Challenges for medicines reverse flows in Brazil: a normative sustainability-based analysis

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Resumo

Medicines reverse flows comprise both well organized and informal activities aiming at a correct disposal or a possible new consumption cycle, although this last alternative embeds controversy in technical, professional, and academic fields. Two concurring problems require attention of the private and public agents dealing with health in Brazil: the wastage, and the lack of affordable medicines to the majority of the population. Health managers face the lack of unequivocal public policies and norms to properly guide such returns. This paper aims to highlight the main normative aspects existing in Federal, State and municipal levels involving medicines returns. After employing normative documental analysis of laws, decrees and directives enacted by governments and regulatory bodies and a sustainability-based framework for effectiveness impact assessment, it is possible to conclude that federal norms propose a management driven by reverse logistics (RL), while State and municipal normatives mix both reverse logistics and circularity directions. It is found that a breakthrough in the medicines reverse flows management is ongoing at municipal level, emphasizing circularity but facing significant procedural fragilities.

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Abstract
Medicines reverse flows comprise both well organized and informal activities aiming at a correct disposal or a possible new consumption cycle, although this last alternative embeds controversy in technical, professional, and academic fields. Two concurring problems require attention of the private and public agents dealing with health in Brazil: the wastage, and the lack of affordable medicines to the majority of the population. Health managers face the lack of unequivocal public policies and norms to properly guide such returns. This paper aims to highlight the main normative aspects existing in Federal, State and municipal levels involving medicines returns. After employing normative documental analysis of laws, decrees and directives enacted by governments and regulatory bodies and a sustainability-based framework for effectiveness impact assessment, it is possible to conclude that federal norms propose a management driven by reverse logistics (RL), while State and municipal normatives mix both reverse logistics and circularity directions. It is found that a breakthrough in the medicines reverse flows management is ongoing at municipal level, emphasizing circularity but facing significant procedural fragilities.

Keywords: medicines reverse flows; normative challenges; reverse logistics; circularity.

Introduction

Medicines reverse flows are widely studied around the world, and the bulk of literature emphasizes methods of optimization considering quantitative amounts, economic costs minimization, with a limited number of stakeholders (FATEMI et al., 2021; GOODARZIAN et al., 2021), or even a selected group of medicines in the context of supply chain operations (VIEGAS et al., 2019). More recently, such approaches have supported issues of Social Corporate Responsibility in order to incentivate firms' participation in such schemes (HOSSEINI-MOTLAGH et al.,2021; TAT et al., 2021).

While optimization production-distribution models are blossoming, the wastage of medicines remain a problem for both public and private agents. In countries such as the UK, approximately USD 300 million of medicines are wasted per year (HUI et al., 2020). At the same time, a considerable part of the population keep deprived in terms of medicines access, mainly due to unaffordable costs. This is a widespread phenomenon – according to DUONG et al. (2018), an average of 30% of the global population cannot pay for basic medicines. Vieira (2018) observe that medicines purchasing represented 22% of the poorer income in Brazil until the 1990's. Thanks to federal public policies adopted early in the 2000's, namely, the popular pharmacies where people could get discount in the purchase of generic medicines, the total average expenses in medicines has lowered to 8.5% of the Brazilians' income (VIEIRA, 2018). However, it was noticed an emptying of such public policy from 2017 on, as the government is since then reduced the per capita amount of investments in the Health Public System (SUS) (HARTMANN, 2022).

In 2010, the Federal government enacted the National Solid Waste Management Policy, that states reverse logistics (RL) as the return of goods or parts of goods from an end-of-use or end-of-life condition to a new cycle of consumption, in the same or other type of productive process (Brazil, 2010). This policy, expressed in the Law 12,305 (BRAZIL, 2010), indicates mandatory reverse logistics for batteries; tires; lubricating oils, their waste and packaging; fluorescent, sodium and mercury vapor and mixed light lamps; electronic products and respective components. It did not included medicines, expired or not. Tools for the implementation of RL programs were named "sectorial agreements" and "terms of committment", in which the stakeholders would be able to propose their targets in terms of technical means, amounts of

returns, type of products destination, and financial support, indicating the respective responsibilities of each supply chain echelon.

Regardless the absence of expired, damaged (end-of-life condition) or not expired (end-of-use condition, not damaged, or brand new products after sale) medicines from the initial scope of RL law, the Federal government, in 2013, started to call the stakeholders of the Pharmaceutical Supply Chain (PSC) in order to organize their own RL system. Two calls were oficially published in 2013 (BRAZIL, 2013) and in 2014 (BRAZIL, 2014) with the aim to gather the stakeholders in negotiation, and a comprehensive report on the overall situation of medicines was organized (HIRATUKA et al., 2013). Nonetheless, the regulation advanced in slow pace, and currently it is observed an uneven situation all over the country, with some advancement in Southeast region. The latest national directive for medicines RL was enacted by the Federal government in 2020 (BRAZIL, 2020). Nevertheless, much debate remain around the best way of addressing the RL procedures, responsibilities, and involvement of the parts. The practices of returns are diversified in the private sector, and new business models has been established with the RL purpose (PEGMED, 2021). There is not an unique understanding on what does mean an unused medicine, and what should be done with pre-expiry, not sold, and with leftover medication stored in medical clinics, homes, and other possible sources of medicines in the end-of-use condition.

