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# "Price cap regulation in the Colombian pharmaceutical market: An impact evaluation"

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# Price cap regulation in the Colombian pharmaceutical market: An impact evaluation

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**Abstract**: We evaluate the impact of a price cap regulation implemented in the Colombian pharmaceutical market between 2011 and 2014. To do so, we take advantage of a unique data set where we observe three sources of variation: i) differences across eighteen groups in the Anatomical Therapeutic Chemical (ATC) classification system of the WHO, ii) the existence of regulated (treated) and unregulated (control) groups within each of these eighteen ATC groups, and iii) differences in time (before and after regulation) for the eighteen ATC groups. A triple differences model with fixed time effects and cluster errors is used to identify the impact of this regulation. We find that the price-cap regulation contributed to reduce prices in three of the eighteen groups and increase average prices for ten of them. We confirm then that the focal point effect generated by a price-cap regulation can generate unintended distortions. More specifically, our results reveal that the implementation of this price cap regulation potentially increased -public and private- expenditure by 30%, only for the 2,422 drugs in the eighteen ATC groups we study.

**Key words**: Pharmaceutical market, Price cap regulation, Impact evaluation.
**JEL**: I18, I13, H51, D02.

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# 1 Introduction

The study of pharmaceutical markets has been of particular interest to policymakers over the world, largely because of the growing participation of medicine expenses in the total expenditure of health systems during the two last decades.[4] In addition, the pharmaceutical sector is characterised by firms with an important market power due to the intellectual property protection. Even though on-patent medicines are not necessarily in a monopoly position since they may compete with me-too drugs that belong to the same therapeutic class (according to the regulation at work), most therapeutic classes are far from being competitive (Bardey *et al.*, 2016a). On the other hand, health insurance coverage makes policyholders quite insensitive to drug prices, yielding the so-called *ex post* moral hazard. Thus, this combination of market power on the supply side and health care demand inelasticity usually justifies regulations on both the demand and supply sides.

In such a context, policymakers usually use two types of instruments: out-of-pockets on the patients' side to reduce *ex post* moral hazard behaviours and drugs' price regulation to limit inefficiency coming from firms' market power. However, as pointed out in Bardey *et al.* (2016b) out-of-pocket schemes, while reducing *ex post* moral hazard may also be useful to reduce firms' market power on the supply side.[5] Consequently, the interplay between both regulations may complicate the impact evaluations of drugs' price regulations.

Out-of-pocket schemes, while lowering inefficiencies caused by *ex post* moral hazard, may also create problems of health care access (Nyman, 1999). Even though health care access is an important issue everywhere, it tends to be stronger in developing countries that are usually characterised by higher level of inequalities. It may be the reason why some developing countries limit the use out-of-pocket schemes and focus on regulations that limit market power on the supply side. For instance, in countries like Colombia that

[4] See OECD report in 2016.

[5] Bardey *et al.* (2016b) show that an out-of-pocket payment scheme that combines in an adequate way an *ad valorem* coinsurance rate and a specific (per unit) copayment can effectively control laboratories' prices, which is then set so that their revenue just covers fixed costs. Therefore, a suitable regulation of the copayment instruments leads to the same reimbursement rule as in under perfect competition for medical products and is able to eliminate laboratories' market power.

has achieved an almost universal coverage and where the healthcare is considered as a fundamental civil right, patients actually pay a relatively small share of the price of healthcare services and interventions, making the demand for drugs inelastic. Thus, it creates a favourable environment to evaluate the impact of medicines price-cap regulation since the interplay with the demand-side is almost nonexistent. Moreover, as the Colombian drugs' market was pretty deregulated since 2006, it eliminates *de facto* interactions with previous regulations.

This deregulation policy agenda yielded to the result that in 2009 Colombia had the most expensive medicines in the region (Health Action International, 2009).[6] In order to reduce general drug prices, the Colombian government responded by implementing two price cap regulation instruments. The first mechanism was the Maximum Recovery Value scheme (VMR in Spanish, *Valor Máximo de Recobro*), which applied only to medicines that were not covered by the social health insurance system's benefits plan, but which were available and usually free of out-of-pocket expenses through a commonly used lawsuit mechanism. The second price cap instrument was the Maximum Price for Sale to the Public (*Precio Máximo de Venta al Público* or PMVP), which sets a maximum price for specific medicines that are covered by the benefits plan. Both regulations aimed at limiting laboratories' market power by decreasing their price fixing leeway.

