITALE, D. *Atual arranjo institucional da política externa brasileira*. Brasília, DF: Ipea, 2010.

VELÁSQUEZ, G. The right to health and medicines: the case of recent negotiations on the global strategy on public health, innovation and intellectual property. *Research Papers n° 35*. Geneva: South Centre, 2011.

WHO - WORLD HEALTH ORGANIZATION. *Resolution WHA56.27*: intellectual property rights, innovation and public health. Geneva, 2003.

WHO - WORLD HEALTH ORGANIZATION. *Resolution WHA59.24*: public health, innovation, essential health research and intellectual property rights - Towards a global strategy and plan of action. Geneva, 2006.

WHO - WORLD HEALTH ORGANIZATION. *Resolution WHA61.21*: global strategy and plan of action on public health, innovation and intellectual property. Geneva, 2008.

---

Received: 17/12/2018  
Resubmitted: 17/06/2019  
Approved: 03/03/2020