In the public sector, some municipalities have organized systems of reception and reassignment of medicines based on municipal laws that define conditions for taking and managing a predefined list of products (BERTOLO, 2019). Such practices are usually based on the work of pharmacists that perform visual inspection with the aim to define whether a given medicine is able or not to be redispensed to citizen that cannot afford it. These municipal systems are surveilled by Pharmacists Councils and Sanitary Surveillance representatives, and their practices largely difer from the federal directives because include both recirculation and final disposal of medicines, depending on the type and conditions of received goods. There is not official data on the number and placement of these municipal establishment, widely called solidary pharmacies (VIEGAS et al., 2021). The main characteristic of the solidary pharmacies is the embedding of circularity beyond simple RL, in an attempt to create closed loops or quasi-closed loops for the best possible harnessing of medicines that otherwise would be wasted. They also promote a sense of sharing while including consumers as providers or reusable goods (VIEGAS et al., 2021).

In Brazil, the first legal reference to the returns of products is the National Solid Waste Management Policy (Law 12,305/2010). This legal text introduces mandatory reverse logistics processes implementation for some economic sectors as pesticides, their residues and packaging, or products whose package, after the use, remain as hazardous waste; batteries; tires; lubricating oils, their waste and packaging; fluorescent, sodium and mercury vapor and mixed light lamps; electroelectronic products and its components. It does not include medicines, but there is a recent federal decree that directly present mandatory procedures including medicines in reverse logistics (BRAZIL, 2020).

Given the wide diferences between the federal and the local systems of medicines returns, this paper aims at analyse the recent normative directions enacted at national level vis-à-vis some State and municipal directions. The questions which guide this research are: (i) do the federal, the State, and the municipal official normative documents on medicines returns provide effective answers to fulfill the problems of wastage and affordability of medicines in Brazil?; (ii) do these documents provide clear concepts, methods, procedures, liability, forbidness, permissions and other directions related to medicines RL or recirculation? In order to answer these questions, a brief literature review on RL and Circular Economy (closed loop systems) of medicines is provided in the section 2; the research design and methods are described in the section 3; results are presented in the section 4; discussion, in the section 5; and final remarks in the section 6.

2 Literature review on medicines returns: reverse logistics and circularity in sustainability context

The theme of medicines RL is relatively new in academic literature, and it is usually mixed with inititatives as humanitary logistics of such type of goods, as donations. The systematic review offered by De Campos et al. (2017) and the taxonomy proposed by Viegas et al. (2019) sumarize the main published academic work on medicines reverse flows in the last two and half decades. Viegas et al. (2019) found that the RL practices in PSC are more associated with a mix of economic, ecological and social sustainability, while the circular practices, or closed loops, are more associated with attempts to enlarge the utility of a medicine along it life cycle. In this sense, RL activities are concerned firstly to correct destination of medicines wastes, and circularity with humanitarian and even informal relationships in the PSC, involving mainly health professionals and consumers in dowstream of the chain.

Differently from RL, originally anchored in the supply chains of not perishable products (CARTER and STEVENS, 2007), Circular Economy (CE) advocate itself as a type of regenerative, restorative set of activities that aims at disassociating the economic grow from the use of the natural resources (KIRCHHERR et al., 2017) with overall coverage in terms of supply chain products. While RL seeks help in diverse theoretical bases (CARTER and ROGERS, 2008), as resouces based view, ecology of populations, resources dependency, and economic transactions costs theories, CE brings even more uncertainty regarding its conceptual foundations. A lot of confusion is found with respect of the clear differences between CE and previous sets of sustainability frameworks employed in inter and intra-organizational levels as cleaner production, industrial symbiosis, ecoefficiency (KIRCHHERR et al, 2017). The regulatory aspects of CE are incipient (THOMAS, 2018; DDIBA et al., 2020), and scholars claim that the political processes of CE implementation are not properly considered (MOREAU et al., 2017). Specifically, CE was not clearly stated in the literature of medicines returns until recently, while the idea of circularity or closed loop is more commonly disseminated (VIEGAS et al., 2019).

