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# Problems in the regulatory policy of the drug market

## Problemas na política regulatória do mercado de medicamentos

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### ABSTRACT

**OBJECTIVE:** Analyze the implementation of drug price regulation policy by the Drug Market Regulation Chamber.

**METHODS:** This is an interview-based study, which was undertaken in 2012, using semi-structured questionnaires with social actors from the pharmaceutical market, the pharmaceuticals industry, consumers and the regulatory agency. In addition, drug prices were compiled based on surveys conducted in the state of Sao Paulo, at the point of sale, between February 2009 and May 2012.

**RESULTS:** The mean drug prices charged at the point of sale (pharmacies) were well below the maximum price to the consumer, compared with many drugs sold in Brazil. Between 2009 and 2012, 44 of the 129 prices, corresponding to 99 drugs listed in the database of compiled prices, showed a variation of more than 20.0% in the mean prices at the point of sale and the maximum price to the consumer. In addition, many laboratories have refused to apply the price adequacy coefficient in their sales to government agencies.

**CONCLUSIONS:** The regulation implemented by the pharmaceutical market regulator was unable to significantly control prices of marketed drugs, without succeeding to push them to levels lower than those determined by the pharmaceutical industry and failing, therefore, in its objective to promote pharmaceutical support for the public. It is necessary reconstruct the regulatory law to allow market prices to be reduced by the regulator as well as institutional strengthen this government body.

**DESCRIPTORS:** Drug Price. Drugs, Essential, economics. National Drug Policy. National Policy of Pharmaceutical Assistance. Health Care Coordination and Monitoring.

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## RESUMO

**OBJETIVO:** Analisar a implementação da política de regulação de preços de medicamentos pela Câmara de Regulação do Mercado de Medicamentos.

**MÉTODOS:** Estudo baseado na realização de entrevistas, em 2012, usando questionários semiestruturados, com atores sociais do mercado de medicamentos, representantes da indústria farmacêutica, de consumidores e do órgão regulador. Foram também compilados preços de medicamentos obtidos em pesquisas realizadas no Estado de São Paulo, nos pontos de venda, entre fevereiro de 2009 e maio de 2012.

**RESULTADOS:** As médias dos preços de medicamentos praticadas nos pontos de venda (farmácias e drogarias) estiveram muito abaixo do preço máximo ao consumidor, em relação à grande parte dos medicamentos comercializados no Brasil. Entre 2009 e 2012, 44 dos 129 preços praticados, correspondentes a 99 medicamentos constantes do banco de preços compilados, apresentaram variação superior a 20,0% entre a média de preços praticados nos pontos de venda e o preço máximo ao consumidor. Ademais, muitos laboratórios se recusaram a aplicar o coeficiente de adequação de preços nas vendas a órgãos públicos.

**CONCLUSÕES:** A regulação implementada pelo órgão regulador do mercado de medicamentos foi incapaz de controlar os preços de quantidade significativa dos medicamentos comercializados, pressionando-os a patamares inferiores àqueles determinados pela indústria farmacêutica e falhando, portanto, no seu objetivo de promover assistência farmacêutica. É necessária reforma da lei regulamentadora para permitir a redução de preços praticados no mercado pelo órgão regulador, bem como fortalecimento institucional desse órgão.

**DESCRITORES:** Preço de Medicamento. Medicamentos Essenciais, economia. Política Nacional de Medicamentos. Política Nacional de Assistência Farmacêutica. Regulação e Fiscalização em Saúde.

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## INTRODUCTION

The high prices of essential drugs are recognized as a serious public health problem in Brazil.<sup>13,a</sup> Given that almost eight out of 10 purchases of drugs are currently paid for by patients,<sup>b</sup> drug prices constitute an important variable for determining the population's access to pharmaceutical products.<sup>8,14,c</sup>

This situation results in the poorer classes being those members of society that are most harmed.<sup>3,5,15,d</sup> According to the *Pesquisa de Orçamentos Familiares* (POF – Brazilian Household Expenditure Survey),

conducted by the Brazilian Institute of Geography and Statistics (IBGE) in 2008-2009, families with a monthly income of less than R\$830.00 spend 4.2% of such income on medicines, whereas families with a monthly income exceeding R\$10,375.00 spend 1.9% of their income on these products.<sup>e</sup> The reason for the high cost of medicines is due to many factors that are mainly economic in nature.<sup>4,6,7,10,12,13,f</sup> Thus, in 2003, the *Câmara de Regulação do Mercado de Medicamentos* (CMED – Brazilian Drugs Market Regulation Chamber) created Law 10,742.<sup>9,13</sup> The purpose of such policy was

