INTERNATIONAL AND NATIONAL REGULATIONS ON MANAGEMENT OF PHARMACEUTICAL PRODUCTS AND THEIR POST-CONSUMER WASTE

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ABSTRACT

Purpose: To analyze the international and national legal and normative devices regarding the management of pharmaceutical products and their post-consumption waste. To guide this review, the following question was posed: what is the national and international evidence on the management of pharmaceutical products and their post-consumption waste?

Method/design/approach: Descriptive review consisting of an investigation of technical and normative documents. To this end, representative countries of the European Union, North America, and South America were included in this review.

Results and conclusion: They were found to be: (1) the European Union model, which is characterized in a general framework for all Member States; (2) the North American model, where most countries are not subject to a common regulatory framework; (3) the South American model, where most countries have legal provisions implemented at the national level. Thus, it is inferred that the countries analyzed have regulations, even if in different spheres of government.

Research implications: The contributions point to the knowledge of the legislations, provoking questioning about the way they are being executed and the concretization of these changes.

Originality/value: The development of this research allows us to know the history of the legislations and have a broader and more critical view of the theme, so that measures can be taken to mitigate and remediate the impacts.

Keywords: legislation, Medicine, Environmentally Adequate Disposal, Waste Management, Environment, Public health.

REGULAMENTAÇÃO INTERNACIONAL E NACIONAL SOBRE GESTÃO DE PRODUTOS FARMACÊUTICOS E DE SEUS RESÍDUOS PÓS-CONSUMO

RESUMO

Objetivo: Analisar os dispositivos legais e normativos internacional e nacional referente à gestão de produtos farmacêuticos e de seus resíduos pós-consumo. Para nortear esta revisão elaborou-se a seguinte questão: quais as evidências nacionais e internacionais sobre a gestão de produtos farmacêuticos e de seus resíduos pós-consumo?

Referencial teórico: Estudos de toxicidade utilizando espécies representativas de diferentes níveis tróficos revelam a amplo possibilidade de efeitos adversos, com impactos na saúde e na reprodução da população exposta e, nesse aspecto, sugerem que possíveis alterações na saúde humana podem estar relacionadas à exposição destes compostos.

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**Método:** Revisão descritiva constituída em uma investigação de documentos técnicos e normativos. Para tanto, foram incluídos nesta revisão países representativos da União Europeia, América do Norte e América do Sul.

**Resultados e conclusão:** Foram encontrados: (1) o modelo da União Europeia, que se caracteriza num quadro geral para todos os Estados-Membros; (2) o modelo da América do Norte, onde a maioria dos países não estão sujeitos a um marco regulatório comum; (3) o modelo da América do Sul, onde a maior parte dos países contam com dispositivos legais implementados no âmbito nacional. Deste modo, infere-se que os países analisados possuem regulamentação, mesmo que em diferentes esferas do poder público.

**Implicações da pesquisa:** As contribuições apontam o conhecimento das legislações, provocando questionamentos sobre a forma como estão sendo executadas e a concretização dessas mudanças.

**Originalidade/valor:** O desenvolvimento desta pesquisa permite conhecer o histórico das legislações e ter uma visão ampliada e crítica acerca da temática, de modo que possam ser tomadas medidas de mitigação e remediação de impactos.

**Palavras-chave:** Legislação, Medicamento, Disposição Ambientalmente Adequada, Gerenciamento de Resíduos, Meio Ambiente, Saúde Pública.

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**1 INTRODUCTION**

The occurrence of pharmaceutical residues in the environment has been recognized as an emerging global issue (Aus Der Beek *et al.*, 2016; Umwelt Bundesamt, 2020). Such an assertion is clarified due to the extensive use of pharmaceuticals in human and veterinary medicine.

Environmental contamination caused by medicines comes from biologically active chemicals that reach the sewage collection networks, through excreta via urine and feces from animal and human metabolisms and the improper disposal of expired or disused medicines (Souza & Falqueto, 2015).

In this context, toxicity studies of pharmaceutical products using representative species from different trophic levels reveal the wide possibility of acute and chronic adverse effects, with impact on the health and reproduction of the exposed population (Morachis-Valdez *et al.*, 2015; Mezzelani *et al.*, 2016; Sehonova *et al.*, 2017; Mathias *et al.*, 2018; Zhou *et al.*, 2019; Silva *et al.*, 2020; Erhunmwunse *et al.*, 2021).

