http://www.periodicos.uem.br/ojs/index.php/CiencCuidSaude
ISSN on-line1984-7513
DOI 10.4025/cienccuidsaude.v20i0.57685

ORIGINAL ARTICLE

REGULATION OF HEALTH TECHNOLOGIES IN BRAZIL: A DOCUMENTAL RESEARCH

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ABSTRACT

Objective: To analyze the main laws in the history of the regulation of the use of healthcare technologies in Brazil. **Method**: Documentary, exploratory research with a qualitative approach. Data collection took place between April and August 2019 on the National Press website, in Section 1 of the Official Gazette of the Union, with a historical clipping from September 1990 to July 2019, through the phonetic search for the expression 'healthcare technology'. Initially, 33,669 records were obtained. The final sample consisted of 11 documents, using the content analysis technique. **Results**: Data were divided into two categories of analysis: "Outline of the healthcare technologies area in the country" and "Dissemination of the use of healthcare technologies". Until the mid-2000s, guidelines for establishing the use of technologies as part of health policies were prioritized. In the subsequent period, there is an evolution in the planning of supply, production, evaluation, and incorporation of technologies by health services, as well as the development of the Health Industrial Complex. **Final considerations**: The responsible production and incorporation of healthcare technologies depend directly on investment in research and scientific innovation, and also it is linked to the country's economic and social development.

Keywords: Unified Health System.Biomedical technology.Technological development.Legislation as a topic.

INTRODUCTION

The "healthcare technologies" mean the application of knowledge organized through devices; medicines; health products, vaccines; procedures; organizational, educational, information and support systems; assistance programs and protocols – developed to provide health care. Thus, it is intrinsic to debate the technologies used in the Unified Health System (SUS)[1].

The correct use of these resources can give greater benefits, safer and more effective care for SUS patients, and greater safety and comfort for their families and caregivers. Therefore, these technologies must be adequate to the health needs of the population, associated with a rigorous evaluation for their use[2].

The incorporation of technologies can be one of the main factors responsible for the increase in the costs of health systems in the world, especially products such as medicines, vaccines, equipment, orthotics/prostheses, and diagnostic tests[3]. In addition to the financial sustainability of the systems, the participation of the assessment process in the incorporation and use of technologies can also contribute to equity and access to health services[4].

In this context of growing debate on the use of health technologies, it is important to know the respective regulatory action in the country to then reflect on how to improve its process of construction and responsible incorporation in the SUS. Thus, this study aims to analyze the main laws in the history of the regulation of the use of health technologies in Brazil.

METHODOLOGY

This is a documentary, exploratory research

[1]Product of the dissertation entitled "Criteria for the Evaluation and Incorporation of Information Systems in the Unified Health System: recommendations based on dissemination and implementation science ", presented to the Graduate Nursing Program at the Federal University of Santa Catarina (UFSC), in 2021.

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with a qualitative approach. This methodology uses original documents that have not yet received any type of analytical treatment. It is up to the researcher, depending on his object of study, to select which types of the document will base his research[5].

We collected data onlineon the National Press website to which the *Diário Oficial da União* (DOU) is linked, with free access to official publications of the Brazilian government, available in digital form. The following search strategy was developed in the website *pesquisa.in.gov.br*, the term 'health technology' was inserted; the newspaper 'DOU1' was selected (Section 1), which reports all normative acts of the government. The type of search selected was 'phonetic' (which allowed the search for texts related to the main search term); in the field related to the period, the research was carried out year by year, placing the start and end dates of the desired publications.

The inclusion criteria were documents that were characterized as regulatory references for technological development in the health area, for the creation, evaluation, dissemination, and use of health technologies (medicines, health products, procedures, systems, and protocols) in the SUS and Supplementary Health. We excluded documents that dealt with budgetary provisions on the subject, composition of government agencies, results of requests for the incorporation of technologies, among others that did not address the scope of the research.

The historical perspective used in the research was from September 1990 to July 2019, a period referring to the officialization of the SUS from Law 8.080/90 (therefore, when it became possible to discuss the use of health technologies in the Brazilian public system) until nowadays.

