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Comparison between maximum consumer prices for medicines and prices practiced on the internet in Brazil: misalignments and regulatory distortions

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Abstract *Since 2003, the Medicine Market Regulation Chamber (CMED, in portuguese) has been responsible for establishing the maximum consumer prices (MCP) for medicines. The aim of this study is to compare prices practiced on the internet with the MCP and identify the average price difference between them in two segments of existing drugs in Brazil, the reference and the generic ones. Drug prices were collected on websites of pharmacies and drugstores and compared with their respective MCP for the year 2019. The analysis included 68 drugs and 268 commercial presentations of generic and reference drugs related to these drugs. A different pattern was observed for the average price difference in relation to the MCP in each market segment, with most generic drugs tending to show the highest differences and the reference drugs the lowest ones. The problem of price distortion in relation to the MCP pointed out by the literature was confirmed mainly in relation to the generic drug market. It was concluded that a periodic review of the MCP would be important, considering retail prices.*

Key words *Government regulation, Drugs price, Drugs generics*

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Introduction

In 2003, through the implementation of Law n. 10,742, the Medicine Market Regulation Chamber (CMED, C*âmara de Regulação do Mercado de Medicamentos*)[1] was created, which started to establish maximum consumer prices (MCP) for medicines, as well as several other controls[2]. In terms of economics literature, this meant adopting the price-ceiling model for price regulation in this market[2].

The rules for the adjustment and establishment of drug prices were implemented through Article 4 of Law n. 10,742/03. Moreover, the readjustments started having a base date in March. The adjustment of drug prices is based on a price-cap model calculated based on: (1) an index – the Extended National Consumer Price Index (IPCA, *Índice Nacional de Preços ao Consumidor Amplo*), which is calculated by the Brazilian Institute of Geography and Statistics (IBGE - *Instituto Brasileiro de Geografia e Estatística*); (2) a productivity factor – expressed as a percentage and which allows passing on to consumers the productivity gains of drug-producing companies; and (3) an intra-sector relative price adjustment factor – calculated based on market power, which is determined by monopoly or oligopoly power, information asymmetry, entry barriers and others, and between sectors – calculated based on the variation of input costs, as long as such costs are not recovered by the index calculation[3].

The drug price adjustment is based on the latest Factory Price (FP). In turn, the maximum consumer price (MCP) is obtained by dividing the FP by the calculated factors, considering the tax burdens of the tax on the circulation of goods and services (ICMS, *Imposto sobre Circulação de Mercadorias e Serviços*) practiced in the destination states and the incidence of contribution to the social integration program and civil service asset formation program (PIS/Pasep, *Programa de Integração Social/ Programa de Formação do Patrimônio do Servidor Público*) and social contribution for social security financing (COFINS, *Contribuição para o Financiamento da Seguridade Social*). The retail trade units must keep updated drug price lists, containing the FP and MCP[4] available to consumers and consumer protection agencies.

In addition to the price adjustment rule, the CMED, through Resolution 2 of 2004, became responsible for controlling the drug entry prices, according to specific rules for each type. The types of drugs addressed in this article are: generic and reference drugs. The segment of generic drugs was implemented in Brazil in 1999, through Law 9,787, which defined these drugs as interchangeable with a reference product and may be produced after the expiration or waiver of patent protection, and must prove their efficacy, safety and quality and being designated by their Common Brazilian or International Denomination[5]. In turn, the reference drug is the innovative product registered in the National Health Surveillance Agency (Anvisa, *Agência Nacional de Vigilância Sanitária*) and marketed in the country, whose efficacy, safety and quality were scientifically proven by the competent federal agency at the time of the registration[6]. With the law on generic drugs, Brazil now has three differentiated market segments: reference drugs, generic drugs and similar drugs, with the latter not being addressed in this study because they may differ from reference drugs in relation to some characteristics and for being identified by brand name, unlike generic ones[6].

Therefore, for the drugs analyzed in this study, Resolution 2, of 2004, established that: (1) for new products (Category I), the FP proposed by the company cannot be higher than the lowest FP practiced for the same product in the countries listed (Australia, Canada, Spain, USA, France, Greece, Italy, New Zealand, Portugal and the FP practiced in the country of origin of the product), adding the applicable taxes, as appropriate; (2) for Category II, new products that do not meet the previous definition, the FP will be defined based on the cost of treatment with the drugs used for the same therapeutic indication, which cannot be higher than the lowest price practiced among the countries listed; and (3) for the generic drug (Category VI), the FP cannot be higher than 65% of the price of the corresponding reference drug[7].

As pointed out by Dias et al.[8], the current price adjustment model has been using MCPs detached from reality, increasing information asymmetry and allowing future abusive increases. Regulatory models based on price-cap, such as the one used in Brazil, presuppose periodic realignments of prices to market values every two, up to a maximum of five years. In Brazil, this model has been used for 16 years, without any realignment, with consequent accumulated distortions between MCP and charged prices[8]. The fact that periodic evaluations of the prices practiced in the market not carried out, adjusting the MCP to something closer to the market reality, seems to be a very relevant problem and with

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implications for the efficiency of regulation and for the well-being of consumers.

In addition, Dias et al.[8] consider several other possibilities in which the regulation described above brings problems, for instance, those related to determining productivity. Moreover, for each generic drug that enters the market, a new MCP is established, which makes the monitoring of market prices more complex. Miziara and Coutinho[9] have already performed a brief analysis of the gap between the MCP and the charged prices, although they focused on a single Brazilian state (São Paulo) with prices being collected from physical stores between 2009 and 2012.

In this article, however, a survey of drug prices practiced on the websites of the largest pharmacy and drugstore chains in Brazil is used, with some of these being regional networks and others operating throughout the country. Despite the diversity of these networks' performance, the surveyed prices correspond to the standard of their own websites, and it is not possible to say that they are identical and cover all regions. Moreover, this article differs from the study carried out by Miziara and Coutinho[9] in that it discusses how the determination of the MCP can affect in different ways two drug segments found in Brazil, namely, reference and generic drugs.

The information asymmetries caused by the dissociation of the prices practiced in the market in relation to the established MCP indicate the need for periodic evaluation of the market prices of drugs in Brazil and their implications for the consumers' well-being. These results can be extremely relevant for the CMED assessment of drug price regulation.

The aim of the article is to compare prices practiced on the internet by Brazilian pharmaceutical retailers with the MCP established by CMED and generate new evidence on the regulation of drug prices in Brazil. It also aims to answer the following research questions: Is there any pattern for the difference between charged prices and MCP in the Brazilian market of generic and reference drugs?

Method

Some private institutions have databases on retail prices; however, access is restricted or may only be available under certain circumstances (e.g., IQVIA, available at https://www.iqvia.com/). Considering the non-availability of a public database for the purposes of this study, a search method was developed for surveying drug prices on websites, as described below.

The list of pharmacies and drugstores available on the website of the Brazilian Association of Pharmacy and Drugstore Networks (ABRAFARMA, *Associação Brasileira de Redes de Farmácias e Drogarias*)[10], which include the largest pharmacy and drugstore chains in Brazil, was the basis for data collection on the internet. Based on this list, pharmacies and drugstores that had websites and that allowed the collection of information were selected. The selected pharmacies and drugstores, as well as other information, are depicted in Chart 1.