In this same aspect, studies suggest that possible alterations in human health may be related to chronic exposure to these compounds. Alves *et al.* (2017) explain that human exposure, even at low concentrations, can affect the endocrine system, and this is related to diseases such as hyperthyroidism and hypothyroidism, diabetes, tumors, among others.

Given the toxicological potential that pharmaceuticals, present in the environment, have and the potential risk to human health related to the exposure of these compounds, it is essential to know the regulatory frameworks on the subject, because the legislation can be understood as the main existing tool to mitigate the problem. Thus, it is possible to have a critical view and it is possible that mitigation measures and remediation of impacts are taken.

Thus, to guide this review, we sought to answer the following question: what is the national and international evidence on the management of pharmaceutical products and their post-consumption waste? The aim was to contribute (1) to the understanding of the Brazilian and global regulatory scenario about the management of pharmaceutical products and their
post-consumption waste, (2) to the need for public awareness, through public policies and environmental education actions, about the correct and environmentally adequate disposal.

2 THEORETICAL FRAMEWORK

Pharmaceuticals are biologically active chemicals that have undergone a synthesis process and have been manufactured in order to produce physiological responses in humans, animals and plants and remain active until they achieve their therapeutic effect (Sanderson et al., 2004; Lima et al., 2017). Their physical and chemical characteristics, such as high chemical stability, low biological degradability, high water solubility, and low absorption and adsorption coefficients, give this group a high tendency to absorb and accumulate in the organism of living beings (Gil & Mathias, 2005; Gaffney et al., 2014; Maculewicz et al., 2022).

In the literature it is possible to find research evaluating the toxicity of different pharmaceuticals and their transformation products on species of different trophic levels - green algae and aquatic plants (Pomati et al., 2004; Grabarczyk et al., 2020), animals (Irwin et al., 2001; Elizalde-Veláquez et al., 2017; Freitas et al., 2019; Huang et al., 2019; Rodrigues et al., 2020; Chandramohan et al., 2021) and humans, from fetal life (Wan et al., 2010; Kristensen et al., 2011; Miodovnik et al., 2011; Mazaud-guittot et al., 2013; Van Den Driesche et al., 2015; Maamar et al., 2017) through adulthood (Tanner, 1973; Auger et al., 1995; Meyboom et al., 1995; Koifman et al., 2002; Bata et al., 2006; Herman-Giddens, 2007).

Given the above, it is understood that these products, essential for human and animal health, have an important role in health, welfare, and quality of life of the population, but also have the potential to negatively impact the environment and, therefore, it is clear that this theme is in direct line with the environmental, economic, and social spheres, considered the triad of sustainable development, and consequently, with the Sustainable Development Goals - SDGs.

In the year two thousand and fifteen the United Nations Organization - UN defined "The 2030 Agenda for Sustainable Development", which includes the Sustainable Development Goals - SDGs, a collection of seventeen global action goals for achievement by two thousand and thirty, designed to be a model for achieving a better and more sustainable future for all (UN, 2015).

The seventeen Sustainable Development Goals - SDGs is a detailed document that came into effect after being approved by one hundred and ninety-three United Nations member states, including Brazil, during the seventieth session of the United Nations General Assembly, and aims to guide actions in the three dimensions of sustainable development - environmental, economic and social - in all participating countries (UN, 2015; SACHS, 2012).

Pharmaceutical products are present in one of the seventeen sustainable development goals: goal number three, related to good health and well-being, which seeks to ensure a healthy life and promote well-being for all at all ages (UN, 2015).

The corresponding targets under this entry are (1) 3.8 - achieve universal health coverage, including financial risk protection, access to quality essential health services and access to safe, effective, quality and affordable essential medicines and vaccines for all; (2) 3.8 - support research and development of vaccines and medicines for communicable and non-communicable diseases, which primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration, which affirms the right of developing countries to make full use of the provisions of the TRIPS agreement on flexibilities to protect public health and, in particular, provide access to medicines for all; and a (3) 3.b.3 - proportion of health facilities that have a core set of
essential and relevant medicines available and affordable on a sustainable basis (UN, 2015; BRAZILIAN INSTITUTE OF GEOGRAPHY AND STATISTICS - IBGE, 2022).