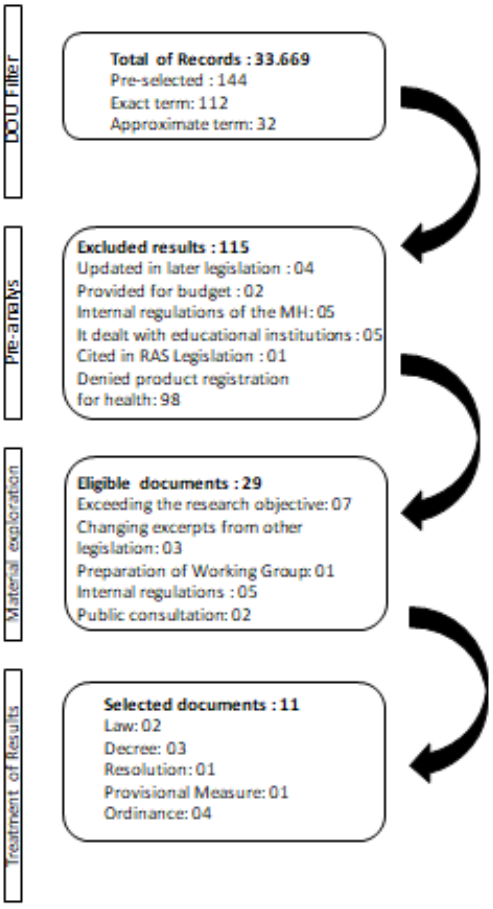

Figure 1. Flowchart of data collection, inspired by the PRISMA model[7].

The data were collected between April and August 2019 and entered into a Microsoft Excel® 365 table with the findings that kept a reference to the research object. The table for recording the results contained the following information: period searched, number of records initially found per period, results that contained the exact search term, results that contained a similar term/relation to the search (all followed by the access link for later analysis).

The content analysis technique evaluated the collected documents identifying the key concepts related to health technologies in Brazil. Content analysis[6] was subdivided into three interdependent stages: pre-analysis, material exploration, and treatment of results.

As procedures for this analysis, we made different filters on the collected material (figure 1). First, we read the titles of the results that appeared on the page of the *Diário Oficial da União* were read. After this first reading, the results were not inserted in the created table, based on the previously defined inclusion criteria. In a second filter, in addition to the titles, we read the justifications outlined by previous legislation and the first articles of the law, which contained in greater depth its legal purpose of the formulation. Finally, a complete reading of the selected legislations that would compose the final research sample was carried outto carry out the relevant categorization and interconnections

We obtained 33,669 records in the phonetic search for 'healthtechnology' in the Journal DOU1, during the period researched, between September 1990 and July 31, 2019. Of this total, considering both a full year (1991 to 2018) and partial year search (1990 and 2019), the year with the lowest number of occurrences was 1990, with only 34, and the largest number of occurrences was in 2017, with 2,331 in total. Considering only the complete search per year (January 1stto December 31st), the year with the lowest number of occurrences in the search was 1997, with only 60.

Of the total occurrences obtained, 144 were registered in the Excel® spreadsheet, which supported data collection during the pre-analysis period. Of these, 112 were occurrences with an exact search term, and 32, with a similar term.

Considering the years of search, 7 of them did not present any occurrence registered in the pre-analysis (1991, 1992, 1993, 1994, 1996, 1997, and 2000); 4 had 1 occurrence (1990, 1998, 2005, and 2010); 3 had 2 occurrences (1999, 2001 and 2004); 1 year had 3 occurrences (2002); 3 years had 4 occurrences (1995, 2012 and 2014); the year 2018 had 5 occurrences; the years 2006 and 2009 had 6 occurrences each; 2005 and 2008 had 7 occurrences each; 2013 presented 8 registered occurrences; 2017 had 9 occurrences; 2007 and 2011 had 10 occurrences; the year 2019 had 14 recorded occurrences; 2015 had 15 occurrences; 2016 was the year with the highest number of occurrences recorded in the table: 22 in total.

Continuing the analysis of the material, 115 records were excluded after rereading their titles and the legal purpose of the document. Thus, 29 were read in full, and after reading focused on meeting the research objective, 11 legislations were selected to compose the final analysis sample.