As for the geographic location of pharmacies and drugstores, it is observed that: (1) *Droga Raia* operates throughout the south region and in the states of São Paulo, Rio de Janeiro, Minas Gerais, Goiás and Mato Grosso do Sul[11]; (2) Drogasil in the south, southeast and midwest regions and in the states of Bahia, Pernambuco, Sergipe, Alagoas, Paraíba and Rio Grande do Norte[12]; (3) Pacheco Drugstores in the states of Rio de Janeiro, Minas Gerais, Espírito Santo, Goiás, Paraná and Distrito Federal[13]; (4) São Paulo Drugstore in the states of São Paulo, Minas Gerais, Rio de Janeiro, Bahia, Pernambuco, Paraíba and Alagoas[14]; (5) Panvel throughout the south region and in the state of São Paulo[15]; (6) Pague Menos Pharmacy in all states and the Distrito Federal[16]; (7) Araujo Drugstore in Belo Horizonte and some cities in the state of Minas Gerais[17]; (8) Nissei Pharmacies in the states of Paraná, São Paulo and Santa Catarina[18]; (9) Venancio Drugstore exclusively in the state of Rio de Janeiro[19]; and (10) Rede Drogal in the countryside of the state of São Paulo[20].

Price collection took place through a programming language developed by the authors in Visual Basic for Applications (VBA) of Microsoft Office Excel. It was built to extract data on drug description, brand name and price directly from the websites of pharmacies and drugstores. These data were organized in an Excel database that was used as the basis for this study. The collection on the internet was carried out between September 11 and 16, 2019.

The choice of drugs, schematically represented in Figure 1, was carried out by convenience. The steps considered comprised: (1) selection of therapeutic subclasses that were identical in two time periods, namely 2001 and 2016 (for more details see Souza[21]); (2) research of drugs from the selected therapeutic subclasses; (3) verification of which reference drugs had generic counterparts; (4) collection of prices of drugs

Chart 1. List of pharmacies and drugstores (n=10).

2018 Billing Ranking	Pharmacies/Drugstores	Websites
1	Drogasil	https://www.drogasil.com.br/
	Raia	https://www.drogaraia.com.br/
2	São Paulo	https://www.drogariasaopaulo.com.br/
	Pacheco	https://www.drogariaspacheco.com.br/
3	Pague Menos	https://www.paguemenos.com.br/
5	Panvel	https://www.panvel.com/panvel/main.do
7	Araujo	https://www.araujo.com.br/
8	Nissei	https://www.farmaciasnissei.com.br/
9	Venancio	https://www.drogariavenancio.com.br/
12	Drogal	https://www.drogal.com.br/

Source: created by the author based on ABRAFARMA[10].

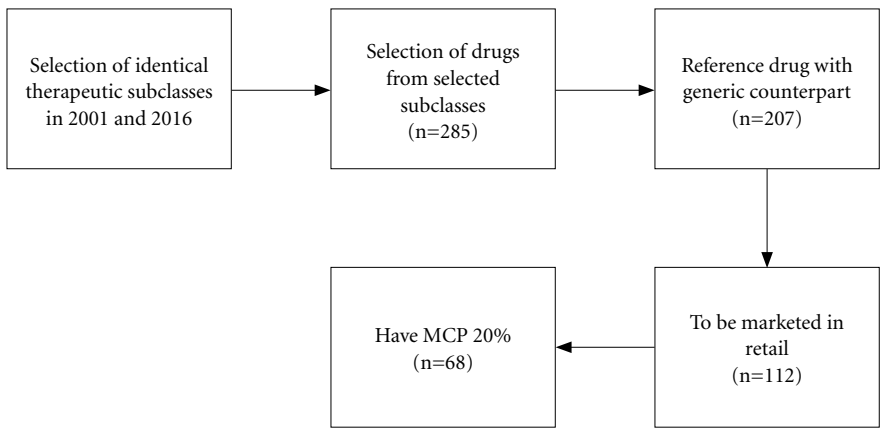

Figure 1. Steps for selecting the analyzed drugs .

Source: Authors' elaboration.

that were sold in pharmaceutical retail; and (5) exclusion of those that did not have 20% MCP established by CMED.

Regarding the last step, it is worth noting that some drugs do not have an MCP because they are: (1) drugs with free prices (CMED Resolution n. 02/2019); or (2) exempt from ICMS[22]. In addition, ICMS varies according to the state of sale and there are six ranges, which vary between 0% and 20%. For data analysis, only extreme ICMS values of 20% were considered – referred to hereafter as MCP (20%). This is a study limitation, as the ICMS variability by state was not evaluated.

Price collection was carried out only for generic and reference drugs. Generic drugs are marketed by the name of their active ingredient, that is, by the name of the drug, facilitating its identification with the reference drug to which they are interchangeable, according to the legislation. The reason for not searching for similar drugs is that, despite the requirement for interchangeability, which exists since 2003, it is not immediately evident because the drug is marketed under its own brand and the guarantee of interchangeability is only included in the drug package insert[23]. Furthermore, there is a delay in meeting the requirement schedule by Anvisa to define the interchangeability of similar drugs. For these reasons, their inclusion in the price comparability would require additional search procedures.

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Therefore, the generic correspondents of reference drugs were searched in generic drug registrations at Anvisa based on the generic drug registration list of August 5, 2019[24]. To verify whether the drug was marketed in retail, a survey on available prices was carried out in the selected websites. Chart 2 shows the final set of the convenience sample consisting of 68 drugs and the brand names of the reference drugs. The price survey was obtained for 268 commercial presentations of generic and reference drugs for analysis (all analyzed commercial presentations are found in the Chart 3).

To compare with the prices collected on the internet, CMED[22] maximum price list of drugs per active ingredient was used, hereafter referred to as CMED Price List, updated on July 1, 2019. The MCP is the maximum price that can be charged by the retail trade of drugs and contemplates both the marketing price margin and the taxes inherent to these types of trade[22].

The procedures for calculating differences in charged prices and the MCP required some attention. As for each generic drug there was an MCP established by a company, correspondences were made between the drug with the price collected at retail and its respective MCP (20%), which should have the same characteristics (same drug, presentation, pharmaceutical form and manufacturer). Therefore, the average of the MCPs (20%) informed by the CMED Price List was calculated. For the reference drugs, as there was a single MCP, it was not necessary to calculate an average for the MCPs (20%). When collecting data from different pharmacies, several and different prices were obtained for each commercial presentation of the drug collected on the internet. Aiming to establish a reference point for comparison with the MCP (20%), the average charged prices were calculated per presentation, both for generic and reference drugs.

The results were divided into two ranges of analysis according to the most frequent patterns of percentage mean difference, namely: (1) upper range, with a percentage mean difference of -60%, where the 12 highest price differences were concentrated; and (2) the lower range, with a percentage mean difference of -10%, where the nine lowest price differences were concentrated. Moreover, general data are presented with a percentage mean difference of -40%, which was used as a divisor for the highest number of drugs, either generic (greater than 40%) or reference ones (less than 40%).