In a direct way, the sustainable development objectives are with actions aimed at providing access to pharmaceutical products in a safe, effective, quality, and affordable manner. There is, therefore, no concern with their environmental impact. In general, most of the studies available in the literature on pharmaceuticals present data on the occurrence of such compounds in aquatic matrices or the ecotoxicological effects. These data are fundamental to understanding the consequences of this complex environmental issue. However, it is understood that collecting information to evaluate the human management behind the use of these products and their associated environmental consequences is equally important, thus, to mitigate potential risks and minimize their impacts it is necessary to relate these variables in order to understand this phenomenon and seek ways to make it more sustainable.

Among the associated aspects dealing with the production and use of pharmaceuticals, two potential ones are connected to the possibility of entering the environment: the monitoring of such compounds in aquatic matrices and the correct and environmentally appropriate disposal.

In Brazil, the monitoring of pharmaceutical products in aquatic matrices is not regulated nationwide. The current legislations that bring specifications on the conditions, parameters, standards and guidelines for effluent discharge in receiving water bodies and that disposes on procedures for the control and surveillance of water quality for human consumption and its potability standard do not cover intervention values for pharmaceutical products in these environments (BRASIL, 2005a; 2011; 2017; 2021a b).

In relation to waste management and the correct and environmentally adequate disposal, throughout this writing there will be an overview of aspects related to the advances in legislation in various countries, a comparative evaluation of what has been done over the past few years.

3 METHOD

This study is a descriptive review (Gil, 2008) and is an investigation of technical and normative documents related to the management of pharmaceutical products and their post-consumption waste. Representative countries from the European Union, North America, and South America were included in this review, chosen for being at different levels of economic and social development.

The European Union was selected for the stage of development of the systems implemented and for the quality of the information available. For North America, the cases of Canada, the United States and Mexico were selected. And for South America, in addition

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4 Resolution from the National Council of the Environment - CONAMA No. 357, of March 17, 2005, provides for the classification of bodies of water and environmental guidelines for their framing, as well as establishing the conditions and standards for the discharge of effluents, and other provisions.
5 Resolution National Council of the Environment - CONAMA No. 430, of May 13, 2011, provides on the conditions and standards for effluent discharge, complements and amends Resolution No. 357, of March 17, 2005, of the National Council of the Environment - CONAMA.
6 Consolidation Ordinance No. 5, of September 28, 2017, consolidation of the rules on health actions and services of the Unified Health System.
7 Ordinance Cabinet of the Minister - Ministry of Health - GM/MS No. 888, of May 4, 2021, amends Annex XX of Consolidation Ordinance No. 5/GM/MS, of September 28, 2017, to provide for the procedures for control and surveillance of the quality of water for human consumption and its potability standard.
to Brazil, the cases of Argentina, Chile and Colombia were selected because they are countries important in the South American pharmaceutical market (Intercontinental Medical Statistics, 2015; Silva & Martins, 2017).

The methodological procedure consisted of surveying the legislation of international and national scope in the official websites of the competent bodies of each country. The theoretical survey used the following descriptors in Portuguese, English and Spanish: (1) pharmaceutical products and (2) post-consumption waste.

This study considered official documents in force, regardless of the year of publication. Documents that did not fit the inclusion criteria cited, or those that only cited the descriptors above and, however, the focus was not the management of pharmaceutical products and their post-consumption waste, were excluded. Finally, we sought to compare the technical and regulatory documents related to the management of pharmaceutical products and their post-consumption waste worldwide.

After the theoretical survey, the consistency of the information obtained was evaluated according to the subject and the proposed objective, in order to answer the research question. This step consisted of a process of inference and interpretation of the information contained in the publications.

4 RESULTS & DISCUSSIONS

This section presents the results of the survey of the legislation pertinent to the theme of the study, discussing its development in each country analyzed.

4.1 European Union

In the year two thousand and one the European Union regulated a Community code relating to medicinal products for human use (European Union, 2001) that establishes guidelines on scope, marketing, manufacture and import, labeling and package leaflet, classification, distribution, advertising, pharmacovigilance, surveillance, and sanctions.