Among the reasons for excluding the documents, 98 cases containing approval or rejection of requests for registration of health products to be marketed in the SUS stand out, such as catheters, syringes, and medicines in general. The other reasons for exclusion are mixed between not responding to the research objective (7), regulations of specific bodies of the Ministry of Health (10), a term related to educational institutions, such as course titles or specializations (5), legislation updated later (7), budget provisions (2), public consultation document (2), term cited in legislation that deals specifically with Health Care Networks (1).

As this is research that used documents in the public domain and free access, approval by the Research Ethics Committee was not required.

RESULTS

Of the 11 documents chosen for analysis (Table 1), 4 were disclosed as Ordinances, 3 as Decrees, 2 as Laws, 1 as a Resolution, and 1 as a Provisional Measure. The results were organized into two categories of analysis entitled "Delineation of the healthcare technologies area in the country" (category 1) and "Dissemination of the use of healthcare technologies" (category 2).

Table 1. Documents analyzed according to type, date, historical relevance, and designated analysis category

Type of legislation and year	Historical relevance	Analysis Category
Law n. 8.080 of September 19, 1990[2]	It provides the conditions for the promotion, protection, and recovery of health, the organization and operation of the corresponding services, and other measures.	Category 1
Provisional measure n. 1685-5 of October 26, 1998[2]	It changes provisions of Law n. 9,656 of June 3, 1998, which provides for private health care plans and insurance, and other provisions.	Category1
Law n. 9,782 of January 26, 1999 [2]	It defines the National Health Surveillance System, creating the *Agência Nacional de Vigilância Sanitária* (ANVISA) and taking other measures.	Category1
Ordinance n. 1418 of July 24, 2003 [2]	It provides for the creation of the Science, Technology, and Innovation Council of the Ministry of Health.	Category1
Resolution 338 of May 6, 2004[2]	It approves the National Pharmaceutical Assistance Policy.	Category1
Ordinance n. 3,323 of December 27, 2006 [2]	It establishes the Commission for the Incorporation of Technologies in the scope of the Unified Health and Supplementary Health System (*Sistema Único de Saúde e da Saúde Suplementar*- CITEC).	Category1
Ordinance n. 978 of May 16, 2008 [2]	It provides for the list of strategic products, within the scope of the Unified Health System (SUS) to collaborate with the development of the Health Industrial Complex (*Complexo Industrial da Saúde* - CIS) and institutes the Commission for Reviewing and Updating that list.	Category2
Ordinance n. 2,690 of November 5, 2009[2]	It establishes, within the scope of the Unified Health System (SUS), the National Health Technology Management Policy.	Category2
Decree n. 7646 of December 21, 2011[2]	It provides for the National Commission for the Incorporation of Technologies in the Unified Health System (*Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde* - CONITEC) and the administrative process for the incorporation, exclusion, and alteration of healthcare technologies by the Unified Health System – SUS, and other measures.	Category2
Decree n. 9,245 of December 20, 2017 [2]	It establishes the National Policy for Healthcare Technological Innovation.	Category2
Decree n. 9,854 of June 25, 2019[2]	It establishes the National Internet of Things Plan and provides for the Chamber for Management and Monitoring the Development of Machine-to-Machine Communication Systems and the Internet of Things.	Category2

Category 1. Outline of the healthcare technologies in the country

From the advent of the SUS until the mid-2000s, the priority was to guarantee guidelines for the establishment of the use of technologies as part of health policies, focusing on their regulation in the SUS and private health institutions.

Law n. 8.080 describes scientific and technological development as one of the fields of action of the Unified Health System, being responsible for formulating policies on medicines, equipment, and other inputs for the health area, as well as participating in its production, control, and oversight. It also points out the resources and financing of research and technological development activities in health, with the presence of a proposal to carry out co-financing, encompassing the following actors: Health System, universities and fiscal budget, and resources from fostering or source institutions external and revenue of the executing institutions[2].

MP n. 1,685-5, from 1998, addresses issues related to the use of healthcare technologies in the sector of private health care plans and insurance. The Supplementary Health Council (*Conselho de Saúde Suplementar* - CONSU), a collegiate body that would integrate the regimental structure of the Ministry of Health, among its attributions, encompasses the regulation of the supplementary sector's activities on care content and models, adequacy, and use of health technologies. Inputs, products, and services continue to be regulated and

inspected by the National Supplementary Health Agency (*Agência Nacional de Saúde Suplementar*- ANS), as established by Law n. 9,656/98(2).