Results

The results show a distinct behavior of charged prices regarding the reference and generic drugs in relation to the MCP. Of the 134 commercial presentations of reference drugs, only 13 had mean prices that were more than 40% below the MCP (20%). While, of the 134 commercial presentations of generic drugs, 96 had mean prices that were more than 40% below the average MCP (20%). Therefore, it was possible to observe a pattern for the distancing of prices arising from the market segment, in which generic drugs, mostly (72%), tended to have percentage mean differences in prices that were more than 40% below the MCP, and most of the reference drugs (88%) tended to have percentage mean differences that were less than 40% below the MCP.

This result seems to indicate a market dynamic that induces generic drugs to be quite distant from the MCP that can be practiced, due to competition between them, and that, in the reference segment, the charged price of drugs is closer to their respective MCP, showing the strength of the brand even in the face of competition with generic drugs.

It was also possible to observe that the percentage mean differences between the charged prices and the MCP in general varied widely, including drugs that had percentage mean price differences of -83% compared to the MCP and drugs that were sold at higher prices (24%) than their MCPs.

As shown in Table 1, among the drugs with mean charged prices that were more than 60% below the average MCP (20%), only two were reference ones: "Cymbalta" and "Prozac", while all others were generic drugs. Therefore, a predominance of generic drugs with prices much farther from the MCP when compared to the reference drugs was observed. Also in relation to Table 1, it is possible to note that, among the drugs with a mean charged price that was lower than 10% below the mean MCP (20%), only "Sodium Divalproate" was a generic drug, while all others were reference ones.

In the data analysis, the existence of drugs that had higher charged prices than their respective MCPs (20%) were identified, namely: the drug "Cosopt" with a concentration of "2%/0.5%", which had the highest charged price, of R$134.36, found in the collection and respective MCP (20%), of R$ 131.43; and the drug "Lyrica" with a concentration of "75mg", with the

Chart 2. List of drugs (n=68).

Generic name	Reference	Generic name	Reference
Cyproterone acetate + ethinylestradiol	Diane 35	Cetirizine dihydrochloride	Zyrtec
Acyclovir	Zovirax	Levocetirizine dihydrochloride	Zyxem
Allopurinol	Zyloric	Pramipexole dihydrochloride	Sifrol
Cefuroxime Axetil	Zinnat	Sodium Divalproate	Depakote
Bimatoprost	Lumigan	Norethisterone enanthate + estradiol valerate	Mesigyna
Clopidogrel Bisulfate	Plavix	Phenobarbital	Gardenal
Carbamazepine	Tegretol	Furosemide	Lasix
Lithium carbonate	Carbolitium	Gabapentin	Neurontin
Cephalexin	Keflex	Zolpidem Hemitartrate	Stilnox
Ceftriaxone sodium	Rocefin	Indapamide	Natrilix SR
Ketoconazole	Nizoral	Lamotrigine	Lamictal
Ciclopirox olamine	Loprox	Latanoprost	Xalatan
Cilostazol	Cebralat	Latanoprost + timolol maleate	Xalacom
Clonazepam	Rivotril	Levothyroxine sodium	Puran T4
Amiloride hydrochloride + hydrochlorothiazide	Moduretic	Loratadine	Claritin
Clindamycin Hydrochloride	Dalacin C	Dexchlorpheniramine maleate	Polaramine
Clomipramine hydrochloride	Anafranil	Dexchlorpheniramine maleate + betamethasone	Celestamine
Dorzolamide hydrochloride + timolol maleate	Cosopt	Midazolam maleate	Dormonid
Duloxetine hydrochloride	Cymbalta	Timolol maleate	Timoptol
Fexofenadine hydrochloride	Allegra	Metronidazole	Flagyl
Fluoxetine hydrochloride	Prozac	Mirtazapine	Remeron Soltab
Naratriptan hydrochloride	Naramig	Nystatin + zinc oxide	Dermodex
Nortriptyline hydrochloride	Pamelor	Fenticonazole nitrate	Fentizol
Propafenone hydrochloride	Ritmonorm	Nitrazepam	Sonebon
Sertraline hydrochloride	Zoloft	Olanzapine	Zyprexa
Tamsulosin hydrochloride	Secotex	Oxalate of escitalopram	Lexapro
Tramadol hydrochloride	Tramal	Oxcarbazepine	Trileptal
Trazodone Hydrochloride	Donaren	Acetaminophen + codeine phosphate	Tylex
Valaciclovir hydrochloride	Valtrex	Pregabalin	Lyrica
Venlafaxine hydrochloride	Efexor XR	Sumatriptan succinate	Imigran
Colchicine	Colchis	Silver sulfadiazine	Dermazine
Desloratadine	Desalex	Neomycin sulfate + bacitracin	Nebacetin
Desogestrel	Cerazette	Brimonidine tartrate	Alphagan
Diazepam	Valium	Topiramate	Topamax

Source: Authors' elaboration.

highest price identified in the collection, of R$ 227.70, and respective MCP (20%), of R$152.19. In these two cases, the commercialization was infringing the regulation that determines the maximum price that can be charged in the market for these drugs.

Discussion

In this article, only one of the problems of price regulation pointed out in the literature was investigated, i.e., the distortion of prices practiced in relation to the MCP.

Chart 3. Analyzed data (n=268).

Drugs (generic; reference)	Pharmaceutical form (quantity)	Mean price practiced (generic; reference) (A)	Mean MCP (20%) (generic; reference) (B)	Difference between price and MCP [(1-A/B)*100]
Cyproterone acetate 2mg + Ethinylestradiol 0.035mg	21 Coated Tablets	R$ 10.45	R$ 19.69	-47%
Diane 35		R$ 24.01	R$ 30.25	-21%
Cyproterone acetate 2mg + Ethinylestradiol 0.035mg	63 Coated Tablets	R$ 22.49	R$ 41.89	-46%
Diane 35		R$ 48.33	R$ 64.48	-25%
Aciclovir 200mg	25 Tablets	R$ 45.04	R$ 122.36	-63%
Zovirax 200mg		R$ 251.13	R$ 304.34	-17%
Aciclovir 50mg/g	10g Dermatological Cream	R$ 13.29	R$ 26.34	-50%
Zovirax 50mg		R$ 42.68	R$ 51.43	-17%
Allopurinol 100mg	30 Tablets	R$ 6.43	R$ 10.79	-40%
Zyloric 100mg		R$ 14.29	R$ 16.88	-15%
Allopurinol 300mg	30 Tablets	R$ 16.23	R$ 31.20	-48%
Zyloric 300mg		R$ 40.37	R$ 49.84	-19%
Axethylcefuroxime 250mg	10 Coated Tablets	R$ 41.09	R$ 78.55	-48%
Zinnat 250mg			R$ 135.20	-8%
Bimatoprosta 0.3mg/ml	3ml Ophthalmic solution	R$ 52.46	R$ 95.55	-45%
Lumigan 0.3mg/ml		R$ 116.88	R$ 146.99	-20%
Bimatoprost 0.3mg/ml	5ml Ophthalmic solution	R$ 82.69	R$ 143.33	-42%
Lumigan 0.3mg/ml			R$ 220.51	-22%
Clopidogrel Bisulfate 75mg	28 Coated Tablets	R$ 42.13	R$ 149.56	-72%
Plavix 75mg		R$ 223.40	R$ 317.31	-30%
Carbamazepine 200mg	20 Tablets	R$ 6.35	R$ 10.30	-38%
Tegretol 200mg		R$ 19.76	R$ 23.72	-17%
Carbamazepine 400mg	20 Tablets	R$ 15.49	R$ 21.84	-29%
Tegretol 400mg			R$ 47.18	-12%
Carbamazepine 20mg/ml	100ml Oral Solution	R$ 10.34	R$ 16.69	-38%
Tegretol 20mg/ml		R$ 23.74	R$ 25.74	-8%
Lithium carbonate 300mg	50 Coated tablets	R$ 20.59	R$ 25.45	-19%
Carbolitium 300mg		R$ 34.06	R$ 40.62	-16%
Cephalexin 250mg/5ml	100ml Suspension	R$ 26.36	R$ 46.38	-43%
Keflex 250mg/5ml		R$ 86.49	R$ 107.03	-19%
Ceftriaxone Sodium 1g	1 Ampoule	R$ 18.72	-	-
Rocefin 1g			-	-
Ketoconazole 20mg/g	30g Cream	R$ 13.39	R$ 21.84	-39%
Topical Nizoral 20mg		R$ 35.90	R$ 42.54	-16%
Ciclopirox Olamine 10mg/g	20g Dermatological Cream	R$ 16.27	R$ 29.94	-46%
Loprox 10mg/g		R$ 42.71	R$ 47.72	-11%
Cilostazol 100mg	30 Tablets	R$ 28.00	R$ 61.72	-55%
Cebralat 100mg			R$ 56.69	-18%
Cilostazol 100mg	60 Tablets	R$ 38.51	R$ 75.21	-49%
Cebralat 100mg		R$ 57.34	R$ 69.33	-17%
Cilostazol 50mg	30 Tablets	R$ 16.36	R$ 30.37	-46%
Cebralat 50mg		R$ 22.54	R$ 28.73	-22%