Studies that embed the circular thinking (SAZVAR et al., 2021; TAT et al., 2021) and the social corporate responsibility (HOSSEINI-MOTLAGH et al., 2020; HOSSEINI-MOTLAGH et al., 2021) as an essential factor in medicines reverse flows are recent. De Campos et al. (2017), after a bibliometric study on medicines RL from 1996 to 2015, found that community programs are part of strategic management activities of the PSC, and aspects of governance and traceability based on technological information resources are still research gaps to be fulfilled. The same authors indicate the lack of studies about policies review and new policies in order to support the destination of end-of-use and end-of-life products (DE CAMPOS et al., 2017). De Campos et al. (2021) shows initiatives of medicines reassignment among Brazilian public healthcare unities in Southern Brazil, enabling to avoid medicines losses and to better manage the public health resources at municipal level. Regulatory and compliance factors are mentioned as critical for the success of these return programs.

RL and CE are intertwined conceptions in the scope of sustainable supply chains, but the CE notions require going beyond traditional reverse practices of waste collection and recycling. It is also noteworthy that both RL and CE encompasse diverse scales as macro (national, regional), meso (municipality, supply chain sectors), and microlevels (single companies and individuals) (JULIANELLI et al., 2020). Furthermore, the context in which reverse flows practice take place must be considered. It is out of the scope of this research the comparison between Brazilian and other national systems of RL or even CE. Rather than this, to understand the Brazilian normative realities in which these flows occur is of utmost need, considering that Brazil does not have an institutional legal framework for CE. It is more in the imaginary of scholars, consultants or even in public opinion mentality than in legal directives. The sociotechnical cognitive construction of goods returns and circularity, as a daily ingrained routines of the society, though, is necessary to link the production and the consumption processes in a possible circular mentality (FRATINI et al., 2019).

3 Research design, methods and procedures

This research is underpinned in qualitative approach. It employs document analysis as main procedural basis. According to Bowen (2009, p. 27), "document analysis is a systematic procedure for reviewing or evaluating documents—both printed and electronic (computer-based and Internet-transmitted) material. Like other analytical methods in qualitative research, document analysis requires that data be examined and interpreted in order to elicit meaning, gain understanding, and develop empirical knowledge". This type of analysis, hereafter named DA, is guided by the normative category of the effectiveness assessment framework of impact assessment proposed by Bond et al. (2013). It is assumed here that RL and CE pursue a certain level of sustainability because both include activities typical of reverse flows as reuse and environmentally correct disposal of goods. While looking for sustainability, RL and CE produce positive and negative impacts. Thus, assessing the sustainability effectiveness of the legal documents and norms that intend to rule such practices, in the context of municipal medicines reverse flows, could help to unveil the characteristics of the impact they cause in the targeted communities.

According to Bond et al. (2013), the effectiveness assessment is comprised by six dimensions that express a wider view of sustainability compared with the usual triple bottom line perspective, in which three dimensions are highlighted: economic, social, and ecological. Goind further, Bond et al. (2013) propose the effectiveness view of sustainability in procedural, substantive, transactive, normative, knowledge and learning, and pluralism dimensions. Procedural effectiveness is linked to the ability of the legal and administrative processes achieving sustainable goals; substantive effectiveness refers to context and outcomes expected with the assessment; transactive effectiveness is associated with the financial and timeliness aspects; normative effectiveness envisages individual, social norms or expectations of the process; knowledge and learning effectiveness express how the assessment process facilitate conceptual and instrumental learning; and pluralism refers to the diversified understanding of sustainability discourses. The present study is limited to the normative aspects of effectiveness assessment, given that the subject of analysis are documents.

Considering the normative dimension of the sustainability effectiveness assessment framework of Bond et al. (2013), the following questions arise with respect to the legal and regulatory documents taken as subject of this study:

(A) Does the document (law, decree, norm) reverse unsustainable/prevailing trends? (It means that the document should contain proactive measures rather than other that minimize or repair damages or losses.)

(B) Does the document integrate all the key intertwined factors affecting sustainability (environmental, social, cultural-heritage, economic, intergenerational)? (It means the document must address the issues of sustainability in holistic way.)

(C) Does the document make explicit the gains of all involved parts and trade-offs minimization? (It means the document may offer means to incentive joint action or action that does not require exchanges, or requires minimal negotiation between the parts.)

(D) Does the document respect contexts in which sustainability assessment takes place? (It means the document needs to be specific in terms of scale and cultural context.)