ANVISA´s institutional purpose is to protect the health of the population and is responsible for carrying out the sanitary control of the production and commercialization of products and services, as well as the environments, processes, inputs, and related technologies within the scope of the public health system. It is ANVISA's role to demand the accreditation of laboratories and services for the control of risks to the health of the population, including those involving the incorporation of new technologies; inspecting products for human use, inputs, and technologies; make the incorporation of new technologies subject to the agency's sanitary control and inspection[2].

The Science, Technology and Innovation Council of the Ministry of Health is responsible for defining the bases of the National Policy on Science, Technology, and Innovation in Health, in addition to thinking about the entire model and management process for scientific and technological development within the scope of the Ministry of Health (MH), and establish research priorities in the area. The National Health Surveillance Agency becomes part of the composition of this council[2].

The National Pharmaceutical Assistance Policy is considered relevant to the healthcare technologies area. Pharmaceutical assistance is understood as one of the public policies that should guide the formulation of many other sectorial policies, including science and technology, in addition to related policies to medicines. Its strategic axis of action is intersectoral articulation for the implementation of a public policy for scientific and technological development involving research centers and Brazilian universities, with the primary objective of technological development aimed at SUS priorities[2].

CITEC assumes the mission of deliberating on requests for the incorporation of technologies, analysis of technologies in use, review, and changes to protocols with a focus on both the SUS and supplementary healthcare[2].

Category 2. Dissemination of the use of healthcare technologies

In 2008, there has been an evolution in the planning of supply and production of technologies, focusing on strengthening national production through partnerships with public and private entities, expanding the Health Industrial Complex (*Complexo Industrial da Saúde*- CIS), and improving evaluation processes for the incorporation of technologies, with greater emphasis on medicines and health products.

The list made official in Ordinance n. 978 has medicines, vaccines, blood products, products for the diagnosis, treatment, monitoring, among the products described as strategic for the SUS, aimed at health needs. The justifications for establishing this list, to strengthen the CIS, range from the economic order and freedom described in the Federal Constitution to the Cooperation and Technical Assistance Term signed between the Ministry of Health and the National Bank for Economic and Social Development[2].

In the National Health, Technology Management Policy instituted, which only considers the public sphere, there is an advance in terms of the conceptualization of important terms for the area, such as the very concept of “management”. It establishes a commitment to the incorporation of technologies that are economically sustainable, safe, and evaluated through scientific evidence[2].

CONITEC assumes the role of advising the MH regarding the incorporation, exclusion, and alteration of technologies for the SUS. Deadlines, flows, cost-effectiveness, conflicts of interest, and other issues that permeate the analysis of technologies are described. “Healthcare technologies” are conceptualized, listing drugs, products, procedures, information systems, and care protocols. Since its establishment, private companies and public representatives can apply for an evaluation process for the incorporation of healthcare technologies[2].

The main focus of the National Policy on Technological Innovation in Health is the regulation of the use of the State's purchasing power in contracts and acquisitions involving strategic products for the SUS, within the scope of the CIS, which is redefined in this policy. The objectives of this policy are to encourage

technological innovation, the creation of public-private partnerships, research, and the creation of technologies in the national territory for use in the SUS, considering the increase in the country's productive capacity and innovation[2].

Ending this historic path through legislation related to healthcare technologies, the National Internet of Things Plan has as its founding objectives to implement and develop the Internet of Things (IoT) in the country, based on free competition and free circulation of data, observing the information security and data protection guidelines. In this plan, IoT (described as an infrastructure that integrates the provision of value-added services with physical or virtual connection capabilities of things with information technology-based devices) does not refer, at any point of its objectives, to the health area specifically. However, it cites scientific and technological development and the increase in the population's quality of life as such. The Ministry of Health, together with four other ministries, becomes the occupant of one of the seats in the IoT Chamber created in this decree[2].

DISCUSSION

The document that started this historic remnant of the regulation of healthcare technologies in Brazil is Law n. 8.080/90, known as the Organic Health Law (*Lei Orgânica da Saúde*- LOS), in which the SUS was first described and organized, after the achievement of the social right to health made official in the 1988 Constitution. In this law, medicines and health equipment are mentioned as the first types of health technology legally mentioned[2].