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Chart 3. Analyzed data (n=268).

Drugs (generic; reference)	Pharmaceutical form (quantity)	Mean price practiced (generic; reference) (A)	Mean MCP (20%) (generic; reference) (B)	Difference between price and MCP [(1-A/B)*100]
Cilostazol 50mg	60 Tablets	R$ 19.75	R$ 37.62	-47%
Cebralat 50mg			R$ 34.55	-15%
Clonazepam 0.5mg	30 Tablets	R$ 5.72	R$ 9.07	-37%
Rivotril 0.5mg		R$ 11.97	R$ 14.06	-15%
Clonazepam 2mg	30 Tablets	R$ 10.20	R$ 15.93	-36%
Rivotril 2mg		R$ 20.59	R$ 24.62	-16%
Clonazepam 2.5mg/ml	20ml Oral Solution	R$ 8.14	R$ 13.10	-38%
Rivotril 2.5mg/ml		R$ 18.79	R$ 22.17	-15%
Amiloride Hydrochloride 2.5mg + Hydrochlorothiazide 25mg	30 Tablets	R$ 6.55	R$ 10.71	-39%
Moduretic 25mg +2.5mg		R$ 10.45	R$ 14.14	-26%
Amiloride Hydrochloride 5mg + Hydrochlorothiazide 50mg	30 Tablets	R$ 11.23	R$ 17.89	-37%
Moduretic 50/5mg			R$ 23.60	-24%
Clindamycin Hydrochloride 300mg	16 Capsules	R$ 40.31	R$ 80.23	-50%
Dalacin C 300mg		R$ 112.16	R$ 133.45	-16%
Clomipramine Hydrochloride 25mg	20 Coated Tablets	R$ 16.49	R$ 28.11	-41%
Anafranil 25mg		R$ 34.99	R$ 43.30	-19%
Dorzolamide Hydrochloride 2% + Timolol Maleate 0.5%	5ml Ophthalmic Solution	R$ 46.82	R$ 86.85	-46%
Cosopt 2%/0.5%		R$ 120.96	R$ 131.43	-8%
Duloxetine Hydrochloride 30mg	30 Delayed-release hard capsules	R$ 63.06	R$ 158.65	-60%
Cymbalta 30mg		R$ 72.38	R$ 244.04	-70%
Duloxetine Hydrochloride 60mg	30 Delayed release hard capsules	R$ 136.95	R$ 317.28	-57%
Cymbalta 60mg		R$ 137.04	R$ 488.10	-72%
Fexofenadine Hydrochloride 60mg	10 Coated Tablets	R$ 16.01	R$ 20.94	-24%
Allegra 60mg			R$ 32.24	-20%
Fexofenadine Hydrochloride 120mg	10 Coated Tablets	R$ 22.86	R$ 41.21	-45%
Allegra 120mg		R$ 49.09	R$ 63.48	-23%
Fexofenadine Hydrochloride 180mg	10 Coated Tablets	R$ 33.62	R$ 61.86	-46%
Allegra 180mg		R$ 82.24	R$ 96.93	-15%
Fluoxetine Hydrochloride 20mg	30 Hard Capsules	R$ 20.66	R$ 59.07	-65%
Prozac 20mg		R$ 104.24	R$ 275.16	-62%
Naratriptan Hydrochloride 2.5mg	4 Coated Tablets	R$ 8.96	R$ 13.34	-33%
Naramig 2.5mg			R$ 20.50	-22%
Nortriptyline Hydrochloride 25mg	30 capsules	R$ 16.75	R$ 29.96	-44%
Pamelor 25mg		R$ 36.37	R$ 46.05	-21%
Nortriptyline Hydrochloride 50mg	30 capsules	R$ 23.77	R$ 43.64	-46%
Pamelor 50mg		R$ 54.87	R$ 67.19	-18%
Nortriptyline Hydrochloride 75mg	30 capsules	R$ 32.51	R$ 58.93	-45%
Pamelor 75mg		R$ 77.74	R$ 90.70	-14%
Propafenone Hydrochloride 300mg	30 Coated Tablets	R$ 34.16	R$ 71.84	-52%
Rhythmonorm 300mg		R$ 95.69	R$ 110.53	-13%
Propafenone Hydrochloride 300mg	60 Coated Tablets	R$ 66.15	R$ 143.67	-54%
Rhythmonorm 300mg		R$ 189.34	R$ 221.08	-14%
Sertraline Hydrochloride 100mg	30 Coated Tablets	R$ 70.36	R$ 151.65	-54%
Zoloft 100mg		R$ 178.99	R$ 233.30	-23%

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Chart 3. Analyzed data (n=268).