In this same respect, in the year two thousand and three adopted an environmental risk assessment policy for the management of pharmacologically active compounds, in which the responsible holder must include an indication of the possible risks to the environment caused by the use and/or disposal of the medicinal product and propose appropriate labeling provisions when applying for marketing authorization (European Union, 2003). In the year two thousand and ten it was amended and strengthened for application to each of its authorized medicinal products (European Union, 2010).

As for the implementation of collection systems for unused or expired pharmaceutical products and their post-consumer waste, Directive 2004/27/EC sets out the obligation of Member States to ensure the establishment of adequate collection systems for these products (European Union, 2004).

4.2 Canada

Since one thousand nine hundred and eighty-seven the government agency Health Canada has been able to request information on the environmental risk of substances regulated under the Food and Drug Act if it feels that there may be a risk of environmental and public health impact, and from this it can develop environmental assessment regulations for new substances, including pharmaceuticals (Canada, 1985; Public Safety Canada, 2013).

In the realm of managing and reducing hazardous or non-hazardous waste that has no further use, Canada does not have federal legislation, however, it states that the responsibility...
is shared between the federal government and the governments of the provinces, territories and municipalities (Government of Canada, 2020).

4.3 United States of America

In the year one thousand nine hundred and sixty-nine the enactment of the *National Environmental Policy Act* requires the federal *Food and Drug Administration* to evaluate environmental impacts as an integral part of the regulatory process for drug approval (United States of America, 1997).

Regarding waste management, in one thousand nine hundred and seventy the enactment of the *Controlled Substances Act* establishes a strict control of pharmaceutical products, in a closed circuit between the patient and the physician, preventing the person or entity receiving the drug from returning it for final disposal (United States of America, 1970).

In this vein, in two thousand ten, the *Secure and Responsible Drug Disposal Act* was enacted which amended the *Controlled Substances Act* to provide controlled substance return provision in certain cases, allowing end consumers to turn over unused controlled pharmaceutical substances to appropriate entities for safe and effective disposal (United States of America, 2010).

In the year two thousand fourteen the *Secure and Responsible Drug Disposal Act* was amended and strengthened to consolidate previously existing regulations and expand and reorganize the options available to collect controlled substances from end users for disposal purposes (United States of America, 2014).

Complementarily, in the year two thousand nineteen, the *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine* was published in order to design a waste handling and disposal strategy more suitable for health and hazardous pharmaceutical waste management (United States of America, 2019). However, this rule applies to all healthcare facilities and all reverse distributors and does not include household generation of pharmaceutical waste.

4.4 Mexico

In the year one thousand nine hundred and eighty-four the *Ley General de Salud* makes reference to and delegates competence to the Ministry of Health for the management and application of medicine safety measures, and also contemplates the destruction of expired medicines (Mexico, 1984).

For the residues generated by the pharmaceutical industry, the legislation provides for its regulated management since the year one thousand nine hundred and eighty-eight through the *Ley General del Equilibrio Ecológico y la Protección al Ambiente en Materia de Residuos Peligrosos*, which states that expired products for pharmaceutical use will be considered hazardous waste and that the manufacturers and distributors of these products will be responsible for their management (Mexico, 1988).

In this same respect, in the year two thousand and three the *Ley General para la Prevención y Gestión Integral de los Residuos* established that the pharmaceutical industry will be subject to the formulation and execution of a management plan of responsibility for hazardous waste derived from its industrial activities and also for the final disposal of those that are discarded by consumers (Mexico, 2003).

In the year two thousand and five the Mexican Official Standard NOM-052- SEMARNAT- 2005 was implemented, which establishes the characteristics of hazardous waste, mentions that expired medicines are considered hazardous waste and therefore must be disposed of responsibly (Mexico, 2005).
4.5 Argentina

In the year one thousand nine hundred and ninety-two, Law No. 24,051 came into effect, which regulated the activities of generation, handling, transport, treatment and final disposal of hazardous waste, including the waste resulting from the production and preparation of products pharmaceuticals and residues of medicines and pharmaceutical products for human and animal health (Argentina, 1992).

In turn, Law No. 25,916 of two thousand and four regulated the management of household waste, understood as elements, objects or substances that, as a consequence of the processes of consumption and development of human activities, are discarded and/or abandoned. However, under this law, pharmaceutical products and drug residues are considered a particular type of waste and, therefore, the competent authorities must establish, within their jurisdiction, special management programs (Argentina, 2004).

