Access to medicines: application of constitutional selectivity in tax on circulation of goods and services

Acesso aos medicamentos: aplicação da seletividade constitucional no imposto sobre circulação de mercadorias e serviços

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DOI: 10.1590/0103-110420195408

ABSTRACT Access to medicines may be limited by their high prices impacted by taxation, especially the Tax on Circulation of Goods and Services (ICMS). This paper discusses the application of the principle of selectivity in the ICMS and its impacts on the tax burden of medicines, with a reflection on the ability of citizens to pay for medicines. The method was literature review, based on documents, norms and theoretical background of Carrazza. The article is divided into three sections: General overview of taxes on medicines; Tax on Circulation of Goods and Services and Principle of selectivity as a vector of human dignity. It was also sought to debate the doctrinal counterpoints, bringing important discussions on the application of selectivity foreseen in the Brazilian Constitution. It was possible to verify tax benefits involving the applicable federal taxes on medicines in the national tax system. It is concluded that the non-application of the principle of selectivity in the ICMS can cause problems, especially regarding the abandonment of treatment and in the occurrence of higher expenses than families can afford, which violates the principle of universality of health making its equity difficult.

KEYWORDS Access to essential medicines and health technologies. Right to health. Drug price. Constitution and bylaws.

RESUMO O acesso aos medicamentos pode ser limitado pelos seus altos preços impactados pela tributação, especialmente pelo Imposto de Circulação de Mercadorias e Serviços (ICMS). O artigo problematiza a aplicação do princípio constitucional da seletividade no ICMS e sua repercussão na carga tributária dos medicamentos, com reflexo na capacidade de pagamento de medicamentos pelos cidadãos. O método foi de revisão de literatura, com base em documentos, em normas e no referencial teórico de Carrazza. O artigo está dividido em três seções: Caracterização do panorama geral dos tributos incidentes nos medicamentos; Imposto sobre Circulação de Mercadorias e Serviços e Princípio da seletividade como vetor da dignidade da pessoa humana. Identificaram-se alguns contrapontos doutrinários, trazendo, importantes debates sobre a aplicação da seletividade prevista na Constituição brasileira. Verificou-se existência de benefícios fiscais envolvendo os tributos federais aplicáveis sobre os medicamentos no sistema tributário nacional. Conclui-se que a não aplicação do princípio da seletividade no ICMS pode ensejar problemas, especialmente no abandono do tratamento e na ocorrência de gastos superiores ao que as famílias podem suportar, o que afronta o princípio da universalidade da saúde tornando dificil sua equidade.

PALAVRAS-CHAVE Acesso a medicamentos essenciais e tecnologias em saúde. Direito à saúde. Preço de medicamento. Constituição e estatutos.

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Introduction

The financial accessibility of people and governments is a significant condition for the realization of the constitutional right to health, which should also be observed when discussing the incidence of taxes¹. At the same time, health costs have been a growing concern of governments and private sectors, posing a challenge in the dynamics of health provision and its financing.

In this scenario, high prices are access barriers to medicines, since these products are essential and fundamental to health care, and, consequently, have been receiving attention by governments in discussions regarding the consequences on health spending in the last decades^{2,3}.

Expenses with pharmaceutical products have an impact on family budgets⁴, especially for the poorest, who, proportionally, commit a large part of their budget for their purchase, which highlights the existence of equity problems in access to medicines in Brazil.

Such a situation is most evident when there is a large imbalance in drug expenditures such as final consumption of health goods and services by product, since they show that direct disbursement by families represents a proportion of almost 90%, and the rest, is the responsibility of government bodies, according to data from the satellite health account, reported by the Brazilian Institute of Geography and Statistics (IBGE)⁵, in the period 2010-2015.

Brazilian tax law is complex, with numerous taxes and rules. There are, as a rule, five tax classes: taxes, special contributions, compulsory loans, fees and contributions to improvement¹. Regarding taxes, they are not linked to revenue, that is, the amounts collected do not need to be used in specific state activity, while for the others, there is some type of intended destination⁶.

The tax burden in Brazil is one of the biggest in the world⁷, remaining, in the 2000-2010 decade, at 29.0% of Gross Domestic Product and reaching a relevant 47.4% in consumer products. This reality ends up impacting all sectors of the economy, including pharmaceutical assistance.