Drugs (generic; reference)	Pharmaceutical form (quantity)	Mean price practiced (generic; reference) (A)	Mean MCP (20%) (generic; reference) (B)	Difference between price and MCP [(1-A/B)*100]
Sertraline Hydrochloride 100mg	14 Coated Tablets	R$ 51.79	R$ 106.97	-52%
Zoloft 100mg			R$ 108.87	-16%
Sertraline Hydrochloride 50mg	30 Coated Tablets	R$ 29.35	R$ 84.64	-65%
Zoloft 50mg		R$ 84.26	R$ 108.51	-22%
Tamsulosin Hydrochloride 0.4mg	30 Tablets	R$ 54.51	R$ 114.89	-53%
Secotex 0.4mg		R$ 124.00	R$ 176.75	-30%
Tramadol Hydrochloride 50mg	10 Capsules	R$ 18.36	R$ 35.35	-48%
Tramal 50mg		R$ 49.79	R$ 63.16	-21%
Trazodone Hydrochloride 100mg	30 Coated Tablets	R$ 31.39	R$ 60.11	-48%
Donaren 100mg		R$ 73.99	R$ 92.47	-20%
Trazodone Hydrochloride 50mg	60 Coated Tablets	R$ 31.44	R$ 60.12	-48%
Donaren 50mg		R$ 57.72	R$ 92.49	-38%
Valacyclovir Hydrochloride 500mg	10 Coated Tablets	R$ 58.38	R$ 109.01	-46%
Valtrex 500mg			R$ 178.45	-15%
Valacyclovir Hydrochloride 500mg	42 Coated Tablets	R$ 281.10	R$ 441.72	-36%
Valtrex 500mg		R$ 515.99	R$ 672.94	-23%
Venlafaxine Hydrochloride 150mg	30 Time-Release Capsules	R$ 110.99	R$ 223.27	-50%
Effexor XR 150mg		R$ 420.99	R$ 520.53	-19%
Venlafaxine Hydrochloride 37.5mg	30 Time-Release Hard Capsules	R$ 40.25	R$ 76.72	-48%
Effexor XR 37.5mg		R$ 114.49	R$ 156.81	-27%
Venlafaxine Hydrochloride 75mg	30 Time-Release Hard Capsules	R$ 70.43	R$ 130.05	-46%
Effexor XR 75mg		R$ 300.99	R$ 366.97	-18%
Colchicine 0.5mg	20 Tablets	R$ 14.78	R$ 24.61	-40%
Colchis 0.5mg		R$ 23.28	R$ 40.30	-42%
Colchicine 0.5mg	30 Tablets	R$ 18.96	R$ 39.29	-52%
Colchis 0.5mg			R$ 60.47	-47%
Desloratadine 5mg	10 Coated Tablets	R$ 24.12	R$ 43.63	-45%
Desalex 5mg		R$ 50.40	R$ 59.52	-15%
Desloratadine 0.5mg/ml	100ml Syrup	R$ 34.42	R$ 59.14	-42%
Desalex 0.5mg/ml		R$ 54.86	R$ 68.15	-20%
Desloratadine 5mg	30 Coated Tablets	R$ 57.11	R$ 124.45	-54%
Desalex 5mg		R$ 70.88	R$ 92.41	-23%
Desloratadine 0.5mg/ml	60ml Syrup	R$ 21.45	R$ 35.83	-40%
Desalex 0.5mg/ml		R$ 37.98	R$ 47.64	-20%
Desogestrel 0.075mg	28 Coated Tablets	R$ 15.61	R$ 28.93	-46%
Cerazette 75mcg		R$ 35.32	R$ 44.54	-21%
Desogestrel 0.075mg	84 Coated Tablets	R$ 38.49	R$ 74.83	-49%
Cerazette 75mcg			R$ 133.64	-38%
Diazepam 10mg	30 Tablets	R$ 11.37	R$ 15.73	-28%
Valium 10mg		R$ 21.72	R$ 25.12	-14%
Diazepam 5mg	30 Tablets	R$ 8.39	R$ 11.63	-28%
Valium 5mg			R$ 18.84	-17%
Cetirizine Dihydrochloride 10mg	12 Coated Tablets	R$ 21.90	R$ 40.09	-45%
Zyrtec 10mg		R$ 51.41	R$ 63.41	-19%
Cetirizine Dihydrochloride 1mg/ml	120ml Oral Solution	R$ 21.70	R$ 34.07	-36%
Zyrtec 1mg/ml		R$ 46.45	R$ 55.46	-16%

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Chart 3. Analyzed data (n=268).

Drugs (generic; reference)	Pharmaceutical form (quantity)	Mean price practiced (generic; reference) (A)	Mean MCP (20%) (generic; reference) (B)	Difference between price and MCP [(1-A/B)*100]
Levocetirizine Dihydrochloride 5mg	10 Coated Tablets	R$ 21.86	R$ 33.52	-35%
Zyxem 5mg		R$ 43.77	R$ 51.56	-15%
Pramipexole Dihydrochloride 1mg	30 Tablets	R$ 85.11	R$ 229.98	-63%
Sifrol 1mg		R$ 307.58	R$ 353.79	-13%
Sodium Divalproate 250mg	30 Coated Tablets	R$ 25.47	R$ 36.98	-31%
Depakote 250mg		R$ 49.77	R$ 58.50	-15%
Sodium Divalproate 500mg	30 Coated Tablets	R$ 44.72	R$ 68.93	-35%
Depakote 500mg		R$ 83.99	R$ 109.05	-23%
Sodium Divalproate 125 mg	30 Capsules	R$ 19.99	R$ 21.57	-7%
Depakote Sprinkle 125mg		R$ 27.64	R$ 34.35	-20%
Norethisterone Enanthate 50mg + Estradiol Valerate 5mg	1ml Injectable Ampoule	R$ 14.53	R$ 22.25	-35%
Mesigyna 50mg + 5mg		R$ 29.36	R$ 34.69	-15%
Phenobarbital 40mg	20ml Oral Solution	R$ 3.74	R$ 6.21	-40%
Gardenal 40mg		R$ 8.22	R$ 9.69	-15%
Furosemide 40mg	20 Tablets	R$ 4.66	R$ 8.64	-46%
Lasix 40mg		R$ 14.45	R$ 18.57	-22%
Gabapentin 300mg	30 hard gelatin capsules	R$ 43.72	R$ 110.05	-60%
Neurontin 300mg		R$ 142.99	R$ 165.24	-13%
Gabapentin 400mg	30 hard gelatin capsules	R$ 54.24	R$ 131.47	-59%
Neurontin 400mg		R$ 166.99	R$ 201.10	-17%
Zolpidem Hemitartrate 10mg	20 Coated Tablets	R$ 29.25	R$ 50.71	-42%
Stilnox 10mg		R$ 62.69	R$ 78.52	-20%
Indapamide 1.5mg	30 Time-Release Coated Tablets	R$ 14.80	R$ 28.65	-48%
Natrilix SR 1.5mg			R$ 42.81	-24%
Lamotrigine 50mg	30 Tablets	R$ 29.78	R$ 58.13	-49%
Lamictal 50mg		R$ 114.72	R$ 251.22	-54%
Lamotrigine 25mg	30 Tablets	R$ 23.09	R$ 43.59	-47%
Lamictal 25mg		R$ 79.24	R$ 141.20	-44%
Lamotrigine 100mg	30 Tablets	R$ 44.86	R$ 104.67	-57%
Lamictal 100mg		R$ 233.32	R$ 439.74	-47%
Latanoprost 50mcg/ml	2.5ml Ophthalmic Solution	R$ 61.07	R$ 117.40	-48%
Xalatan 50mcg/ml			R$ 180.62	-16%
Latanoprost 50mcg + Timolol Maleate 5mg	30 Tablets	R$ 84.72	R$ 131.88	-36%
Xalacom		R$ 168.52	R$ 194.48	-13%
Levothyroxine Sodium 100mcg	30 Tablets	R$ 5.03	R$ 8.35	-40%
Puran T4 100mcg		R$ 10.29	R$ 12.88	-20%
Levothyroxine Sodium 112mcg	30 Tablets	R$ 9.74	R$ 16.42	-41%
Puran T4 112mcg			R$ 25.27	-22%
Levothyroxine Sodium 125mcg	30 Tablets	R$ 7.36	R$ 12.25	-40%
Puran T4 125mcg		R$ 14.99	R$ 18.88	-21%
Levothyroxine Sodium 150mcg	30 Tablets	R$ 7.82	R$ 13.19	-41%
Puran T4 150mcg		R$ 15.95	R$ 20.28	-21%
Levothyroxine Sodium 175mcg	30 Tablets	R$ 9.90	R$ 16.64	-41%
Puran T4 175mcg		R$ 20.09	R$ 25.63	-22%
Levothyroxine Sodium 200mcg	30 Tablets	R$ 15.06	R$ 28.81	-48%
Puran T4 200mcg		R$ 34.87	R$ 44.33	-21%

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Chart 3. Analyzed data (n=268).