In this vein, in the year two thousand and sixteen Resolution No. 522 establishes objectives, definitions and guidelines for the development of a national strategy regarding the sustainable management of special waste generated universally, including medicines (Argentina, 2016).

In the year two thousand and nineteen it was strengthened through the implementation and creation of national strategies for sustainable management of special waste of universal generation, with specific procedures that guarantee the return of this waste by the consumer (Argentina, 2019).

In a complementary manner, in the year two thousand and twelve, Provision No. 5358 established to pharmaceutical industries the formulation and execution of a risk management plan, which seeks to identify, characterize, prevent or minimize risks related to medicines derived from their industrial activities and the evaluation of the effectiveness of these interventions (Argentina, 2012).

4.6 Chile

In Chile, in the year one thousand nine hundred and ninety-four, the regulation of Law No.19,300 establishes that the projects or activities that may cause environmental impact, in any of its phases, must be submitted to the Environmental Impact Evaluation System (Chile, 1994).

In two thousand and three, Decree No. 148 was enacted, approving health regulations for hazardous waste management, and establishing the minimum health and safety conditions to which the generation, possession, storage, transport, treatment, reuse, recycling, final disposal, and other forms of hazardous waste disposal must be subject. It stipulates that the generator of such waste is in charge of disposing of its hazardous waste in disposal facilities that have the proper health authorization that includes such waste (Chile, 2003).

In this regard, in the year two thousand and sixteen, Law No. 20,920 establishes a framework for waste management, expanded producer responsibility and the promotion of recycling with the aim of decreasing waste generation and promoting its reuse, recycling and other types of recovery in order to protect people's health and the environment (Chile, 2016).

Despite the existence of regulations that establish the final disposal of hazardous waste and make the producers of these wastes responsible for their disposal, these do not include the disposal of medicines by the general population, because the correct and environmentally adequate disposal only takes place inside the facilities of the producing company and when the medicines arrive at its facilities.
4.7 Colombia

In Colombia, in the year two thousand and five the Ministerio de Ambiente y Desarrollo Sostenible - MADS published the environmental policy for the integral management of waste and hazardous waste, which defines and establishes the basis of the public environmental policy to prevent the generation of waste or hazardous waste and promote environmentally correct management in order to minimize the risks to human health and the environment, thus contributing to sustainable development (Colombia, 2005a).

In the same year, Decree No. 4741 was enacted, which partially regulated the prevention and management of waste or hazardous waste, with the aim of preventing its generation and regulating its management in order to protect human health and the environment. To this end, it instituted a management plan for the return of post-consumer products, including expired pharmaceuticals and medications (Colombia, 2005b).

However, it was only with the publication of Resolution No. 0371, in the year two thousand and nine, that the elements that must be considered in the management plans for the return of post-consumption products of expired drugs or medications were established, for their correct and environmentally appropriate management, making use of shared responsibility (Colombia, 2009).

4.8 Brazil

In Brazil, in the year two thousand and four, the Resolution of the Collegiate Board of Directors - RDC No. 306, which provides on the technical regulations for the management of health service waste, came into force with the aim of minimizing the production of waste and provide the waste generated with a safe and efficient forwarding. To this end, it establishes that generators must prepare a Management Plan for Health Service Waste - PGRSS (Brazil, 2004). Subsequently, in the year two thousand and eighteen, it was changed to the RDC No. 222 which provides on the good management practices of health services waste (Brasil, 2018).

In this same aspect, in the year two thousand and five came into force Resolution No. 358 that provides for the treatment and final disposal of waste from health services. In which the waste generators and the person legally responsible are responsible for the management of this material, from generation to final disposal (Brazil, 2005b). However, these legislations are limited to health establishments, not covering the disposal of medicines by the general population.

In parallel, the RDC No. 44, enacted in the year two thousand and nine, provides for good pharmaceutical practices for the sanitary control of the operation, dispensing and marketing of products and the provision of pharmaceutical services in pharmacies and drugstores, allows these establishments to participate in programs for the collection of medicines to be discarded by the community, in order to preserve public health and the quality of the environment (Brazil, 2009).