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<sup>a</sup> Agência Nacional de Vigilância Sanitária. Regulação econômica do mercado farmacêutico. Brasília (DF); 2001 [cited 2012 may 15]. Available from: <http://portal.anvisa.gov.br/wps/wcm/connect/>

<sup>b</sup> Sindicato do Comércio Varejista de Produtos Farmacêuticos. Dois gargalos na saúde: financiamento e acesso a medicamentos. São Paulo (SP); 2010 [cited 2013 apr 15]. Available from: <http://www.sindifarmajp.com.br>

<sup>c</sup> Follador W. Alguns aspectos da variação de preços de medicamentos no Brasil no período de 1980 a 2001 [dissertation]. São Paulo (SP): Faculdade de Ciências Farmacêuticas da USP; 2001.

<sup>d</sup> Santos SCM. Busca na equidade no acesso a medicamentos no Brasil: os desafios impostos pela competição extra-preço [dissertation]. Rio de Janeiro (RJ): Escola Nacional de Saúde Pública da Fiocruz; 2001.

<sup>e</sup> Instituto Brasileiro de Geografia e Estatística. Pesquisa de orçamentos familiares 2008-2009. Rio de Janeiro (RJ); 2010 [cited 2011 mar 16]. Available from: [http://www.ibge.gov.br/home/estatistica/populacao/condicaoodevida/pof/2008\\_2009\\_encaa/pof\\_20082009\\_encaa.pdf](http://www.ibge.gov.br/home/estatistica/populacao/condicaoodevida/pof/2008_2009_encaa/pof_20082009_encaa.pdf)

<sup>f</sup> Oliveira RR. Os conceitos de regulação em saúde no Brasil [dissertation]. São Paulo (SP): Faculdade de Medicina da USP; 2010.

to increase pharmaceutical financial support to the public through economic regulation of the drugs market. The economic regulation exerted by the CMED is based on the prerogative of establishing criteria for establishing and adjusting medicine prices, as well as for fixing product profit margins to be observed by sales representatives, distributors, pharmacies and drugstores.<sup>18,g</sup>

This field remains underexplored, and as a result there are few scientific studies that focus on the Brazilian Drugs Market Regulation Chamber or drug price regulation. The Brazilian Government itself still does not have any evaluations of the regulation practiced by the CMED, as is the case regarding the effectiveness of this regulatory policy. The scientific literature on the subject is limited to analysis of the regulatory legislation, with there being no research on the results of implementing the regulation.<sup>1-3,7,11,15,16,18</sup>

The aim of this study is to analyze the implementation of the regulatory policy of drug prices that has been executed by the regulator.

## METHODS

This study was developed based on four steps.

- Step 1: Legislative analysis on the subject and bibliographical research

The analysis focused on the regulatory legislation – Law 10,742/2003, which establishes the guidelines for the economic price regulation policy and creates the Brazilian Drugs Market Regulation Chamber – and on the resolutions issued by the regulating body. The legal instruments used by CMED are resolutions that establish regulatory criteria that must be observed by those who work in the pharmaceutical market, especially the pharmaceutical industry, distributors, pharmacies and drugstores.

- Step 2: Holding interviews

Because there are so few scientific studies on the implementation and effectiveness of economic regulation of the drug market by the CMED, it was necessary to hold interviews with social actors from the pharmaceutical market. From February to December 2012, the interviews were conducted, in person using semi-structured questionnaires, with the following social actors from the pharmaceutical market: representatives from the

CMED (three advisors from the Executive Secretariat); a representative from a consumer protection agency (an economist at the Brazilian Consumer Protection Institute); a representative from the scientific community (an economist at the Universidade de São Paulo and the Brazilian Foundation for Economic Research which is involved in market research for medicinal products).<sup>h</sup>

The main questions that were put to the interviewees were as follows: *Why regulate prices in the pharmaceutical market? What are the major difficulties and bottlenecks of the current policy for price regulation implemented by the CMED? Which measures could be used to make the CMED regulatory policy more efficient in terms of increasing the pharmaceutical support that is available to the population? Can better monitoring of drug prices positively influence the price control policy's effectiveness? Does the CMED monitor actual drug prices, i.e., the prices charged on the market now?*

- Step 3: Price research

A database was built based on real drug prices, which are defined as those charged in retail outlets. This database was built in order to compare market prices with the price ceiling as established by the CMED, the Maximum Price to the Consumer (MPC), while seeking to observe variations and any failure to comply with regulatory standards.