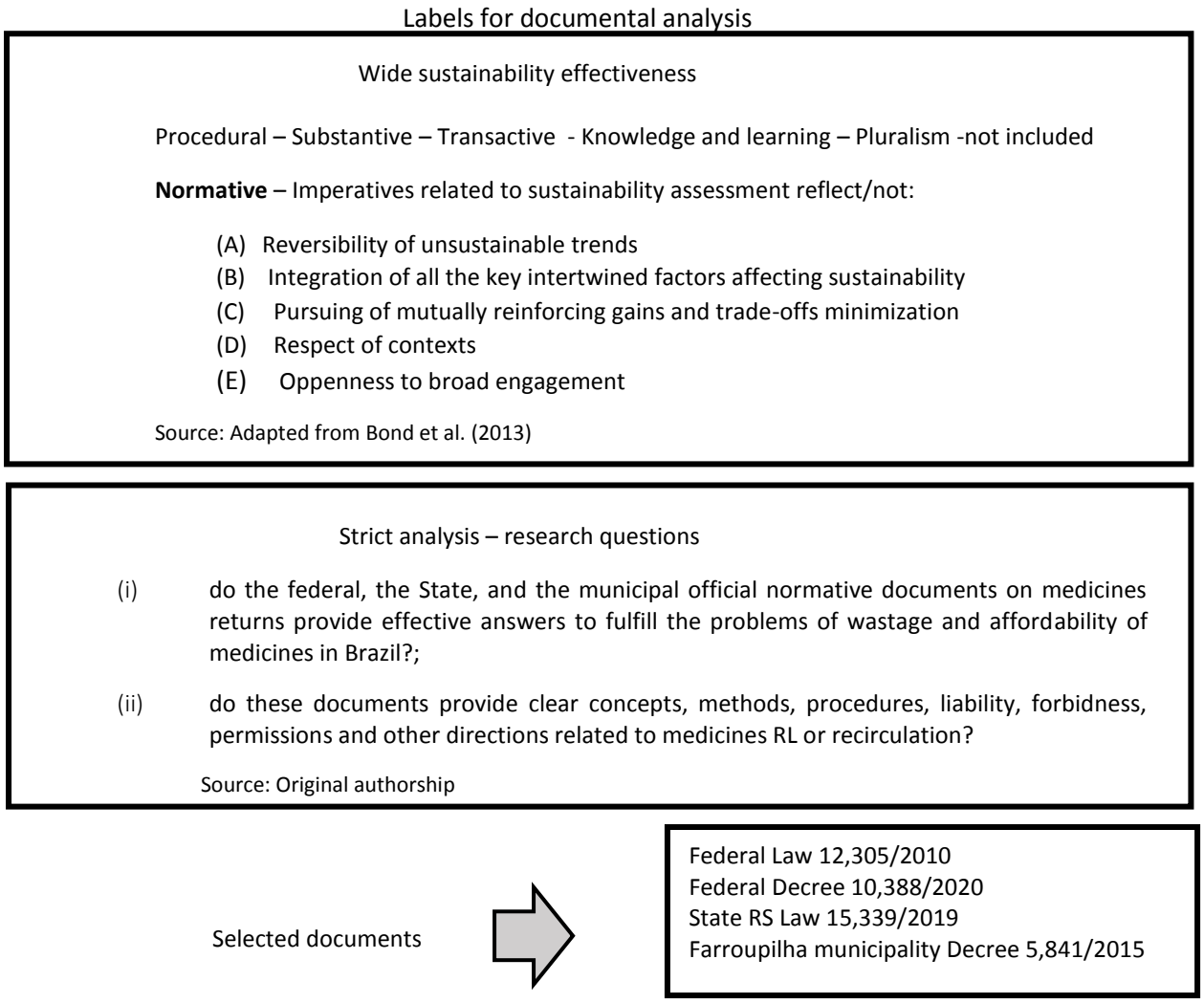
(E) Does the document refer to open and broadly engagement of the involved parts? (It means the document may support collaboration.)

This checklist must be considered in the perspective of the specific questions posed in the Introduction of this research: (i) do the federal, the State, and the municipal official normative documents on medicines returns provide effective answers to fulfill the problems of wastage and affordability of medicines in Brazil?; (ii) do these documents provide clear concepts, methods, procedures, liability, forbidness, permissions and other directions related to medicines RL or recirculation?

While the adapted framework provides directions to assure sustainability normativeness, the specific questions guide the assessment of RL and CE issues.

The research design, is therefore, planned from a wide to a narrow view of the documents.
The selected documents for analysis were: The National Policy of Solid Wastes (Law 12,305/2010); the federal decree on RL (Decree 10,388/2020); one State Law of Rio Grande do Sul on solidary pharmacies and medicines RL (Law 15,339/2019) (RIO GRANDE DO SUL, 2019); and one municipal decree on solidary pharmacies, Rio Grande do Sul (Farroupilha municipality, Decree 5,841/2015) (FARROUPILHA, 2005).
It is necessary to justify such choices. At the federal level, the selected documents are, respectively, the seminal legal framework on solid wastes management, and the more recent RL regulament on the subject of study (medicines reverse flows). At State level, although many Brazilian States have their own solid waste management policies, such policies follow the national policy, with considerable redundancy in terms of content. So, it was brought to analysis the case of Rio Grande do Sul State, where there is a normative focused in medicines RL. Finally, the municipal document was selected taking in account recent movements for the return of medicines at local scale.
The documents were retrieved from the official websites where they are stored (Official Diary of the Union, Official Diary of Rio Grande do Sul State, municipality of Farroupilha). They were available in their original language (Portuguese). It is possible to access the full documents through the references of this article.
Each document was read and compared with the first protocol (normative sustainability effectiveness checklist). The questions of this protocol were coded in sequence, from A to E letters. Each document was read and submitted to the research protocols and to the research questions, in sequence.
Figure 1 summarizes the research design.