The development and distribution of medicines, supplies, and equipment for health services need to be aligned with public health needs and are historically essential to improve the quality of life and survival of the population. In this sense, the regulation, safety, efficacy, and quality of medicines need to be controlled and guaranteed by the State. Technological evolution must be accompanied by the development of methodologies and legislation that guarantee the quality of medicines[8], supplies, and equipment created.

Health research is essential for the development and strengthening of the SUS and should be considered both in the biomedical and clinical and epidemiological fields.[3]Therefore, these efforts are directly associated with the development of the healthcare technologies area. However, even foreseen since the institution of LOS, technological development in the area is still a challenge in the country.

A study aimed at analyzing new medicines registered in Brazil from 2003 to 2013, from the perspective of the burden of disease and pharmaceutical care in the SUS, showed a disproportionate relationship between the percentage of new medicines and the burden of disease, with a deficiency the sector in the drug registrations for infectious respiratory, cardiac and digestive diseases, denoting the importance of encouraging research and development of drugs that meet the country's health needs[9].

Investing in research and development is essential for the growth of any nation, as it helps social transformation while boosting the economy. Despite this, it is possible to observe that investment in research is still insufficient in Brazil, both from the government and from the private sector[10].

The appearance of the private sector in the original text of the LOS (described several times and with regulated complimentary participation in the different fields of action of the SUS) can be considered a reflection of the government in office at that historical moment, which, despite the achievement of a constitution that considers, essentially, the State as a provider of the population, initiates an outline of neoliberalism in the governments of the 1990s[11]. This posture is also present in subsequent periods, and from 1998 onwards, there are publications of laws and provisional measures that deal with the complementation of the private sector in the SUS and the regulation of healthcare technologies in this sector.

In this scenario, the incorporation of technologies in health systems must be linked to safety, efficacy, and effectiveness for patients, which makes their evaluation essential to ensure such goals. The assessment of healthcare technologies was introduced in Brazil in the 1990s by an external imposition. Therefore, it focuses on product technologies with great economic weight and proximity to the

international productive sector, which is sometimes seen by researchers and scholars of collective health as a threat to compliance with SUS guidelines[12].

Technologies must be linked to patient safety and their evaluation process must produce scientific and technical knowledge, inserted in a political perspective that has the common good and public health for the Brazilian populationas its objects. If the assessment of healthcare technology, in a developing country like Brazil, is centered on carrying out the economic assessment in the light of rationality, it can lead to restriction of access to quality healthcare and an increase in inequities[12].

At the end of the 1990s, Brazil was experiencing important concerns: theft of drug shipments, drug counterfeiting, sale of illegal drugs and drugs of low quality or expired validity, insufficient structures to fulfill the mission of health surveillance provided for in the legislation of the SUS and weak health regulation. In such a scenario, regulatory agencies were created in the social area: ANVISA and ANS[13].

ANVISA is an important milestone in the history of the use of healthcare technologies disseminated on the national scene. However, despite its important institutional purpose, there are complaints that the process is difficult for the registration of foreign companies in the country (considering the large economic and potentially lucrative market that Brazil represents)[14], and lamentation of temporal results indicative of that the role of "sanitary police" performed by the institution has not slowed down sanitary infractions[15]. Thus, ANVISA plays a leading role in the preservation of human health and the planet, and challenges cross-sectoral interests – items that are permeated by organized pressure from lobbies. Commercial and financial interests cannot overlap with the interests of preserving human life and the Planet[13].

In this study, only after thirteen years of LOS the Ministry of Health's Council for Science, Technology and Innovation was created in the country, and the following year, the National Policy on Pharmaceutical Assistance was approved.

SUS management bodies are responsible for almost 33% of the drug market; 90% of the vaccine market; 50% of the healthcare equipment market; 100% of the services provided to all Brazilians through Law n. 8080/90; for the formulation and promotion of research for health in the country. As a result, there is a large number of researchers in public educational institutions in the country who study human health[16]. The importance of Brazil investing in professional qualification in the areas of teaching, research, and science is evident so that scientific findings contribute to the population's access to and quality of health.