Although the scenario in question is applicable to the taxation of all segments in Brazil, its impact on the production chain of the pharmaceutical sector (industry, distribution, retail sector) is especially relevant not only because there are even more specific rules for these types of products and services, but, above all, because it involves the theme of health.

In this area, it can be seen that there is a great impact of the Tax on the Circulation of Goods and on Services of Interstate and Intermunicipal Transportation and Communication (ICMS) on the final price taken to the consumer, given the high rates of this tax and its general incidence on medicines⁸.

The ICMS is the major responsible for the high tax burden on medicines⁷, given its high rates compared to other taxes and the few tax exemption policies, for reasons that should be understood. Thus, we have that the ICMS is a true indirect tax, incident, especially, on the sale of goods, with the payment made by business companies and whose transfer and liens are directly borne by the consumer, as they are embedded in the final price of the product.

In this sense, the observation of fiscal justice and the violation of contributory capacity are central elements, because, since the amount of attribute is equal, regardless of who buys it, it is evident that the transfer will entail greater burden for the poor, especially when dealing with essential products such as medicines. This sheds light and criticism on the so-called 'regressive tax' effect, that is, that the amounts paid as tribute end up being proportionally higher, exactly for the lower income population, characteristic of indirect taxes, among which, the ICMS^{9,10}.

Discussing regressiveness implies, furthermore, analyzing the fair and constitutional application of the tax law, that is, whether such application is consistent with the concept of tax justice and which criteria delimit a taxation capable of promoting the objectives described in article 1 of the Constitution of the Federative Republic of Brazil of 1988 (CRFB), as the dignity of the human person and citizenship, observing also the role of the contributory capacity for the construction of this system¹¹.

This complex theme, still little studied in the field of public health in Brazil, should be marked by dialogue between health and law professionals, aiming at improving access to medicines for the population.

Thus, the objective of this article is to discuss and problematize the application of the principle of selectivity in the ICMS and its possible impacts on the tax burden of medicines from the literature review, which include from classic and seminal texts, as recent productions on the subject highlighting the elements on the tax scenario of medicines and the application of constitutional provisions.

This article is based on the master's dissertation research on tax incidence, especially, the ICMS on medicines and the possibility of applying the selectivity principle to make the price of this input more accessible to the population.

After the methodological path, some points are presented divided into three sessions. In the first one, the general panorama of the incident taxes on medicines is characterized. In the second, the ICMS tax in the Brazilian context is emphasized. In the third section, the debate on the application of the principle of selectivity is exposed, as set out in the CRFB, which should consider attributes of essentiality of the consumed goods, especially, medicines and their possible impact on the reduction of drug prices and better access to these products, as a vector of the dignity of the human person. Finally, the conclusion is presented on the benefit of applying the principle of selectivity.

Methodological path

This is a descriptive and exploratory study, developed from a narrative review of the literature, both scientific and normative, and involving the analysis of public documents of open access. In addition, it included consulting duly published books on the topic and related issues.

Despite the constitutional importance of the principle of selectivity, the present work was aligned with the dissonant doctrine supported by literature published by Roque Carrazza¹⁰, which advocates the obligation to apply this principle also to the ICMS, in view of its direct connection with the guarantee of the dignity of the human person in the tax scope.

The ICMS was the chosen tax, because, as previously mentioned, it currently reflects the tax with the greatest impact on medicines, given the high applicable rate. Moreover, the tax in question is one of the major responsible for the collection of state public entities and has a complex regulatory landscape, given the freedom of federal entities to legislate on the subject. There are other factors that generate ICMS, besides the simple circulation of goods, such as importation and exportation. However, such hypotheses have not been studied in the present work, since the main focus of the research is on the fact that generates more frequency and impact on the national pharmaceutical market.

Initially, a search was performed in several databases, such as the Digital Law Library (BDjur), which is a repository maintained by the High Court of Justice; the Virtual Health Library (VHL); the Capes Theses Database and Google Scholar, using the keywords 'burden' and 'tax' and 'medicines' and 'ICMS'. Another database consulted was the SophiA repository, which belongs to the Court of Justice of the State of Rio de Janeiro, using the keywords 'ICMS', 'selectivity' and 'medicines'.