Figure 1 - Research procedures



4 Results

The results follow the sequence of the documental analysis presented in the Figure 1, taking in account the wide sustainability assessment with respect to normative criteria, and the research questions posed in the Introduction section of this work. For each document, one subsection was assigned, with two other respective subsections.

4.1 Law 12,305/2010

4.1.1 Normative requirements

(A) *Reversibility of unsustainable trends* - This requirement is fulfilled because the law incentive sustainable production and consumption patterns (Articles 3^0, 6^0), proposes RL (Articles 3^0, 33) advocates the principles of prevention and precaution (Article 6^0), and propose a hierarchy for solid wastes management that goes from no generation at all to reduction, reuse, recycling, until final disposal (Article 7^0; Article 9^0). Also, it is clear given the priority of irregular dumping elimination, followed by incentive to recycling, and economic autonomy of waste pickers in cooperatives (Article 17). Another clear highlight to reverse unsustainable trends is written in the Article 30, that enacts the shared responsibility of all supply chain, private and public agents, and consumers, by the whole life cycle of the products.

(B) *Integration of all the key intertwined factors affecting sustainability* - This feature is mainly observed in the statement of solid waste management systemic view, which considers environmental, social, cultural, economic, technical and public health variables, and the integrated solid wastes management policy (Article 6^0); it is also noticed in the Article 8^0, where diverse types of tools - political, economic, environmental, technological - are declared to support a Federal solid wastes management policy. In the Article 30, the convergence of sustainability factors is expressed with respect to RL - economic, social, managerial, and environmental aspects of RL are intended to be convergent.

(C) *Pursuing of mutually reinforcing gains and trade-offs minimization* - The law does not directly indicate the mutual gains for the supply chain participants. Indirectly, it reinforces: the ecoefficency and respective social returns; wastes value and social outcomes; recycling and technical cooperation between public and private sectors; the creation of waste pickers cooperatives (Article 6^0); technical and financial cooperation for the creation of new products and methods (Article 8^0); incentive joint solutions between municipalities for waste management (Article 11). In terms of trade-offs, it forecasts fiscal incentives (Article 8^0), provision of Federal resources conditioned to programs or actions aligned with the solid waste management policy (Article 15), and input of Federal resources in municipalities that propose joint solutions for solid wastes management and implement cooperatives for selective collection of wastes (Article 17). Other trade-offs are provision of incentives to municipalities that act jointly to implement solutions in solid wastes management (Article 18), and encouragement of business creation in municipalities, aligned with the solid waste management policy (Article 19). Besides, there are financial incentives provisions for initiatives of wastes generation prevention, clean technologies (Article 42), and projects supporting recycling, life cycle extending initiatives and urban cleaning activities (Article 44). Incentives to consumers that participate on selective collection plans are left to be carried out by municipalities (Article 37).

(D) *Respect of contexts* - It is expressed in statements respecting local and regional diversities (Article 6^0), regional solutions (Articles 11 and 15), micro-regional and integrated solutions (Articles 16, 17, 18), as well as municipal specific plans (Article 18) for solid wastes management.

(E) *Oppenness to broad engagement* - The issue of participation is presented in two main forms in this law. The first one is the common paticipation (as mobilisation) in the National Plan of Solid Wastes (Article 15), as presence of municipalities in micor-regional plans (Article 17), as participation of any group or cooperatives in local solid waste management plans (Articles 18, 19), as public participation in committment terms arranged by parts of a supply chain (Article 31). The second form of participation is called social control, and it is defined as mechanisms or procedures to assure the public participation in diverse processes supported by the law. Social control is mentioned in the articles 3^0, 6^0, 8^0, 10, 14, 15, 17, 19, 22. In fact, social control is a mediated participation in which the government rules the process.

4.*1.2 Specific research questions*

The Law 12,305/2010 does not address requirements for RL of medicines; although it mandates RL for some types of goods (Article 33), medicines are out of the list; so it does not address (i) issues of wastage, affordability neither (ii) gives clear concepts, methods, procedures, liability, forbidness, permissions and other directions related to medicines RL or recirculation.

4.2 Decree 10,388/2020

4.2.1 Normative requirements

(A) Reversibility of unsustainable trends - The Decree is intended to regulate the Article 33 of the Federal Law 12,305/2010, and it refers to the Article 3^0 of the law, where it advocates sustainable production and consumption - a combination of provisions to revert unsustainable trends. It also refers to RL in the same article, which is an argument opposed to unsustainable tendencies. The Decree gives directions to the organisation of a RL system that includes all the possible pharmaceutical supply chain. It does not sustain alternatives as reuse, recycling, and takes as sustainable the route of correct disposal of domestic medicines, both expired or unused.