In the context of pharmaceutical care, for example, when evaluating the Brazilian system of registration and quality control, failures in pharmacovigilance are identified. The responsible agencies in the country need to review the current system used in the manufacture and control of medications, improve it, better structure pharmacovigilance and prepare to resolve upcoming demands in the sector[8].

The constructed technologies are incorporated into the health system after their evaluation by the responsible agency – initially, in 2006, by CITEC and, after 2011, by CONITEC. The assessment of health technologies in the country, considering decision-making regarding financing and access to products in the SUS, has been based on rationality, the presence of evidence presented on the effectiveness of the product, aggregate cost, and the result of public consultation to the make decisions regarding the technologies to be incorporated[17]. The analysis and incorporation flow organized by CONITEC is similar to that of agencies in countries such as Australia, Canada, and the United Kingdom. This similarity may be because these are countries with consolidated universal health systems[18]. It should be noted that these countries are quite different from Brazil in terms of economic and social context.

Investment in scientific rigor, transparency, and independence in CONITEC's decisions is necessary, especially because of the underfunding of the public health system[17]. As far as transparency is concerned, some situations are questionable: the non-publication of its plenary sessions; the contracting through letters of agreement of only a few research centers, with the potential to generate inequity in the

allocation of resources; the growing participation of professionals from the private hospital and productive sector; outsourcing the development of studies; not prioritizing public sector professionals in training in healthcare technology assessment[12].

With the expansion and solidification of the SUS, the health industries also grew on a global scale, with both domestic and imported products being used in the country. In the field of health economics, the initial expansion of the CIS has a strong influence in capitals and other urban spaces, in addition to a strong corporate logic of organization[19].

However, the Health Industrial Complex, or Health Industrial Economic Complex (*Complexo Econômico Industrial da Saúde*- CEIS)[2], which emerged from the association between health and development, has very complex economic and social roots, which requires considering it also from the point of view of the dynamics of national economic contexts and their relationship with the world economy. As the Covid-19 pandemic has shown in Brazil (which, despite having the largest universal health system in the world, presents great difficulties in the acquisition of products and technologies to fight the pandemic), the strengthening of the CIS collides so much in the internal scenario economic stagnation and international protectionism[20].

In this sense, actions to strengthen innovation and technological development policies are essential and must be addressed in an intersectoral manner. However, in the Brazilian context, even it has been foreseen since the SUS became official, it was only in 2009 that a National Policy for Health Technology Management was instituted considering only the public sphere[2]Since 2017, the National Policy for Technological Innovation in Health together with other national policies, helps to provide legal support for the development of science, technology and innovation actions in the country[21].

In this scenario of healthcare globalization, the debate about what the development of the Internet of Things will represent for this field of knowledge also expands. A study revealed that, worldwide, the development of remote patient monitoring systems is highlighted in the productions related to the theme[22], which is consistent with the accelerated development of information and communication technologies.

The expansion of this field can also help to encourage the development and use of technologies, such as software, also in the greater participation of health professionals in this process[23] and the consequent reduction of recurrent problems in daily work, such as related adverse events patient safety and medication errors[24]. However, despite the great potential that the development of IoT represents for the consolidation of access and the right to health, it also requires a broader debate on issues of privacy and data storage[25].

Thus, the National Internet of Things Plan as the last document to emerge from this research is relevant, especially if we consider health technologies related to information, organizational, educational systems, and to the sharing and interprofessional communication of the protocols developed. These technological strategies were superficially mentioned in previous legislation; however, they have not received specific treatment considering their development and expansion, which is a possible historical reference to think about the diffusion of these technologies in the health area.

As some limitations of the study, we observe that this research was restricted to the historical outline from 1990 to 2019, not encompassing the events from the Covid-19 pandemic in its scope. In this way, space is opened for the development of new documentary research that specifically covers this period and the new legal configurations arising from this historical moment.

FINAL CONSIDERATIONS

The concern with the offer of healthcare technologies to be used in the country was a striking feature in the research, initially with the establishment of policies within the SUS and Supplementary Health that helped in the design of this area and, in the following periods, with the evolution of health actions for the evaluation and incorporation of these items, especially about drugs, vaccines, and other products related to diagnostic and therapeutic processes. This posture of the Brazilian State is accompanied by

the growing participation of the private sector – in addition to national companies – in Brazilian health, configuring a growing economic and market scenario.