The search strategy with the keywords (rubrics) used and already mentioned above portray the nodal aspects that sought to reach academic productions that deal, albeit in a tangential way, with the objective of capturing different reflections and doctrinal positions. Thus, texts published in Portuguese or English were selected, as the theme is very specific to the Brazilian context. However, it is necessary to consider that the subject under discussion involves legal issues and is extremely specific, since Brazilian tax law is unique in the world. Despite the existence of international articles on the tax burden of medicines, the ICMS itself, the main object of the research has no international equivalent, so that most of the important references could be published in Portuguese.

These sources of information were used in view of their large amount of collections involving themes of national legal system and health, pharmaceutical industry and medical area. No regulations were introduced that addressed: a) the tax in question in an extremely general manner; b) those that involved areas of law other than tax and c) those that discuss aspects of medicines that are distant from their pricing.

With the intention of raising the scenario related to drug tax exemptions agreements, a manual search was carried out on the website of the National Finance Policy Council (Confaz), which is publicly accessible and which has, on an orderly basis, the publication of the agreements.

Throughout the above, it was found that the regulations, laws, agreements and other normative instruments constituted a source of data of high value, since, from the highlighting and analysis of their devices, it was possible to glimpse the context in that the pharmaceutical sector is inserted in Brazil, in regulatory and tax terms.

Finally, the CRFB, the maximum instrument of implementation of human dignity and the most important Brazilian legal diploma, was the most important source, since it originates the concept of selectivity, essentiality and tax justice, nodal points of the work.

Characterization of the overview of taxes on medicines

In the case of the pharmaceutical chain, the most relevant taxes for the activity are the ICMS, the Tax on Manufactured Products (IPI), the Program for Social Integration (PIS), the Program of Formation of the Patrimony of the Public Server (Pasep) and the Social Security Financing (Cofins)¹² (chart 1).

Chart 1. Taxation of the pharmaceutical industry supply chain (industry, distribution, re	etail)
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Тах	Initials	Aliquot	Competence
Tax on Manufactured Products	IPI	Segue Tipi Federal	Federal
Tax on the Circulation of Goods. Interstate and Intercity Transporta- tion and Communication Services	ICMS	0 a 20%	State
Social Integration Plan	PIS	1.65%	Federal
Contribution for Social Security Financing	Cofins	7.6%	Federal
Services tax	ISS	2 a 5%	Municipal
Import Tax	П	0 a 20%	Federal
Guarantee Fund for Time of Service	FGTS	8%	Federal
ITax on Financial Transactions	IOF	6%	Federal

Chart 1. (cont.)			
Corporate Income Tax	IRPJ	15%	Federal
Social Contribution on Net Profits	CSLL	8%	Federal
Social Security contribution	INSS	28.8%	Federal

Source: Own elaboration from Perilo et al.7.

Tipi: Table of the Tax on Manufactured Products.

It is considered that the total taxation on medicines is estimated at around 33.1% of their final selling price⁷, which reveals, from now on, the relevance of studying the subject.

The composition of drug prices in Brazil is directly regulated, under the terms determined by Law n^o 10.742/2003, in addition to the issuance of numerous Resolutions, among other regulations, especially of the Brazilian Drugs Market Regulation Chamber (CMED), standardization and parameterization in view of its evident impact on the quality of life of the Brazilian population. The CMED is a multi-ministerial body, with the National Health Surveillance Agency as the executive secretary^{13,14}.

Within the Brazilian scope, among the existing strategies, the option was to control prices through the establishment of ceilings, namely: factory price, maximum consumer price and maximum sale price to the government. This Chamber publishes annual resolutions with the maximum prices of the medicines to be observed¹⁴. It also stablishes the prices to be set by companies wishing to enjoy the special presumed credit scheme under the positive list medicines.

This classification into lists, positive, negative or neutral (*chart 2*), carried out according to the class of the medicine, its relevance and defined by the executive branch; will lead to higher or lower PIS/ Cofins taxation. The positive list provides, in practice, exemption from IPI on related medicines. In case of negative list, the tax will only be paid once along the chain, by the manufacturer – single phase – and the amount paid can be used as credit at the end of the production chain. The neutral list enables the common tax regime, with the incidence of PIS/Cofins at each stage of the chain¹².