(B) Integration of all the key intertwined factors affecting sustainability - It is not explicit in the Decree; it is addressed to the technical and economic procedures of RL rather than to the ecological or social aspects.

(C) Pursuing of mutually reinforcing gains and trade-offs minimization - Mutual gains are not provided by the Decree; it mandates retailers to bear the costs of providing collection points (Article 10), the logistics agents, in tandem with industry and importers, to provide the transportation of expired or unused medicines (Article 15); and industry, with importers, pay for the correct disposal of such returned goods (Article 18). Besides, all parties must disseminate knowledge to the consumers take the medicines back to retailers (Article 20). The trade-offs are clear: there is a shared responsibility between the agents of the supply chain for the RL system. The Decree clearly establishes trade-offs rather than minimize them.

(D) Respect of contexts - This criteria is not applied to this Decree, as it does not refer to any cultural context; it is otherwise a set of procedural obligations of the supply chain agents.

(E) Oppenness to broad engagement - This criteria is not applied to the Decree, because the parties are called to fulfill duties rather than to spontaneously participate in decisions.

4.2.2 Specific research questions

Regarding que question (i), the problem of wastage is partially addressed in the main parts of the Decree, as it defines obligations for each part of the supply chain in order to collect, transport and correctly dispose the expired or unused medicines; however, medicines wastage cannot be solved only through RL plans; it also depends on upstream parts of the supply chain (industry), on the physicians prescriptions, on the patients/consumer behaviors; the Decree, indeed, does not offer solutions to the problem of medicines affordability in Brazil, as it does not address the needs of consumers that cannot pay for such goods.
With respect to question (ii): clear concepts are provided in the Articles 2^0 and 3^0 of the Decree. It enacts chronological procedures as the creation of a RL system in tho phases - namely, the performance group creation, its structure, and tasks regarding reports on amounts of medicines collected and returned (Article 7^0), and the protocol creation for medicines wastes transportation (Article 8^0). However, detailed methods are not provided. Articles 11 to 19 present the liability of each supply chain stakeholder and some permissions to manage the RL system, as: the form in which medicines collectors will be available to the consumers (Article 11); the way of transportation management, with the possibility of hiring services (Article 15), and the possibility of hiring external agents to manage the RL process (Article 17). Forbidness is not explicit in the Decree, but it reinfores liability of the supply chain agents and possible

penalities forecasted in the law of environmental crimes - Law 9605/1998 and respective regulamente (BRAZIL, 1988).

4.3 Rio Grande do Sul State Law 15,339/2019

4.3.1 Normative requirements

(A) Reversibility of unsustainable trends -This law enables the donation, reassignment, and redispensation (Article 1^0) of a significant types of medicines (those registered in the Health Surveillance Authority, Anvisa), not expired, and pre-assessed by pharmacist, although preventing some conditions (Article 2^0) and exceptions (Article 7^0) with regard of medicines types. It involves all potential donators in local communities (Article 1^0), including health professionals in donation of free samples, for instance (according to the Article 2^0), and in the inspection of potential redispensable medicines (pharmacists, according to the Article 7^0). Such medicines are offered for free (Article 3^0), which characterise the potential of the law in avoiding medicines wastage (through recirculation) and in fulfilling the needs of persons that cannot afford medicines. Thus, it reverts a socio-environmental unsustainable trend in terms of medicines systems of production and consumption.

(B) Integration of all the key intertwined factors affecting sustainability - The law is focused on socio-economic aspects (Articles 1^0, 2^0,7^0), does not make explicit the environmental benefits of medicines recirculation, but provides the possibility of the correct disposal of expired or damaged medicines (Article 7^0).

(C) Pursuing of mutually reinforcing gains and trade-offs minimization - In the Articles 1^0 and 3^0, the law indirectly enables to realise the gains of the needy persons (those that cannot buy medicines), but does not make clear the burden of medicines collection, inspection, storing, correct disposal.
(D) Respect of contexts - This criteria is not clearly inferred in this law, as it refers mainly to municipalities that can or cannot adhere to the so-called Solidary Pharmacy Program (Articles 4^0, 6^0).

(E) Oppenness to broad engagement - It is widely expressed the possibility of any physical person or municipality to participate in the RL/recirculation system proposed by the law, in accordance with the respective terms.

4.3.2 Specific research questions

Regarding the specific research questions: (i) this municipal law is totally devoted to address both, the wastage problem, and the lack of affordability of medicines in the State municipalities; (ii) however, no concepts are provided, although procedures are stated with respect of medicines dispensing (Articles 7^0, 8^0, 11), and storage (Article 11). Furthermore, this law underpins liability: of the establishments that follow the Solidary Pharmacy Program (Article 3^0), of the municipal Health Authority in which the establishment is settled (Article 5^0), and of the municipalities themselves (Article 6^0). Also, the liability of the pharmacists are expressed (Articles 7^0, 8^0). Some constraints and forbidness are posed in the law, with respect: of special medicines, damaged medicines, and other subject to further examination before a destination decision (Article 12), and with respect to the liability of the beneficiaries of the program (Article 9^0). The law enables any State municipality to participate in the program (Article 4^0).