Drugs (generic; reference)	Pharmaceutical form (quantity)	Mean price practiced (generic; reference) (A)	Mean MCP (20%) (generic; reference) (B)	Difference between price and MCP [(1-A/B)*100]
Levothyroxine Sodium 25mcg	30 Tablets	R$ 5.30	R$ 8.85	-40%
Puran T4 25mcg		R$ 11.23	R$ 13.64	-18%
Levothyroxine Sodium 50mcg	30 Tablets	R$ 5.82	R$ 9.80	-41%
Puran T4 50mcg		R$ 12.52	R$ 15.11	-17%
Levothyroxine Sodium 75mcg	30 Tablets	R$ 6.37	R$ 10.71	-41%
Puran T4 75mcg		R$ 12.53	R$ 16.48	-24%
Levothyroxine Sodium 88mcg	100ml Syrup	R$ 7.65	R$ 12.90	-41%
Puran T4 88mcg		R$ 15.03	R$ 19.85	-24%
Loratadine 1mg/Ml	12 Tablets	R$ 17.50	R$ 23.53	-26%
Claritin 1mg/ml			R$ 49.42	-16%
Loratadine 10mg	12 Tablets	R$ 22.90	R$ 37.30	-39%
Claritin 10mg		R$ 46.29	R$ 53.83	-14%
Dexchlorpheniramine Maleate 0.4mg/ml	120ml Oral Solution	R$ 11.25	R$ 15.28	-26%
Polaramine 0.4mg/ml		R$ 22.71	R$ 24.70	-8%
Dexchlorpheniramine Maleate 2mg	20 Tablets	R$ 7.79	R$ 11.01	-29%
Polaramine 2mg		R$ 17.91	R$ 19.71	-9%
Dexchlorpheniramine Maleate 10mg	30g Dermatological Cream	R$ 9.71	R$ 11.74	-17%
Polaramine 10mg		R$ 16.32	R$ 18.14	-10%
Dexchlorpheniramine Maleate 0.4mg + Betamethasone 0.05mg	120ml Syrup	R$ 15.29	R$ 33.16	-54%
Celestamine		R$ 41.39	R$ 51.59	-20%
Midazolam Maleate 15mg	30 Coated Tablets	R$ 38.39	R$ 70.41	-45%
Dormonid 15mg		R$ 85.74	R$ 108.42	-21%
Timolol Maleate 0.5%	5ml Ophthalmic Solution	R$ 5.36	R$ 11.19	-52%
Timoptol 0.5%		R$ 14.03	R$ 17.16	-18%
Metronidazole 250mg	20 Tablets	R$ 8.11	R$ 12.61	-36%
Flagyl 250mg		R$ 18.29	R$ 20.07	-9%
Metronidazole 100mg/g	50g Vaginal Jelly	R$ 18.02	R$ 29.49	-39%
Flagyl 100mg/g		R$ 39.89	R$ 46.82	-15%
Mirtazapine 15mg	30 Orodispersible Tablets	R$ 60.99	R$ 90.74	-33%
Remeron Soltab 15mg		R$ 89.49	R$ 139.59	-36%
Mirtazapine 30mg	30 Orodispersible Tablets	R$ 108.59	R$ 181.53	-40%
Remeron Soltab 30mg		R$ 176.99	R$ 279.28	-37%
Mirtazapine 45mg	30 Orodispersible Tablets	R$ 170.99	R$ 258.07	-34%
Remeron Soltab 45mg		R$ 176.99	R$ 397.05	-55%
Nystatin 100.000UI/g + Zinc Oxide 200mg/g	60g Ointment	R$ 17.05	R$ 32.90	-48%
Dermodex		R$ 47.75	R$ 64.97	-27%
Fenticonazole Nitrate 0.02g/g	40g Vaginal Cream	R$ 27.22	R$ 42.74	-36%
Fentizol 0.02g/g		R$ 29.95	R$ 67.30	-55%
Nitrazepam 5mg	20 Tablets	R$ 6.78	R$ 10.95	-38%
Sonebon 5mg		R$ 9.92	R$ 11.68	-15%
Olanzapine 10mg	30 Coated Tablets	R$ 323.36	R$ 701.28	-54%
Zyprexa 10mg		R$ 1.149.49	R$ 1.253.68	-8%
Olanzapine 2.5mg	30 Coated Tablets	R$ 88.11	R$ 250.18	-65%
Zyprexa 2.5mg		R$ 388.99	R$ 424.34	-8%

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Chart 3. Analyzed data (n=268).