List of Medicines	Incidence	Calculation
Positive (are those that depend on prescription – prescrip- tion only medicine and controlled drugs)	Single-phase – 2.1% (PIS/ Pasep) and 9.9% (Cofins)	Right to presumed profit Zero tax burden.
Negative (Medicines not mentioned in Decree nº 3.803/01. but with Table of the Tax on Manufactured Products stablished in Law nº 10.147/00)	Single-phase - 2.1% (PIS/ Pasep) and 9.9% (Cofins)	No right to presumed profit
Neuter	Multi-phase: 0.65% (PIS/ Pasep) and 3.0% (Cofins)	

Similarly, in the case of IPI, there is a stipulation of 0% tax rate for the vast majority of medicines, as shown in the Table of Incidence of Tax on Industrialized Products provided for in Decree n^o 8.950, of December 29, 2016¹⁶.

The evolution, at the federal level, of the taxation on medicines is noticed, since they are treated differently in the case of the taxes of competence of the Union, in order to benefit such consumer goods, essential for human life.

Nevertheless, the same scenario does not apply to the incidence of ICMS, for possible reasons: this tax is largely responsible for the high tax burden on medicines, very high rates compared to other taxes and the difficulty of creating effective tax exemption policies, besides the fact that taxation is under the jurisdiction of the Brazilian federative units.

Tax on Circulation of Goods and Services

ICMS is levied on 'transactions relating to the movement of goods' involving commercial legal transactions, not mere commodities or any kind of circulation¹⁷. Thus, at every step of the productive stage from manufacturing, distribution and sale, the tax in question will be imposed.

This is a States' competence tax, noncumulative, whose triggering factor is the occurrence of operations related to the movement of goods and the provision of interstate and intercity transport services and communication, even if operations and services begin abroad. Additionally, its characteristics show its extra-tax character^{18,19}.

States, by means of ordinary laws, define their own regulations regarding this tax, which involve internal rules, such as mechanisms for transfers to municipalities, percentages internally destined for economic and/or social sectors, among others.

In addition, CFRB now has, in its article

155, paragraph, item III, the constitutional provision of the application of selectivity to tax, due to the essentiality of goods and services^{11,20}.

In the case of ICMS, provision has been made for minimum and maximum rates in foreign operations, as well as interstate rates, by resolution of the Federal Senate. Internal rates will apply when the operation does not exceed the territorial limits of that state, while interstate taxes involve operations in which the goods are intended for the final consumer, whether or not taxpayer, destined for a state other than that of exit of the goods¹.

In domestic operations, imports and services rendered abroad, States usually set the basic rate of 17% or 18%, while in communication services the rates are higher (25% or more)²¹. In Brazil, currently, the rate of ICMS between states varies from 12% to 20%.

Within the vast regulatory framework, Resolution nº 22, of May 19, 1989, of the Federal Senate, provided for ICMS rates applicable to interstate operations, with a value of 12%. In the case of operations and installments performed in the South and Southeast, the rates will be 7% when destined to the North, Northeast and Center-West, and the state of Espírito Santo. It is noteworthy that, in interstate operations, the so-called rate differential will be applied, that is, the receiving State shall bear the difference in the aliquot between the interstate (minor) and its internal (major) rate. The purpose of this mechanism is to avoid the 'fiscal war' and redistribute the collected ICMS values. This is because, without such payment, there would always be greater sale of goods produced in states with lower ICMS tax rate²².

The tax performs a function in economic activity, involving various operations. Still, the position held by Paulsen²² prevails that 'circulation' is a transfer of ownership, that is, there is circulation only when the commodity is transferred from ownership or possession. In the case of ICMS, the calculation basis will be the value of the commercial operation and the price of interstate and intercity transportation services and communication.

In relation to the ICMS, great controversy involves the so-called 'inside calculation', that is, the integration of the tax itself in its calculation basis, which is provided for in article 13, paragraph 1, I of Complementary Law n° 87/96.

Paulsen²² exposes the doctrinal criticism, in the sense that the above legal provision ends up giving rise to a true tax on the tax, rather than a tax on commercial operations, including a violation of tax jurisdiction. It can be seen, therefore, that the 'inside calculation' system eventually results in an increase in the effective tax rate on the final amount payable, which will never correspond to the fixed nominal tax rate²¹.

Chart 3 illustrates the difference in the form of calculating the 'inside' and 'outside' tax, as occurs in other systems, such as the United States. The consequence of the adoption of such a system is verified: while in the 'outside calculation' the rate to be paid by the consumer is 25%, corresponding to the nominal rate itself, in the 'calculation from the inside', the same nominal rate will represent a rate effective 33%.