The prices charged at the sale points were obtained from surveys conducted by the *Instituto de Defesa do Consumidor* (IDEC – Brazilian Consumer Protection Institute) and by the *Fundação de Proteção e Defesa do Consumidor* (PROCON-SP – Foundation for Consumer Protection and Defense), from 2009 to 2012. The MPC from the respective periods was obtained through the CMED resolutions, which were available in the portal of the *Agência Nacional de Vigilância Sanitária* (ANVISA – Brazilian National Health Surveillance Agency).<sup>i</sup>

Few surveys on drug prices have been performed in Brazil, especially those done by the IDEC or the PROCON-SP,<sup>j,k,l,m</sup> which were used to compose the prices database produced during this study. Such surveys are based on a yearly collection of drug prices in various Brazilian cities. The list of compiled drug prices changed from year to year, making any temporal analysis of one drug's price evolution impossible. Only 10 medicines from the drafted prices database had their

<sup>g</sup> Teixeira L. Reajustes de preços administrados no setor da saúde. Brasília (DF): Câmara dos Deputados; 2006 [cited 2014 may 15]. Available from: [http://bd.camara.gov.br/bd/bitstream/handle/bdcamara/1646/reajustes\\_precos\\_teixeira.pdf?sequence=4](http://bd.camara.gov.br/bd/bitstream/handle/bdcamara/1646/reajustes_precos_teixeira.pdf?sequence=4)

<sup>h</sup> The initial goal was also to interview a representative from the pharmaceutical industry. However, despite numerous attempts, there were no members of the pharmaceutical industry who agreed to grant interviews for the purposes of this study.

<sup>i</sup> Agência Nacional de Vigilância Sanitária. Listas de Preços de Medicamentos. Brasília (DF); 2015 [cited 2015 feb 21]. Available from: <http://portal.anvisa.gov.br/wps/portal/anvisa/anvisa/regulado>

<sup>j</sup> Instituto de Defesa do Consumidor. Remédio pro bolso. *Rev IDEC*. 2009;130:16-20.

<sup>k</sup> Instituto de Defesa do Consumidor. Meio cheio ou meio vazio? *Rev IDEC*. 2010;142:22-5.

<sup>l</sup> Instituto de Defesa do Consumidor. Diferença além da conta. *Rev IDEC*. 2012;162:16-9

<sup>m</sup> Fundação de Defesa e Proteção do Consumidor do Estado de São Paulo. Pesquisa comparativa de preços de medicamentos. São Paulo (SP); 2014 [cited 2014 jun 13]. Available from: <http://www.procon.sp.gov.br/categoria.asp?id=903>

prices collected for all of the years during the observed period (2009 to 2012).

It was possible to observe that a significant amount of medicines, in different Brazilian cities, had mean point of sale prices that fell far short of the MPC stipulated by the CMED.

Given that the interviews were designed to find data that are already available in the public domain and is non-classified, no submission of the study to the research ethics committee was required.

## RESULTS AND DISCUSSION

Regulatory legislation analysis showed that the economic regulation exerted by the CMED took shape mainly in terms of defining criteria for establishing and adjusting drug prices, and determining the price adequacy coefficient to sales that is performed by public agencies.<sup>8,n</sup> As regards the price adjustment, the CMED distinguishes between price control for drug manufacturers and price control directed towards other traders.<sup>o</sup> The drug manufacturers have to observe the ceiling established by the factory price;<sup>p</sup> while the other traders, responsible selling drugs at retail outlets, have to observe the MPC.<sup>q</sup> The factory price is the maximum price at which a laboratory or distributor may market a drug, while the MPC is the highest price at which a medicine may be sold to the consumer in pharmacies or drugstores.<sup>5</sup> The factory price and the MPC are both fixed annually and calculated by a numerical formula that considers, among other factors, the productivity and the broad consumer price index for the period involved.<sup>r</sup> The CMED also establishes the price adequacy coefficient, which consists of a compulsory discount regarding certain medicines that are sold to supply the public health system.<sup>5</sup> This coefficient is recalculated annually from the mean ratio between the gross domestic product *per capita* in Brazil and in nine developed countries, while taking the human development index into account.

The interviews and the data extracted from the prices database made it possible to observe two major problems for implementing the drug price regulation policy set out by the CMED: (i) the mean drug prices charged in retail outlets (pharmacies and drugstores) were far below the MPC, which represents a considerable portion of the drugs marketed in Brazil; (ii) many laboratories refused to apply the price adequacy coefficient in sales made to public agencies.