In the year two thousand and ten, Law No. 12.305, which establishes the National Solid Waste Policy - PNRS, providing on its principles, objectives and instruments, as well as on the guidelines for the integrated management and solid waste management, including hazardous, and also establishes the shared responsibility of manufacturers, importers, distributors and traders, consumers and the government in the correct and environmentally appropriate destination given to the products, in order to minimize the volume of waste and refuse generated, as well as to reduce the impacts caused to human health and environmental quality arising from the life cycle of products (Brazil, 2010).

According to this law, drug waste generated by users began to be contemplated on June 5, 2020 with the publication of Decree No. 10,388, which provides for the structuring,
implementation, and operationalization of the reverse logistics system for expired or unused human medicines, industrialized and manipulated, and their packaging after disposal by consumers (Brazil, 2020).

With its recent publication it is possible to observe that there are gaps in the ten-year interval between the implementation of the National Policy for Solid Waste - PNRS and the effectiveness of a legislation related to expired or disused household medications, therefore, the Brazilian states saw the need to adapt and create their own legislations.

Below, Table 1 presents a summary of the legislations that have been adopted by the government at the state level.

Table 1 - Summary of the state laws on correct and environmentally adequate disposal

<table>
<thead>
<tr>
<th>STATE</th>
<th>LEGISLATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACRE</td>
<td>Law No. 2,720, of July 25, 2013</td>
</tr>
<tr>
<td>AMAPÁ</td>
<td>Law No. 679, of June 04, 2002</td>
</tr>
<tr>
<td></td>
<td>Law No. 2,505, of August 10, 2020</td>
</tr>
<tr>
<td>AMAZONAS</td>
<td>Law No. 3,676, of December 12, 2011</td>
</tr>
<tr>
<td>PARÁ</td>
<td>Normative Instruction No. 1, of June 18, 2021</td>
</tr>
<tr>
<td>RONDONIA</td>
<td>Law No. 3,175, of September 11, 2013</td>
</tr>
<tr>
<td>RORAIMA</td>
<td>-</td>
</tr>
<tr>
<td>TOCANTINS</td>
<td>-</td>
</tr>
<tr>
<td>ALAGOAS</td>
<td>Law No. 8,371, of January 12, 2021</td>
</tr>
<tr>
<td>BAHIA</td>
<td>Law No. 14,123 of September 12, 2019</td>
</tr>
<tr>
<td>CEARÁ</td>
<td>Law No. 15,192, of July 19, 2012</td>
</tr>
<tr>
<td>MARANHÃO</td>
<td>Law No. 9,727, of December 11, 2012</td>
</tr>
<tr>
<td>PARAÍBA</td>
<td>Law No. 9,646, of December 29, 2011</td>
</tr>
<tr>
<td>PERNAMBUCO</td>
<td>Law No. 14,461, of November 07, 2011</td>
</tr>
<tr>
<td>PIAÚ</td>
<td>Law No. 6,287, of December 19, 2012</td>
</tr>
<tr>
<td>RIO GRANDE DO NORTE</td>
<td>Law No. 10,094, of August 04, 2016</td>
</tr>
<tr>
<td>SERGIPE</td>
<td>Law No. 7,913, of November 3, 2014</td>
</tr>
<tr>
<td>FEDERAL DISTRICT</td>
<td>Law No. 5,092, April 3, 2013</td>
</tr>
<tr>
<td>GOIÁS</td>
<td>Law No. 19,462, dated October 11, 2016</td>
</tr>
<tr>
<td>MATO GROSSO</td>
<td>Law No. 10,600, of September 26, 2017</td>
</tr>
<tr>
<td>MATO GROSSO DO SUL</td>
<td>Law No. 4,474, of March 6, 2014</td>
</tr>
<tr>
<td>HOLY SPIRIT</td>
<td>Law No. 10,994, of May 27, 2019</td>
</tr>
<tr>
<td>MINAS GERAIS</td>
<td>-</td>
</tr>
<tr>
<td>RIO DE JANEIRO</td>
<td>Law No. 8,135, dated October 18, 2018</td>
</tr>
<tr>
<td>SÃO PAULO</td>
<td>-</td>
</tr>
<tr>
<td>PARANÁ</td>
<td>Law No. 17,211, of July 3, 2012</td>
</tr>
<tr>
<td>RIO GRANDE DO SUL</td>
<td>Law No. 13,905, of January 10, 2012</td>
</tr>
<tr>
<td></td>
<td>Law No. 15,339, of October 02, 2019</td>
</tr>
<tr>
<td>SANTA CATARINA</td>
<td>Law No. 18,336, of January 06, 2022.</td>
</tr>
</tbody>
</table>

Source: Prepared by the authors (2021)

In view of the above it can be observed that almost all the states have legislation at the state level about the correct and environmentally adequate disposal, so that it is possible
to notice a growing environmental concern after the implementation of the National Solid Waste Policy.