In this research, we develop an empirical strategy that allows for an evaluation of the impact of the second regulation instrument (*i.e.*, the PMVP) on average prices and the consequent pharmaceutical expenditure, for a sample of drugs in Colombia. We focus on eighteen groups of drugs defined by the World Health Organization's ATC classification. These particular 18 groups contain a total of 2,422 pharmaceutical products. This impact evaluation takes advantage of the way the price cap scheme was implemented: drug prices were regulated individually, not by ATC group. Since drugs belonging to the same ATC group are comparable by definition, we find a natural reference group of drugs within the same ATC, and thus have a counter-

[6]For instance, a comparison with a sample of 93 countries reveals that *Ciprofloxacine* -an off patent antibiotic used to treat different kinds of infections- costed US$131 in Colombia, while its cost in China was about US$31 (in the same period). More generally, the Colombian Health Ministry has pointed out that, from a list of 59 high-demand drugs, 55 were found to be more expensive in the country than in Spain.

factual to identify the causal effect of the price regulation *ex post*. Thanks to information provided by the *System of Information for Medicine Prices* (SISMED in Spanish), this study has access to a longitudinal database of monthly reports on a set of characteristics for each pharmaceutical product (including the sale price) over a period of four years (2011 to 2014). This rich database allows us to develop a model of triple differences with fixed effects at the time period and individual drug levels.

Our results reveal that, in the aggregate, the regulation had an unexpected impact on regulated drugs in the eighteen ATC groups included in our analysis. Specifically, we find that the PMVP price-cap scheme reduced average prices for regulated drugs in only three of the eighteen ATC groups, with reductions ranging between -10% and -87%. However, the same regulatory instrument increased average prices of regulated drugs in ten of the eighteen ATC groups. These increases range between 15% and 91%.[7] We also study the consequences of this regulation in terms of the system's pharmaceutical expenditure. This calculation is made based on the expenditures registered on November 2012, the last month in which none of the drugs taken into account in the study were regulated. For this month, we point out that, in the aggregate, regulation led to an average increase of 30% in the expenditure in these eighteen ATC groups.

In the existing literature there is not a definitive, unique and unambiguous conclusion about the effects of price regulation schemes, given that it depends completely on the method for fixing the specific price caps and the institutional context in which they are implemented. A first obvious effect of a scheme like the PMVP is that drug prices should decrease under the cap, specially brand-name products that usually have an important positive price margin. Nevertheless, a second -and less obvious- effect is that this regulation may generate a convergence in the prices of medicines towards the imposed ceilings (Danzon and Liu, 1996). In his literature review, Puig-Junoy (2010) reveals that the application of price cap regulation is generally associated with an increase in the price of generic (as opposed to brand-name) pharmaceuticals. Therefore, the reduction in prices of brand-name drugs and the increase in generics leads to an uncertain net effect. In our estimation, for some therapeutic classes, we interpret that the average increase in drug

[7] Our results do not indicate significant effects for the other five ATC groups.

prices is likely to be due to this "focal point" effect.[8]

The second section describes the recent behaviour of the market for medicines in Colombia and briefly presents the relevant regulatory framework. In the third section, we present the causal identification strategy and the estimated econometric model. In the fourth section, the sources of information and data are presented. Finally, in sections 5 we discuss the results obtained and we conclude in section 6.

# 2 The pharmaceutical market in Colombia

In Colombia, the health system operates under a *Managed Care Competition* scheme, which aims at controlling healthcare costs and expenditures, by promoting quality competition among private and public insurers. This social insurance system, introduced in 1993 through the emblematic *Ley 100*, has successfully achieved an almost universal health insurance coverage in the country (reaching 95% in 2018, compared to 29% in 1995). Under this insurance scheme, a standardized benefit package is established, which includes preventive attention, medical-surgical care and essential drugs. Evidently, the improvement in the system's coverage resulted in an increase in the supply of medicines. In 2011, total expenditure on medicines amounted to 3,844 million US dollars, which corresponded to 16.5% of total health system expenditure for the country in that year (Afidro, 2012).