Despite the difficulty encountered while compiling drug prices during this study, which made it impossible to assess price evolution patterns of one drug over the long term, it was possible to observe that the biggest problem for implementing the CMED's regulatory policy is the large difference, which exists in most Brazilian cities, between the mean drug prices sold in retail outlets and the ceiling established by the regulator through the MPC. From 2009 to 2012, 44 of 129 prices, referring to 99 drugs listed in the price database, presented more than a 20.0% variation between the mean prices that are charged in retail outlets and the MPC for the respective period.<sup>1</sup> This affirmation indicates that the regulation implemented by the CMED is unable to push the prices of marketed medicines to levels that are lower than those determined by the pharmaceutical industry, thereby failing in its goal to facilitate access to medicines and in turn promote pharmaceutical support for the public. Thus, the CMED price regulation appears to be ineffective, due to being unable to interfere in the arbitration of prices for the most part of the drugs industry.

According to a representative from the interviewed consumers, a variation of less than 20.0% would be acceptable between prices at the point of sale and the ceiling established by the CMED. However, the mean variations were considerably higher than those deemed acceptable by this expert.

Contrary to what might be believed, this disparity between prices at the points of sale and the MPC established by CMED does not portray the benefits bestowed by pharmacies to consumers through "discounts", but it

<sup>n</sup> Batista LB. Regulação econômica do mercado farmacêutico brasileiro [dissertation]. Rio de Janeiro (RJ): Universidade Cândido Mendes; 2005.

<sup>o</sup> Andrade A, Andrade CAP, Uliam FO. Controle de preços de remédios. *ETIC*. 2010 [cited 2015 feb 20] 6 (6). Available from: <http://intertemas.unitoledo.br/revista/index.php/ETIC/article/viewArticle/2412>

<sup>p</sup> Agência Nacional de Vigilância Sanitária, Câmara de Regulação do Mercado de Medicamentos. Resolução 1, de 25 de fevereiro de 2005. Estabelece os critérios de composição de fatores para o ajuste de preços de medicamentos a ocorrer em 31 de março de 2005. *Diário Oficial Uniao*. 12 mar 2007;Seção 1:1.

<sup>q</sup> Agência Nacional de Vigilância Sanitária, Câmara de Regulação do Mercado de Medicamentos. Resolução 4, de 27 de julho de 2004. Dispõe sobre a forma de definição do Preço Fabricante e do Preço Máximo ao Consumidor dos medicamentos, estabelece a forma de apresentação de Relatório de Comercialização à Câmara de Regulação do Mercado de Medicamentos, disciplina a publicidade dos preços dos produtos farmacêuticos e define as margens de comercialização para esses produtos. *Diário Oficial Uniao* 29 mar 2004;Seção 1:4.

<sup>r</sup> Agência Nacional de Vigilância Sanitária, Câmara de Regulação do Mercado de Medicamentos. Resolução 1, de 27 de fevereiro de 2004. Estabelece os critérios de composição de fatores para o ajuste de preços de medicamentos a ocorrer em 31 de março de 2014. *Diário Oficial Uniao*. 28 fev 2004;Seção 1:2.

<sup>5</sup> Agência Nacional de Vigilância Sanitária, Câmara de Regulação do Mercado de Medicamentos. Resolução 4, de 18 de dezembro de 2006. Dispõe sobre o Coeficiente de Adequação de Preços – CAP, sua aplicação, e que e altera a Resolução CMED 2, de 5 de março de 2004. *Diário Oficial Uniao*. 12 mar 2007;Seção 1:1-2.

<sup>1</sup> For more information regarding the prices database cfr. Miziara NM. Market regulation of medicines: the CMED and price control policy [entitled dissertation]. São Paulo (SP): Faculdade de Direito da USP; 2013.

does show the limits of drug price regulation in Brazil. The ceiling set by the Government is too high and such a discrepancy is harmful for consumers, due to the fact that sudden price changes may occur at any time. It is worth remembering that the annual readjustment overseen by the CMED is established based upon the maximum price for marketing a product (factory price or MPC) rather than in percentages.