Drugs (generic; reference)	Pharmaceutical form (quantity)	Mean price practiced (generic; reference) (A)	Mean MCP (20%) (generic; reference) (B)	Difference between price and MCP [(1-A/B)*100]
Olanzapine 5mg	30 Coated Tablets	R$ 122.66	R$ 407.42	-70%
Zyprexa 5mg		R$ 574.99	R$ 626.80	-8%
Escitalopram Oxalate 10mg	30 Coated Tablets	R$ 39.02	R$ 155.49	-75%
Lexapro 10mg		R$ 169.60	R$ 294.87	-42%
Escitalopram Oxalate 15mg	30 Coated Tablets	R$ 67.19	R$ 209.33	-68%
Lexapro 15mg		R$ 168.49	R$ 353.95	-52%
Escitalopram Oxalate 20mg	30 Coated Tablets	R$ 87.29	R$ 280.09	-69%
Lexapro 20mg		R$ 251.63	R$ 560.46	-55%
Escitalopram Oxalate 10mg	60 Tablets	R$ 64.49	R$ 383.56	-83%
Lexapro 10mg		R$ 174.99	-	-
Escitalopram Oxalate 20mg/ml	15ml Oral Solution	R$ 48.39	R$ 191.73	-75%
Lexapro 20mg/ml		R$ 267.49	R$ 294.89	-9%
Oxcarbazepine 300mg	60 Coated Tablets	R$ 47.89	R$ 98.50	-51%
Trileptal 300mg		R$ 150.32	R$ 174.17	-14%
Oxcarbazepine 600mg	60 Coated Tablets	R$ 82.74	R$ 192.59	-57%
Trileptal 600mg		R$ 286.99	R$ 334.16	-14%
Paracetamol 500mg + Codeine Phosphate 30mg	12 Tablets	R$ 12.82	R$ 20.56	-38%
Tylex 30mg		R$ 28.67	R$ 34.18	-16%
Paracetamol 500mg + Codeine Phosphate 30mg	24 Tablets	R$ 23.40	R$ 40.54	-42%
Tylex 30mg		R$ 58.99	R$ 66.68	-12%
Paracetamol 500mg + Codeine Phosphate 30mg	36 Tablets	R$ 32.96	R$ 58.52	-44%
Tylex 30mg		R$ 81.99	R$ 90.03	-9%
Pregabalin 75mg	28 Hard Capsules	R$ 51.09	R$ 98.91	-48%
Lyrica 75mg		R$ 188.09	R$ 152.19	24%
Sumatriptan Succinate 50mg	2 Coated Tablets	R$ 14.95	R$ 22.75	-34%
Imigran 50 mg		R$ 29.80	R$ 35.06	-15%
Sumatriptan Succinate 100mg	2 Coated Tablets	R$ 26.86	R$ 45.12	-40%
Imigran 100mg		R$ 62.72	R$ 93.33	-33%
Silver Sulfadiazine 10mg/g	30g Cream	R$ 14.39	R$ 21.69	-34%
Dermazine 10mg/g		R$ 29.31	R$ 33.98	-14%
Silver Sulfadiazine 10mg/g	50g Cream	R$ 17.28	R$ 32.22	-46%
Dermazine 10mg/g		R$ 35.92	R$ 42.84	-16%
Neomycin Sulfate 5mg/g + Bacitracin 250iu/g	15g Ointment	R$ 6.92	R$ 9.77	-29%
Nebacetin		R$ 13.89	R$ 17.57	-21%
Neomycin Sulfate 5mg/g + Bacitracin 250iu/g	50g Ointment	R$ 11.56	R$ 21.67	-47%
Nebacetin		R$ 27.79	R$ 36.36	-24%
Brimonidine Tartrate 2 mg/ml	5ml Ophthalmic Solution	R$ 26.18	R$ 63.90	-59%
Alphagan 2 mg/ml		R$ 83.74	R$ 98.32	-15%
Brimonidine Tartrate 1.5mg/ml	5ml Ophthalmic Solution	R$ 23.04	R$ 53.09	-57%
Alphagan P 1.5mg/ml		R$ 77.23	R$ 98.32	-21%
Topiramate 50mg	60 Coated tablets	R$ 91.82	R$ 227.36	-60%
Topamax 50mg		R$ 225.99	R$ 332.73	-32%
Topiramate 25mg	60 Coated tablets	R$ 47.25	R$ 110.43	-57%
Topamax 25mg		R$ 148.32	R$ 203.73	-27%
Topiramate 100mg	60 Coated tablet	R$ 186.58	R$ 389.78	-52%
Topamax 100mg			R$ 670.90	-37%

Source: Authors' elaboration.

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Table 1. Drugs with lower and higher mean price differences in relation to the MCP.

Analyzed drugs	Type (quantity)	Percentage mean price difference of observed concentrations
Sodium Divalproate (125 mg)	Generic (1)	-7%
Cosopt (2%/0.5%); Polaramine (0.4mg/ml); Tegretol (20mg/ml); Zinnat (250mg); Zyprexa (10mg, 2.5mg and 5mg)	Reference (5)	-8%
Flagyl (250mg); Lexapro (20mg/ml); Polaramine (2mg); Tylex (30mg)	Reference (4)	-9%
Polaramine (10mg)	Reference (1)	-10%
Duloxetine Hydrochloride (30mg); Gabapentin (300mg); Topiramate (50mg)	Generic (3)	-60%
Prozac (20mg)	Reference (1)	-62%
Acyclovir (200mg); Pramipexole dihydrochloride (1mg)	Generic (2)	-63%
Fluoxetine Hydrochloride (20mg); Sertraline Hydrochloride (50mg); Olanzapine (2.5mg)	Generic (3)	-70%
Olanzapine (5mg); Cymbalta (30mg)	Generic (1); Reference (1)	-72%
Clopidogrel Bisulfate (75mg); Cymbalta (60mg)	Generic (1); Reference (1)	
Escitalopram Oxalate (10mg, 15mg, 20mg, 10mg and 20mg/ml)	Generic (1)	-75%, -68%, -69%, -83% e -75%

Source: Created by the authors based on the analyzed data.

The evidence observed in the collection of charged prices confirms the presence of this problem in Brazilian regulation, broadening the perception previously expressed in the article by Miziara and Coutinho[9]. The main argument to explain the greater distancing regarding the price of generic drugs may be the number of discounts offered by the manufacturers of these drugs to encourage the sale of their products, as identified by Palmeira Filho[25].

As observed in this study, the percentage mean differences between charged prices and MCPs were quite significant, especially regarding generic drugs, of which approximately 72% of these drugs tended to have differences that were more than 40% below the MCP, which is imposed on them. Therefore, it can be inferred that the price-cap imposed by CMED on drugs in this segment in the Brazilian market seems to be so high that it ends up undermining the objective of the regulation itself for generic drugs and, in this case, competition seems to be the main factor of stimulus to price reduction[21].

In 2012, the report of Ruling 3,016 of the Federal Accounting Office (TCU, *Tribunal de Contas da União*)[26] had already recommended the Ministry of Health to review and correct the regulatory model provided for in Law n. 10,742/03, in order to dissociate readjustments from the inflation. After finding that 86% of the drugs in a drug sample with the highest billing had a price above the international mean, with 46% having the highest price in Brazil, they also recommended the periodic review of prices based on criteria such as international comparison, exchange rate variation and costs of the different treatments. The §9 of Article 4 of Law 10,742/03 states that, exceptionally, a negative price adjustment can be determined on August 31, 2003. However, the current price reduction by the adjustment formula is not foreseen.

The Court ruling gave rise to a public consultation, which culminated in the change of parameters for calculating the price adjustment, showing that some degree of change in the way the parameters are calculated is feasible, even though the current law is in force[8]. This became clear with the publication of the Provisional Measure (MP, *Medida Provisória*) 754/16[27]. CMED now has the possibility of determining the downward adjustment of the current price[9,28]. However, this MP was terminated in the same year, after a letter

of explanatory memorandum[29] stating that "the negative price adjustment must occur, exceptionally, when price distortions are observed, in order to promptly attack the detected distortions, provide a balance of conditions and generate greater competitiveness in the market".

Another aspect that may explain the observed results is that the market dynamics for generic and reference drugs occur in different ways. For generic drugs, competition tends to occur via prices or discounts, whereas for reference drugs, competition for differentiation of products distinguished by patents and brands predominates[2,30]. Therefore, the competition between reference and generic drugs, even after patents expire, occurs under different conditions. Brand loyalty guarantees a price-inelastic demand for reference drugs; and the perception of the generic as interchangeable between several generics and the reference drug makes demand elastic to price[30].

This market dynamics may be one of the reasons that make generics distance further from the MCP than the reference drugs. This point was corroborated by Dantas and Mendonça[31] when they showed that the price reduction policy through the introduction of generics is an indirect way of controlling prices, since it acts on competition and not on the characteristics that directly define prices. The model adopted by the authors suggested that a type of market segmentation may be occurring due to the increase in the distance between the prices of generic and reference drugs[31].