'Inside' calculation	'Outside' calculation
Initial price of the goods/service: R\$ 100	Initial price of the goods/service: R\$ 100,00
Nominal rate 25%	Nominal rate 25%
Amount charged from user: R\$ 133,33	Amount charged from user: R\$ 125,00
Invoice: tax is highlighted for mere control purposes.	Invoice: there is the addition of the tax to the value of the goods/service

Source: Adapted from Moreira and Teixeira²⁴

Another relevant factor applied to medicines refers to the existence of several agreements entered into by states under Confaz with the purpose of granting tax exemptions to specific products, such as the treatment of HIV/Aids, items for cancer treatment, among others.

Agreements are, this way, the most relevant instrument in Brazilian law for the determination of different ICMS values for medicines, given the restriction determined by article 155, XII, 'g' of the CRFB¹¹.

However, it is noted that the exemption of ICMS for medicinal products only covers a small quota (*chart 4*), most of which, is restricted to cases of public purchases and, as regards private purchases, in general, it applies only to diseases whose combat has been the subject of major government policies¹.

Theme	Agreement
Exemptions on public purchases	ICMS Agreements nº 87/02, 26/12, 170/15 e 13/17
Exemptions on HIV treatment medicines	ICMS Agreements nº 70/87, 130/92, 51/94, 10/02
Exemptions on cancer treatment medicines	ICMS Agreements nº 162/94, 34/96, 104/01 e 114/14.
Exemptions on Dengue treatment medicines	ICMS Agreement nº 95/98
Serum and vaccine exemptions	ICMS Agreement nº 05/00 e 73/00
Exemptions on medicines in belonging to the Popular Phar- macy program	ICMS Agreement nº 56/05 e 81/08
Exemptions on medicines used in human research	ICMS Agreement nº 09/07
Exemptions on medicines for treatment of Influenza A (H1N1)	ICMS Agreement nº 73/10

Source: Own elaboration.

Principle of selectivity as a vector of human dignity

The national tax scenario foresees the existence of multiple indirect taxes, among which, the ICMS, responsible for most of the tax burden, especially in the area of medicines, as already widely portrayed before.

The Constituent of 1988, finding that the existence of the same rates for all goods violated the principle of equality and, in the tax bias, the idea of contributory capacity, began to provide, in its article 155, paragraph 2, III, the selectivity as a vector also for the ICMS¹¹, providing that this tax may be selective, due to the essentiality of goods and services.

Thus, great debate was stablished in the national doctrine about the best interpretation of the device in question, dividing between those who understand it is the legislator's competence²⁵ the determination of lower tax burden on certain goods and those, such as Carrazza¹⁰, who understand that the use of selectivity in ICMS is a true constitutional determination, that is, cogent norm. For this latter author, the principle of selectivity is a vector of application of the dignity of the human person in tax law and, thus, its theoretical framework is the basis on which the discussion was explored in the sequence.

Still, the CRFB also listed the so-called "limitations on the power to tax", set forth in its article 150¹¹. Thus, the principle of equality, that is, the determination of identical treatment by law; unequally dealing with unequal cases, according to criteria sheltered by the legal system, was listed in item II of article 150 as a limit to the State when setting the taxation guidelines²⁶.

In the same vein and deriving from the above limitation, the idea of contributory capacity, that is, the economic capacity of the individual to contribute to the maintenance of the State, according to Danilevicz²⁶, appears within the tax law as a true guarantor of the application of equality, observing the income inequalities between different individuals, at least partly addressing health equity. Thus, these elements are in line with doctrinal precepts of the Unified Health System, especially regarding the attribute of equity.

In indirect taxes, that is, those whose final burden is passed on to the taxpayer in fact, the taxpayer capacity is mitigated, since, in the above terms, the transfer of the tax burden is fully made to the consumer, regardless of their income. Thus, heavy taxation on consumption has a clear regressive effect on consumption, including the purchase of medicines, since all consumers, regardless of their income, bear the same amount of taxes.

An example of this fact in Brazil is the finding that in 2005, those earning up to two minimum wages paid 48.8% of income in taxes, while those receiving more than 30 salaries spent 26.3%²⁷.

Taxation on consumption ends up by, thus, exacerbating social inequality, further burdening disadvantaged sections of the population. In this regard, it is worth recalling the data that have been presented by family budget surveys that already show the 'weight' of medicines for the poorest segments⁴, as well as data from the health accounts of the IBGE5.