The interviews showed considerable reasons behind the difference between the MPC and the prices charged in the market, such as the absence of effective monitoring of the drug prices at the points of sale and the lack of legal provision to make reductions in regulated prices possible. The CMED does not monitor drug prices at retail outlets and therefore has no information regarding the actual prices of these products in the market. This regulator relies solely on price figures from annual reports issued by pharmaceutical laboratories and publications by *Associação Brasileira do Comércio Farmacêutico* (ABCFARMA – Brazilian Pharmaceutical Trade Association). These price sources cannot match those that monitor prices at retail outlets, since the ABCFARMA publications use the pharmaceutical industry as a direct source of information. Therefore, the CMED does not have any actual data regarding market prices, but rather information provided by the industry itself – which can be assumed to be skewed – and subsequently has no way to control whether the regulation is effective in practice or not. As a practical result of having no way to monitor actual prices, the formula for determining the factory price and the MPC takes its information regarding prices directly from the pharmaceutical industry. Consequently, there is a significant difference between the price ceiling established by CMED and prices that are actually charged in the market. Within this considerable gap between actual prices and the MPC are the readjustments that, in percentage terms and in practice, become much larger than those stated by the CMED and therefore become inflated for the period.

This also shows the regulator's dependence on industry to obtain information, without which it cannot perform its institutional task properly. In the literature on regulation, this problem was coined as "capture" and is considered as one of the reasons why regulatory action can ultimately serve the interests of the industry being regulated, all to the detriment of the collective interest.<sup>17</sup>

Based on interviews with representatives from the CMED, it was possible to observe that the regulator recognizes the problem and justifies the significant difference between the so-called "discount" provided by the pharmaceutical industry and the established ceiling, thereby assigning this situation to the high prices that charged and informed about by the

pharmaceutical industry a short time before the creation of the new regulatory body, and also to the fact that the Law 10,742/2003 no longer expressly contemplates the possibility of reducing prices that are already charged. Based on the absence of any explicit forecast of cases in which they could operate a negative adjustment, any regulatory standard that involves price reductions might be deemed illegal, thereby generating legal disputes initiated by the pharmaceutical industry. Thus, the absence of calibratory or adjusting mechanisms of the regulatory standards ends up mitigating the effectiveness of the law, which becomes unable to react, as would be expected from a regulatory standard in an industry as dynamic as medicines, to the unpredictability and dynamism that defines it.

In addition to the aforementioned problems, the regulation practiced by CMED also faces implementation difficulties in terms of applying the price adequacy coefficient, which is an obligatory discount that must be obeyed by the pharmaceutical companies that sell certain medicines to government bodies. The price adequacy coefficient is applied to product prices in the following circumstances: exceptional dispensation of drugs, drugs for the National STD/AIDS Program, drugs included in the Blood and Hemoderivative Products Program, antineoplastic drugs or those used as adjuvants in cancer treatment, drugs and products purchased by judicial order. In practice, many laboratories fail to apply this discount of approximately 24.0% to medicines sold to regional health departments, with it being a common occurrence for the government to overpay, the result of which is a risk for shortages in the public health system. When laboratories are obliged to apply this coefficient, many of them choose not to participate in bids to win contracts to be drug suppliers to public administrations. According to the Sao Paulo State Public Health Secretariat, 66 laboratories have already chosen not to participate in such bids in their State.<sup>18</sup>

In most cases, when there are instances where public bodies have been overcharged, the health secretariats are not notified and the CMED knows nothing about such an event, which implies an institutional communication problem within the government. The legislation is flawed, since it does not provide legal mechanisms that ensure dialog, and make such become indispensable, between the CMED and the public bodies who purchase the drugs. There is also no legal provision for instruments that can make sure that the price adequacy coefficient is applied on the behalf of the CMED. Consequently, even though this is the only regulatory body that has jurisdiction to punish those laboratories that refuse to apply this coefficient, no sanction is applied to those who flout the regulatory standard.

<sup>17</sup> Credendio JE, Pinho A. Laboratório boicota remédio com desconto. *Folha S. Paulo* 2011 Apr 4;Cotidiano:3.

In summary, the Law 10,742/2003 does not provide mechanisms that allow drug prices, which are already in the pharmaceutical market, to be reduced, which represents a problem for the CMED's regulatory effectiveness. As regards the considerable amount of drugs, this chamber does not influence price decision-making in the industry, therefore it is failing in its institutional goal to promote pharmaceutical support to the public. There is no doubt that legislative modification along these lines would facilitate increased pharmaceutical support by the CMED.

However, problems surrounding the price regulation practiced by this regulatory agency are not limited to normative quality issues. One of the major problems to be addressed is regarding the institutional capacity of the CMED to perform its tasks. There seems to be a lacking of a sufficient structure in this body to allow it to perform essential tasks in terms of regulating the market, such as, e.g., monitoring actual drug prices and creating mechanisms to monitor the application of the price adequacy coefficient, which, in practice, compromises the quality of price regulation.

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