4.4 Farroupilha Municipal Decree 5,841/2015

4.4.1 Normative requirements

(A) Reversibility of unsustainable trends - The Decree considers the surplus of medicines available in homes of the municipal dwellers as subject to RL; it also considers the environmental impacts of medicines surplus, incorrect discharge, and the lack of medicines affordability that affects part of the local population. It also refers to responsible consumption. These statements are in the justification of the project as forewords, and provide a clear picture of the intentions to revert unsustainable trends.

(B) Integration of all the key intertwined factors affecting sustainability - The Decree integrates environmental and socioeconomic aspects of sustainability in the justification.

(C) *Pursuing of mutually reinforcing gains and trade-offs minimization* - It is not clear in the Decree. There are not economic provision for the Solidary Pharmacy Program, neither clear trade-offs.

(D) *Respect of contexts* - The Decree refers to a partnership between the local government and the society for the collection and distribution of medicines through the Solidary Pharmacy, but it does not indicate a formal partnership. The context is the municipality of Farroupilha, and there is not explicit mention to other parties than the local inhabitants and the municipal government.

(E) *Oppenness to broad engagement of the involved parts* - It is stated that awareness campaigns regarding medicines donations would be carried out (Article 9^0), but it is not as the same as broadly social engagement. In the justification of the project it is possible to infer the intention to boost awareness regarding the problem of medicines wastage, environmental impacts of incorrect medicines discharge, and lack of medicines affordability.

4.4.2 Specific research questions

With respect of effective answers to fulfill the problems of wastage and affordability of medicines (i), the Decree offers such intention and provide means for it (Articles 2^0 to 9^0); (ii) does not provide clear concepts and methods, but some procedures for the work of the pharmacists. It clarifies liability of both municipality (Articles 5^0,6^0) and pharmacist (Article 7^0), and some forbidness related to the types of medicines to be dispensed (Article 7^0) and constraints for dispension and contorl of stored medicines (Articles $7^0$and 9^0).
Figure 2 summarises the main findings of the document analysis for normative effectiveness, and Figure 3 shows the findings for research questions.

Figure 2 – Summary of normative effectiveness assessment

Criteria / Document		**Federal Law 12,305**	**Federal Decree 10,388**	**State Law 15,339**	**Municipal Decree 5,841**
Normative effectiveness assessment	A	Prevention/precaution Sustainable production-consumption issues Shared responsibility and hierarchy for solid wastes - RL	Sustainable production-consumption issues (only medicines) Disposal as solution - RL	Donation, reassignement, dispensation of medicines - CE	Responsible consumption of medicines and environmental impacts of medicines wastage are focused - CE
	B	Integrates environmental, social, cultural, economic, technical and public health issues	Addresses mainly economic aspects	Integrates socioeconomic aspects; environmental are not explicit	Integrates all environmental and socioeconomic aspects
	C	Does not indicate mutual gains. Many trade-offs are suggested: fiscal, financial incentives for joint solutions, clean technologies, consumers participation	Does not make explicit mutual gains. Presents several trade-offs	Reinforces gains of the needy people. Does not provide trade-offs. Burden of collection, selection, inspection, storage, dispensation, disposal are not mentioned	Mutual gains are not clear. No trade-offs are mentioned
	D	Respects diverse contexts	Does not define any cultural context	Does not mention context, unless municipal	Does not mention context, unless municipal
	E	Supports broad participation of citizens and municipalities	Does not provide tools for participation, but imposes duties	Expresses the possibility of broad participation	Mentions the possibility of compaingns for medicines donations, but does not clarify means for public participation

Figure 3 – Summary of results from research questions

Document / Research question	**Federal Law 12,305**	**Federal Decree 10,388**	**State Law 15,339**	**Municipal Decree 5,841**
(i)	Does not provide answers to medicines wastage/afforability issues	The medicines wastage problem is addressed only through RL solution of final disposal	It is totally devotated to avoid wastage and to fulfill the needs of needy persons	It attains both medicines wastage and affordability problems
(ii)	Does not provide clear concepts, methods, procedures, liability, forbidness, permissions and other directions related to medicines RL or recirculation	Clear concepts on medicines RL are provided, but ot detailed methods. Some permissions to hire services are delcared. Focus on liability of the supply chain agents, but not in forbindness. Relates to the Environmental Crimes Law to support answers for action against the environment	Does not provide concepts, but provides procedures for medicines stoarege, dispensing and disposal. Liability for solidary pharmacies and pharmacists are listed.	Does not provide concepts, methods, but some procedures for the pharmacist work and respective solidary pharmacies routines.