The maintenance of this system, according to Ribeiro²⁸⁽¹³⁾, meets

much more to the collection interests of the State, from the liberal perspective of neutrality and economic efficiency, than to the idea of fiscal justice, the fight against inequality or the strengthening of the Social State.

Therefore, the principle of selectivity is essential in order to, in the words of Danilevicz²⁶⁽²³⁷⁾,

minimize the consequences of the transfer of tax burden and apply, even minimally, the principle of contributory capacity to those who end up paying the tax inserted in the price of the product, merchandise or service.

The prevalence of the notion of distributive justice gives rise to the conception that not only the collection is relevant, but that the allocation of resources needs to be directed towards equity, either to reduce economic inequalities between groups and regions^{29,30}, investigating how each citizen can contribute to public spending²⁶ and choosing contributory capacity as a true limit to public spending. Therefore, the moral foundation of tax law would be the construction of a cooperative and egalitarian society²⁸, a common good and universality of health.

The critique, already explained when analyzing the inequality generated by excessive taxation on consumption and the need to build a tax system focused on income taxation, culminates in the issue of the severe burden on indirect taxes, which are precisely on consumption, with implications for the lower income population.

Thus, selectivity emerges as enabling the contributory capacity in indirect taxes, seeking to determine that taxation occurs in proportion to the essentiality of the good consumed and to ensure the reduction of regressiveness inherent in the transfer of tax repercussions to the final consumer.

This is how the principle of selectivity is directly linked to the concept of essentiality, determining that the economic burden of a tax falls on goods and services in the direct reason of their superfluity and the inverse reason of their need, making popular consumption a parameter, according to Carraza¹⁰.

It is logical to state that the more essential a certain product is for a dignified life, the lower should be the taxation of ICMS on its final price. This allows for lower cost of acquiring basic items and greater accessibility in order to apply the principle of justice, recognizing it as a human right.

It is noteworthy that selectivity can be applied through various forms of quantitative change in the tax burden, not only through the variation of rates, but also the basis of calculation, creation of tax incentives and the granting of presumed credit, which they are examples of mechanisms of realization of selectivity¹⁰.

In the case of medicines, it is important to emphasize the difference between the essentiality for the purpose of applying the selectivity provided for in the CRFB, that of the classically used by the World Health Organization. This international forum has for many years presented the classic concept of essential medicines, referring to those prioritized according to their relevance to public health, according to criteria of evidence of safety, efficacy and cost-effectiveness².

Undoubtedly, the price of medicines, with little variation in demand as a function of price, directly affects the purchasing power of patients, which can lead to extreme situations, such as high spending or treatment abandonment³¹, that is why differential tax treatment as a way to improve access to medicines in the Country is important.

Final considerations

The idea of tax justice and the realization of the dignity of the human person, in the prism of tax law, permeates the cogent application of the principle of selectivity in the ICMS, expanding access to basic necessities, such as medicines.

The existence of a tax system cannot, simply, be based on economic criteria, but is only concerned with maximum resource efficiency and the best formula for growth. It is, therefore, necessary to adopt an ethical-legal criterion capable of reconciling economic and social issues.

Tax law has a daily impact on the lives of Brazilian citizens, but, due to the innumerable bundle of rules and specificities, it is misunderstood by the majority of the population. This situation is evidently detrimental, since what is unknown remains immune to criticism and construction, constituting itself as a distant knowledge.

There is no doubt, therefore, that, when tax justice is effective, the essential nature of medicines is recognized, and the incidence of ICMS is adequate through the principle of selectivity, the access of population to treatment can gain breadth, making the constitutional right to health effective. Tax Law is, therefore, privileged as a vector of social justice and mitigating element of inequality, which, without neglecting the collection of the State, is capable of addressing the deepest needs of the human being, respecting and reinforcing the dignity of the human person.

Collaborators

Michelli LAMF (0000-0002-9101-121X)* contributed to the conception, elaboration, analysis and approval of the final version of the manuscript. Vilardo MAT (0000-0002-6632-2622)* contributed to the critical review of the content and approval of the final version. Silva RM (0000-0002-6243-5179)* contributed to the planning, critical review of the content and approval of the final version.

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Received on 08/09/2019 Approved on 10/15/2019 Conflict of interests: non-existent Financial support: non-existent