More importantly, in 2009 Colombia had the unflattering title of being the country in the region with the highest average pharmaceutical prices (Health Action International, 2009). For this reason, the Ministry of Health and Social Protection (MSPS in Spanish) and the National Commission for Medicine Prices (CNPM in Spanish) decided to reintroduce price regulation

[8] An important part of the existing literature focuses on the effects of regulation on competition. Specifically, several studies aim at understanding the impact of regulatory schemes on the entry of generics into the medicines market (see Aronsson *et al.*, 2001; Dalen *et al.*, 2006; Brekke *et al.*, 2011; Brekke *et al.*, 2015). Our results depend on the market structure *within* the therapeutic classes considered. Thus, we believe our results suggest that that the price-cap impact depends on the level of competition varies within ATC groups. However, the time period of our study does not allow us to investigate in depth the dynamics of market structures.

for this market. We present in the the appendix a timeline documenting the most important changes in the recent Colombian normative framework. In the year 2010, prices caps (called VMR) were introduced only for a group of drugs that were excluded from the standardized benefits plan. In 2013, another price cap scheme was implemented (PMVP) for the 863 drugs included in the benefits plan (across all ATC groups). More precisely, the prices were regulated at the wholesalers' level. In particular, it was said that a specific product market would be regulated when any of the following two characteristics were present: (1) less than three bidders, or (2) a Herfindahl-Hirschman Index (HHI) greater than 2,500.

For regulated ATC, the International Reference Price (PRI in Spanish) was applied, taking the price to the 25th percentile in the price list of the 17 countries used for reference. When the national price reference was greater than its international equivalent, the market was regulated by equalizing these prices. Otherwise, the regulation did not apply. It should be noted that this regulation was carried out at the product level and associated with a Unique Medication Code, instead of regulating by ATC group (which includes direct substitutes in terms of the organ or system on which they act and their therapeutic, pharmacological and chemical properties). As we explain below, this point is crucial for our identification strategy, and may also explain some of the results we obtain.

# 3 Identification strategy

Every impact evaluation has the essential challenge of selecting a control group that serves as a counter-factual to identify and quantify, without a bias, the attributable treatment effect. To this extent, the identification strategy that we propose is not only based on the comparison of average prices before and after the implementation of the PMVP regulation (that is, before and after "treatment"), but also contrasting drugs subject to the price cap scheme (*i.e.*, the treatment group) and comparable drugs that were not regulated (*i.e.* the control group). Specifically, we take advantage of three sources of variation to identify the causal effect of this regulation scheme on the market. The first variation comes from the available panel data structure: drug prices and quantities are observed over time and, more

importantly, under different regulatory regimes. Thus, our empirical strategy exploits variation of prices over time, before and after the implementation of the price cap regulation. The second source of variation we observe and exploit comes from the (non-random) assignment of complete ATC groups to treatment. In this case, our empirical strategy takes advantage of the fact that not all ATC groups were regulated, throughout the period of analysis (*i.e.*, assignment varied across ATC groups). Finally, the third and most important source of variation is the (non-random) assignment to treatment of specific drugs, within a ATC groups.

As mentioned before, the ATC taxonomy identifies the chemical structure of pharmacological substances and drugs, the system or organ on which it acts, its pharmacological effect and the therapeutically relevant indications. The first level in this taxonomy –identified by a letter and comprising fourteen subgroups– shows the organ or system on which the medicine acts. Table 1 describes the anatomical level of the classification system. The next classification level, given by a two-digit number, identifies the therapeutic subgroup. The third and fourth levels (two consecutive letters) identify the chemical, pharmacological or therapeutic subgroups of the drug. The fifth level of the ATC code establishes the chemical substance (again a two-digit number).

It is important to underline again the fact that the ATC classification system groups drugs according to the main therapeutic use of its active ingredient to treat a distinct organ. In other words, ATC codes group pharmaceutical substances according to the expected effect that a specific chemical has in the treatment of a specific disease, on a specific body part or system. To this extent, a drug can be assigned to more than one ATC codes, if it is available in the market in more than one forms of administration, which define different intensities of treatment for different organs.[9] Therefore, ATC codes provide a clear cut definition of comparable medicines.[10] Our iden-

[9]For example, this happens in the case of sexual hormones. With some specific doses, such hormones are used against cancer and are classified under the $L02$ code, which corresponds to endocrinian therapy. Exactly same pharmaceutical substance (sexual hormones), with another dosage, is used to modulate genital systems and belongs to group $G03$. In other words, the same active principle can be associated to different ATC codes, given that it has different uses and dosage.