5 Discussion

From the summary presented in the Figure 2, it is found that all documents prevent unsustainable trends. The federal documents address it from the RL point of view, while the State and the municipal documents provide sustainable solutions aligning RL and CE. It reinforces the conception of intertwined conceptions involving RL and CE (JULIANELLI et al., 2020), but makes clear the incipiente condition of CE regulatory aspects (DDIBA et al., 2020; THOMAS, 2018), as the Brazilian legislation for medicines returns does not explicitly mentions recirculation or closed loops attempts (VIEGAS et al., 2021).

The issue of sustainable production and consumption is highlighted in three of four legal norms, showing their tendency to advocate the reversibility of unsustainable trends.

The integration of all sustainability aspects with respect of medicines reverse flows is noticed at municipal level, where circular thinking seems more evident (SAZVAR et al., 2021; TAT et al., 2021). At State level, environmental aspects are not explicit, and at Federal level, the focus is on economic results from RL, which resonates what the academic literature shows in terms of results optimization in the processes of returns and final disposal (FATEMI et al., 2021; GOODARZIAN et al., 2021).

The gains of the society are explicit in the State Law of medicines reverse flows; they are not clearly stated at the Federal and municipal levels. Such gains has been recenlty traduced by scholars as a type of social responsibility (HOSSEINI-MOTLAGH et al.,2021; TAT et al., 2021). Trade-offs, differently, appear in both Federal documents, which imply the tendency of regulatethe reverse flows through agreements or mechanisms able to economically engage the

diverse involved stakeholders. At municipal and State scales, there is no mention to provisons on how to bear the costs of the reverse flows and circularity of medicines.
The context in which the reverse flows occur are better framed in the Federal law, although it does not contain directives to medicines rather than to RL, embracing a wide set of other goods. So, a gap is here indentified on how to contextualise the cultural aspects of medicines returns. It confirms the findings of De Campos et al. (2017) on the lack of specific policies for end-of-life pharmaceutical products, and the informal movements of medicines reassignment within health unities in the same municipality (DE CAMPOS et al., 2021). Perhaps a lack of formal cultural support for such practices arises as a topic of future research.
The participation of ciizens in the processes of returns is a common provision of all analysed documents, except of the Federal decree, which imposes mainly duties for the participation in the RL system.
With respect to the research questions (Figure 3), namely the first one, it is noteworthy that State and municipal documents support circularity as a natural routine (FRATINE et al., 2019), while federal ones underpin RL as a tool for economic development more than an instrument for solving the lack of medicines affordability (DUONG et al., 2018; VIEIRA, 2018). Regarding the second question, it is observable that concepts are detailed in the Federal decree, all targeting RL systems. Liablity is also well defined and stressed in this document, although the State and the municipal documents refer to liability in broader sense. The Federal decree is more incisive with respect to liability and forbidness for RL compared with State and municipal legal norms. It indicates the possibility of a bifurcate comprehension on the logics of medicines reverse flows: from one side, in large scale, the normative system tends to pursue more rigor and looks to the medicines as wastes to be disposed; from another, in local scale, the norms attempt the conciliation of a traditional RL with the closed or quasi-closed loops aiming at socioeconomic purposes of those that cannot afford medicines.

6 Final remarks

This article intended to investigate whether and how current Brazilian legal documents on RL and medicines returns address problems as medicines wastage, affordability, and to what extent they enact clear concepts, methods, procedures, liability, forbidness, permissions, and other directions related to medicines RL or recirculation. To achieve these purposes, a document analysis (Bowen, 2009) was combined with a normative sustainability assessment set of criteria adapted from the sustainability assessment framework of Bond et al. (2013). Normative assessment aims at verify the individuals and social expectations regadring the employment of enacted or commonly assumed directives. The normative criteria employed helped to screen whether the documents support the reversibility of unsustainable prevailing trends; if they integrate the maximum factors affecting sustainability; whether explicit gains are stated, and trade-offs are minimised, with the expectation to avoid enforced, exprensive, unsustainable solutions in long-term; whether the contexts of sustainability are respected; and if engagement of the parts are assured. In overall sense, it is possible to conclude that federal norms propose a waste management system driven by reverse logistics (RL), while State and municipal normatives mix both RL and circularity directions.
This work was designed as an exploratory attemp to assess the recent movements for addressing the medicines RL and circularity, once CE is not yet present as a formal public policy in Brazil. It presents some constraints. Firstly, there was limited the number of documents for the sake of clarity. There are many other municipal laws on solidary pharmacies able to be included in the assessment. Also, there is a recent federal decree (enacted in the beginning of 2022) offering more strict directions to the overall RL system. Such documents were not included to preserve the objectivity of a first comparative study on the subject of medicines reverse flows. It is therefore recommended a further assessment of these documents in tandem with the already

considered. Also, it is interesting to provide more empirical insights on how the CE is being considered in the national policy system with respect to RL system whose regulation has been deployed.

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