As demonstrated by the results, the determination of the MCP by CMED seems to make much more sense for the reference drugs, which have been charging prices very close to their MCPs. Miziara and Coutinho[9] also observed that the mean prices of drugs practiced in pharmacies and drugstores were far below the MCP. Between 2009 and 2012, 44 of the 129 charged prices showed a variation greater than 20% between the mean of prices practiced and the MCPs. This disparity, according to the authors, depicts the limits of drug price regulation carried out in Brazil, which is unable to pressure the prices of a significant number of drugs to levels below those determined by the industry. In addition, as shown by Dias et al.[8], the mean practiced "discounts" in relation to prices ceiling increased from 34.69% in 2012 to 41% in 2016, that is, a greater tendency towards the distancing of prices has been observed the over the years. As this regulation has never been revised, the increase in the distancing between the charged prices and MCPs has progressed, potentially causing losses to consumers.

In this same sense, Monte[32] points out that what has been observed is a fragmented and ineffective regulation, considering that fixed prices are distorted, being incapable of preventing abusive adjustments. Such distortions allow the practice of high commercialization margins, even after the end of the patent validity period, when one supposed that the costs of research and development had already been paid. The conclusion reached by Monte[32] is that the current regulatory model does not guarantee the expansion of access to medicines, nor the reduction of prices, nor the interest of companies in increasing productivity and reducing costs. The evaluation and monitoring of fluctuations in the final prices of drugs are essential, along with communication with other data systems and price records, so that CMED can truly act as a regulatory agency. To curb the abusive prices imposed by the pharmaceutical industry, the way, without a doubt, is the transparency in the establishment of prices and joint actions by state entities[32].

As already stated by Miziara and Coutinho[9], the main reasons for observing these considerable differences between the MCP and the charged prices are the absence of effective monitoring of drug prices at points of sale by CMED and the lack of legal provision for the possibility of reduction in the regulated drug prices. In 2017, amidst controversies, CMED even issued Interpretive Guidance No. 2, clarifying that the CMED Price List is just a price ceiling list[8]. However, it makes no sense to believe that a regulation is only intended to serve as a price list that depicts maximum prices, but it is not capable of effectively pushing drug prices down, without exerting any kind of pressure on the pharmaceutical industry. Therefore, although the CMED Price List is just a simple price ceiling list, it has ceased to perform its main function, i.e., pressuring down drug prices in Brazil, becoming innocuous in many ways.

This understanding is also expressed by Maluf[33], who states that the CMED is an important regulatory agency and cannot be restricted to the mere issuing of price lists. Maluf[33] states that the matter of inadequate standards, or inappropriate interference, in addition to making access to medicines difficult, does not solve the issue of their lack, further aggravating the problem, intensifying the market's own inequalities and failures; moreover, it scares away the economic agents and their investments, leaving the popu-

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lation more deprived of medicines, concluding that poor regulation is even worse than the absence of regulation.

The model that determines the price ceiling in Brazil is used for drugs in general, whether it is a generic or a reference one. The price readjustment, however, differs by the degree of concentration at which these drugs act. Nevertheless, it was possible to observe that reference drugs have kept their prices closer to the established ceiling than generic ones, which tend to further detach their prices from the MCPs. In Norway, as shown by Brekke et al.[34], when the price-cap model was in force, mandatory only for the reference drugs, they observed that the price of these drugs tended to fluctuate close to the established ceiling, while the price of generic drugs tended to show a significant decrease. Thus, the adoption of the price-cap model for generic drugs as well, such as the one currently practiced in Brazil, may be one of the factors that has led to the ineffectiveness of the current regulation.

As pointed out by Delgado[35], economic regulation must adopt new strategies to correct or adjust the cost of drugs for the final consumer, who does not have or has little access to drugs considered essential in a market in which the creation and development of new drugs have a higher value. The author suggests that competitive conditions in this market make access to drugs for the population a challenging issue, hindering the achievement of what is expected from good regulation, that is, maximizing social and consumer welfare, without harming the pharmaceutical production chain and vice-versa.

Recently, amidst the COVID-19 pandemic, although the readjustment of drug prices has been postponed for two months, some experts observed that this would not solve the problem of rising drug prices on the market. This would occur mainly because, as discussed in this article, manufacturers have a wide margin that allows them to increase drug prices within the current legal limit established by CMED. The readjustment does not tend to directly impact on drug prices, but on the price ceiling. As this ceiling is very high, in practice it does not limit the prices of these products, as stated by Ana Navarrete from the Brazilian Institute of Consumer Protection[36].

After two months of drugs price readjustment suspension, the Federal Government authorized the readjustment of drug prices for 2020 on June 1st. According to the CMED resolution published in the Brazilian Federal Register, the maximum adjustment allowed for 2020 would be applied in three ranges, of 5.21%, 4.22% and 3.23%, depending on the type of drug. The ceiling of the authorized increase for 2020 is higher than that of the previous year, which was 4.33%. However, on June 2, 2020, the Senate approved a bill (PL 1,542/2020) that aims to extend the suspension period for drug price readjustments to 120 days. The proposal would still have to be voted by the House of Representatives[37,38].

What has been observed in practice, despite the fact that the prices of drugs have not been readjusted, are several complaints from consumers regarding the increase in drug prices during the Covid-19 pandemic[39,40-42]. However, when allegations of abusive pricing practices are analyzed by the Consumer Protection and Defense Program (PROCON, *Programa de Proteção e Defesa do Consumidor*), it is observed that prices are within the limits established by CMED. This confirms what was observed in this article, that at certain times there is a huge margin that manufacturers can use to raise drug prices, which are often far below the ceiling.

Among the limitations of this article, we can mention: (1) the variety of values established for the ICMS, which was not taken into consideration; (2) the use of data on drug price and availability collected only from the internet, which may differ from charged prices in physical stores; (3) the non-differentiation between charged prices per state; (4) the use of a small and convenient sample of drugs; (5) the use of a price sample related to a single moment in time; (6) the non-inclusion of independent pharmacies, using only the large chains; and (vii) the non-inclusion of similar drugs.

Final considerations

Based on the study presented in this article, it was possible to observe that there has been a significant gap between the charged prices and the MCPs established for drugs in Brazil. The differences between charged prices and MCPs were quite significant, especially regarding generic drugs, where about 72% of these drugs tended to show differences that were more than 40% below the MCP. Whereas approximately 88% of the reference drugs tended to have price differences that were less than 40% below the MCP.

This greater distancing between charged prices and MCPs allows, in times of crisis, such as the COVID-19 pandemic, pharmaceutical

companies to increase the price of their products in the market, without disrespecting the current regulation. It is noteworthy that this can happen not only in times of crisis, but the fact that the crisis reinforces the space that these companies have. For this reason, it is important that periodic assessments of market prices and a realignment of established price ceilings occur, especially for generic drugs, so that the charged prices are not higher than those that should in fact prevail.

In conclusion, it can be acknowledged that the price ceiling imposed on drugs has made more sense for reference drugs than for generic ones. For this reason, it is expected that the results of this article can alert about the need for in-depth evaluations on the method used to establish a price-cap for drugs in Brazil, complementing the evidence pointed out herein, which indicate the need for a review of the currently adopted regulation.

Collaborations

Study conception and design: CMA Souza, J Paranhos and L Hasenclever. Data analysis and interpretation: CMA Souza. Writing of the manuscript: CMA Souza. Critical review of the manuscript: J Paranhos and L Hasenclever. Approval of the version to be published: CMA Souza, J Paranhos and L Hasenclever.

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