[10]This ATC classification -provided by the WHO- has been used by several groups of authors that aim to assess different drugs regulations schemes. See for instance: Brekke *et*

Table 1: Organ or system on which the drug operates (Anatomical Level)

| Letters | System or organ |
|---|---|
| A | Digestive system and metabolism |
| B | Blood and hematopoietic organs |
| C | Cardiovascular system |
| D | Dermatologic medications |
| G | Genitourinary system and sex hormones |
| H | Systemic hormonal preparations and sexual hormones |
| J | Anti-infectives in general for systemic use |
| L | Anti-neoplastic and immuno-modulatory agents |
| M | Musculo-skeletal system |
| N | Nervous system |
| P | Anti-parasitic products, insecticides and repellents |
| R | Respiratory system |
| S | Organs of the senses |
| V | Various |

Source: Adapted from the World Health Organization. See: https://www.whocc.no/atc/structure_and_principles/

tification strategy capitalizes this by comparing regulated and unregulated drugs within an ATC code, after accounting for particular characteristics at the individual substance level.[11]

We include in our analysis eighteen ATC groups, which were selected following three criteria. First, that the ATC group contained unregulated (control) and regulated (treatment) drugs. Second, that the ATC groups contained more than twenty medicines.[12] This second criteria was included in order to have large enough groups so that we could assume the usual sta-

*al.* (2007), Brekke *et al.* (2011); Brekke *et al.* (2015); Dalen *et al.* (2006) y Kaiser *et al.* (2013). Moreover, countries such as Belgium, Bulgaria, Croatia, Denmark, Finland and France use this ATC classification (up to level 5) to pool together drugs and set reference prices.

[11] As mentioned before, drugs registered under the same ATC code differentiate themselves given specific characteristics, such as the company that produces it and whether they are generic or branded-name drugs.

[12] Only one of the selected groups contains less than thirty drugs. We decide to include it in order to enhance statistical power in our estimations.

tistical properties and sampling distributions for our regression coefficients. Finally, we select ATC groups that have drugs before and after the implementation of the price-cap regulation.

# 4 Econometric model

To achieve an adequate control group definition that minimizes possible biases in our estimates, we use a triple-differences econometric model. Specifically, this empirical model exploits: (i) differences in time, (ii) differences across ATC groups, and (iii) differences within ATC groups. In addition, this model includes time fixed effects to control for period specific differences that are common to all markets and affect average prices (see Pavnick, 2002).[13] Finally, cluster errors (at the ATC group level) are included in the model, taking into account that unobserved variables may affect ATC groups differently and generate heterogeneous error distributions.[14]

The regression model to be estimated for drug $i$, belonging to ATC group $j$, in period $t$, is given by the following equation:

$$\begin{aligned} \ln(P_{ijt}) &= \beta_0 + \beta_1 T_{it} + \beta_2 D_i + \beta_3 T_{it} D_i + \textstyle\sum_{j=1}^{18} \beta_{4j} G_j \\ &+ \textstyle\sum_{j=1}^{18} \beta_{5j} T_{it} Gj + \sum_{j=1}^{18} \beta_{6j} D_i Gj + \sum_{j=1}^{18} \beta_{7j} T_{it} D_i Gj \\ &+ X_{ijt}\alpha + \Theta_t + \varepsilon_{ijt}, \end{aligned} \tag{1}$$

where $\ln(P_{ijt})$ is the natural logarithm for the price of drug $i$, belonging to ATC group $j$, in period $t$.[15] In this estimation, the variation of the drug price is explained by the binary variable of treatment $D_i$ that takes the value of 1 when the drug is regulated by the PMVP (that is, it is part of the treatment group); the binary variable $T_{it}$, which takes the value of 1 if $t > \bar{T}$, $\bar{T}$ being the period in which the price-cap scheme starts for drug $i$; the binary

[13] These time fixed effects are included to capture the variability of macroeconomic variables, such as price inflation and economic cycles.

[14] We use standard errors clusters anticipating that maybe the independence assumption is not satisfied. In other words, we do not assume away heterocedascity since there is a strong correlation within ATC groups and some no observable variables may vary within ATC groups. Thus, we may expect that the errors' distribution vary across ATC groups.

[15] As usual, we use the natural logarithm of the price in order to interpret our coefficients as a semi-elasticity.

treatment variable $G_j$, which takes the value of 1 when the drug is part of ATC group $j$; the vector of control variables $X_{ijt}$; and the fixed time effects $Theta_t$. In this way, $\beta_{4j}$, $\beta_{5j}$, $\beta_{6j}$ and $\beta_{7j}$ are vectors with 18 parameters, one *per* ATC group.