5 COMPARATIVE ANALYSIS

An analysis was made on important aspects, based on what was found about the international and national experiences. In Chart 02 a synthesis of these experiences is presented through the following aspects: country and national legislation.

Table 2 - Synthesis of international and national experiences

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LEGISLATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORTH AMERICA</td>
<td>CANADA NO -</td>
</tr>
<tr>
<td></td>
<td>U.S.A. NO -</td>
</tr>
<tr>
<td></td>
<td>MEXICO YES Ley General para la Prevención y Gestión Integral de los Residuos, el 08 de octubre de 2003.</td>
</tr>
<tr>
<td></td>
<td>BRAZIL YES Decree No. 10.388, of June 05, 2020.</td>
</tr>
<tr>
<td></td>
<td>CHILE NO -</td>
</tr>
</tbody>
</table>

Source: Own Authors (2021)

Based on what was analyzed about the international and national experiences, three points were found:

1. The European Union model, which is characterized in a general framework for all member states.
2. The North American model, where most of the countries analyzed are not subject to a common regulatory framework.
3. The South American model, where most of the countries analyzed have legal provisions implemented at the national level.

Resulting from this framework found in Canada, the United States of America, and Chile, these experiences are marked by the inexistence of federal legislation with definitions of general guidelines, objectives, goals, deadlines, and established responsibility attributions.

About the attributions of responsibility Dal Piaz and Ferreira (2011, p. 5) explain that "to establish an exercise and a practice of participatory management it is assumed the development of processes of collective construction". In this context, "the participation of society is also vital to achieve legal compliance" (Diniz & Abreu, 2018, p. 13).

In parallel, a point found is in relation to risk assessment and environmental impact caused by pharmaceutical products, in which some countries have adopted this tool as an integral part of their regulatory process (Canada, 1985; Chile, 1994; United States of America, 1997; European Union, 2003; European Union, 2010; Argentina, 2012; Public Safety Canada, 2013). Similarly, Brazil requires for the pharmaceutical sector a process based on a risk analysis of the production process during the product development stage (Brazil, 2010b).
Through this tool it is possible to find alternatives and proposals that can be adopted to minimize negative impacts on the environment, seek and find a point of balance between social development, economic growth and the use of natural resources, and therefore help in the conservation, preservation and restoration of the quality and balance of the environment (Sánchez, 2013; Barbosa, 2014).

6 CONCLUSION

To guide this review, we sought to answer the following question: what is the national and international evidence on the management of pharmaceutical products and their post-consumption waste? Thus, the international and national evidence allows us to infer that the legislation is diverse among the countries analyzed. All countries have regulations for the correct and environmentally appropriate disposal of pharmaceutical waste and post-consumption waste, even if in different spheres of government.

Therefore, it was observed that the objective of this work was achieved, since it allowed the understanding of the international and national legal and normative devices related to the management of pharmaceutical products and their post-consumption waste. It is worth mentioning that this approach was intended to contribute to an expanded and critical reflection on the theme.

Regarding the limitations of the study, it is important to emphasize that the research was conducted with the delimitation of a few countries. Thus, we recommend that future research include other countries in order to enrich the study and bring new perspectives to the theme.

In addition, they should be complemented with: (1) analysis study regarding the compliance with the legal and regulatory provisions of the countries analyzed, verifying the development of programs for the collection of pharmaceutical products and their post-consumption waste, in order to highlight the importance of the correct and environmentally appropriate disposal; (2) elaboration of strategies for the dissemination of information on the practice of correct and environmentally appropriate disposal; (3) health strategies and community initiatives to promote the correct and environmentally adequate disposal, in order to mitigate the undesired environmental consequences; (4) orientation to the population about the consequences of the inadequate disposal and the creation of public policies about the correct and environmentally adequate disposal, through educational campaigns of awareness and sensitization.

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