So far, little has been discussed about the presence of information, educational and organizational systems as technologies to be expanded and/or regulated in the SUS, and they are only mentioned in specific legislation dealing with CONITEC. However, considering the growing debate about the use of these resources in the health care of the population, it is possible and important that we see a new regulatory period being expanded in Brazil regarding the use of information technologies for the dissemination of these technologies is now supplied and developed in the country.

In general, it was evident, in the legislations studied, that the expansion, development, and responsible incorporation of healthcare technologies in Brazil are directly related to the strengthening of the Unified Health System, to invest in research and scientific innovation, to a scenario stable economic and capable of dialoguing with other sectors and countries to strengthen the Health Industrial Economic Complex.

REGULAMENTAÇÃO DAS TECNOLOGIAS EM SAÚDE NO BRASIL: UMA PESQUISA DOCUMENTAL

RESUMO

Objetivo: Analisar as principais legislações que compõem o histórico da regulamentação do uso de tecnologias em saúde no Brasil. **Método**: Pesquisa documental, exploratória, de abordagem qualitativa. A coleta de dados ocorreu entre abril e agosto de 2019no *site* da Imprensa Nacional, na Seção 1 do Diário Oficial da União, com recorte histórico de setembro de 1990 a julho de 2019, por meio da busca fonética da expressão 'tecnologia em saúde'. Foram obtidos inicialmente 33.669 registros. A amostra final foi composta por 11 documentos, utilizando-se a técnica da análise de conteúdo. **Resultados**: Os dados foram divididos em duas categorias de análise: "Delineamento do campo das tecnologias em saúde no País" e "Disseminação do uso das tecnologias em saúde". Até meados dos anos 2000, foram priorizadas as diretrizes para o estabelecimento do uso de tecnologias como parte das políticas de saúde. No período subsequente, nota-se uma evolução do planejamento do abastecimento, produção, avaliação e incorporação das tecnologias pelos serviços de saúde, bem como o desenvolvimento do Complexo Industrial da Saúde. **Considerações finais**: A produção e a incorporação responsáveis de tecnologias em saúde dependem diretamente do investimento em pesquisa e inovação científica, além de estar atreladas ao desenvolvimento econômico e social do País.

Palavras-chave: Sistema Único de Saúde. Tecnologia em saúde. Desenvolvimento tecnológico. Legislação em saúde.

REGULACIÓN DE TECNOLOGÍAS EN SALUD EN BRASIL: UNA INVESTIGACIÓN DOCUMENTAL

RESUMEN

Objetivo: analizar las principales legislaciones que componen el histórico de la regulación del uso de tecnologías en salud en Brasil. **Método**: investigación documental, exploratoria, de abordaje cualitativo. La recolección de datos tuvo lugar entre abril y agosto de 2019 en el sitio electrónico de la Prensa Nacional, en la Sección 1 del Diario Oficial de la Unión, con recorte histórico de septiembre de 1990 a julio de 2019, por medio de la búsqueda fonética de la expresión 'tecnologia em saúde'. Fueron obtenidos inicialmente 33.669 registros. La muestra final fue compuesta por 11 documentos, utilizándose la técnica del análisis de contenido. **Resultados**: los datos fueron divididos en dos categorías de análisis: "Delineamiento del campo de las tecnologías en salud en el País" y "Diseminación del uso de las tecnologías en salud". Hasta mediados de los años 2000, se priorizaron las directrices para el establecimiento del uso de tecnologías como parte de las políticas de salud. En el período subsiguiente, se nota una evolución de la planificación del abastecimiento, producción, evaluación e incorporación de las tecnologías por los servicios de salud, así como el desarrollo del Complejo Industrial de la Salud. **Consideraciones finales**: la producción e incorporación responsables de tecnologías en salud dependen directamente de la inversión en investigación e innovación científica, además de estar vinculadas al desarrollo económico y social del País.

Palabras clave: Sistema Único de Salud. Tecnología en salud. Desarrollo tecnológico. Legislación en salud.

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Submitted: 22/07/2021
Accepted: 08/10/2021

FINANCIAL SUPPORT

This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) – Brazil – Finance Code 001.