Three assumptions must be satisfied to ensure that the estimation is correctly specified. First, drugs' fixed effects must be correlated with the stochastic error of the equation (see equation 2). This implies that the variation in drugs' prices must be partially explained by unobserved variables that do not vary over time but are contained in the error term $\varepsilon_{ijt}$. Formally:

$$Corr(\gamma_i, \epsilon_{ijt}) \neq 0. \tag{2}$$

Second, the treatment indicator $D_i$ must not be correlated with the stochastic error (equation 3). Being a natural experiment, assignment to treatment is given by the assignment to the regulation scheme at the drugs' level (and at the ATC level). Since this is not a random process, it is possible that, although exogenous, the treatment assignment is not perfect in the sense that in the assignment process systematic differences are generated between the treatment and control groups. Therefore, the variables that explain these systematic differences must be included in the econometric model to correct the potential selection bias that generates such non-probabilistic assignment. Hence, in our estimation we include a vector of observable variables to control for pre-existing differences, especially with regard to characteristics that vary in time.

$$Corr(D_i, \epsilon_{ijt}) = 0. \tag{3}$$

Finally, variables contained in $X_{ijt}$ must not be correlated with the error term (equation 4); as well as the time effects (equation 5). That is, the observable variables, which explain the pre-existing differences to treatment (contained in $X_{ijt}$), must not be correlated with non-observable variables contained in the error $\varepsilon_{ijt}$. Furthermore, the fixed time effects (which control for the period-specific variation that affect the outcome variable) must not be correlated with the error term. This assumption is necessary because a correlation different to zero would indicate that unobserved time-varying variables still explain variations in price, which would generate a bias in treatment effect estimates.

$$Corr(X_{ijt}, \varepsilon_{ijt}) = 0, \tag{4}$$

$$Corr(\Theta_t, \varepsilon_{ijt}) = 0. \tag{5}$$

In this impact evaluation we aim to identify the average impact of the regulation on regulated drug prices. Ideally, this average impact corresponds to the difference between average of prices in the group of regulated drugs and the theoretical average prices of the same drugs if the price-cap regulation would not had been implemented. We use as empirical counter-factual a group of non-regulated drugs that belong to the same ATC groups, which we believe to be comparable to the treated drugs. When estimating the triple differences model we implicitly seek to simultaneously obtain the 18 partial derivatives presented in equation 6 (one for each of the 18 ATC groups):

$$\frac{\partial \ln(P_{iJt})}{\partial G_J} = \beta_{4J} G_J + \beta_{5J} T_{it} G_J + \beta_{6J} D_i GJ + \beta_{7J} T_{it} D_i G_{J.} \tag{6}$$

For example, the effect of the change in prices for ATC group $J$ is given by the derivative of $ln(P_{ijt})$ when $G_J = 1$ and $G_j = 0$ for all $j \neq J$. Upon replacing $G_J = 1$, we obtain:

$$\frac{\partial \ln(P_{iJt})}{\partial G_J} = \beta_{4J} + \beta_{5J} T_{it} + \beta_{6J} D_i + \beta_{7J} T_{it} D_i. \tag{7}$$

From equation 7, we obtain four equations that explain the behavior of the treatment ($D_i = 1$) and control ($D_i = 0$) groups, before ($T_{it} = 1$) and after ($T_{it} = 0$) the start of the price-cap regulation implementation, inside of ATC group $J$. Average prices for regulated and unregulated drugs in ATC group $J$ in different scenarios are represented by the following equations: regulated drugs after regulation (equation 8), regulated before regulation (equation 9), non-regulated after regulation (equation 10), and non-regulated before regulation (equation 11):

$$\frac{\partial \ln(P_{iJt})}{\partial G_J}(D_i = 1, T_{it} = 1) = \beta_{4J} + \beta_{5J} + \beta_{6J} + \beta_{7J} \tag{8}$$

$$\frac{\partial \ln(P_{iJt})}{\partial G_J}(D_i = 1, T_{it} = 0) = \beta_{4J} + \beta_{6J} \tag{9}$$

$$\frac{\partial \ln(P_{iJt})}{\partial G_J}(D_i = 0, T_{it} = 1) = \beta_{4J} + \beta_{5J} \tag{10}$$

$$\frac{\partial \ln(P_{iJt})}{\partial G_J}(D_i = 0, T_{it} = 0) = \beta_{4J} \tag{11}$$

Given this, changes in average prices for regulated drugs (treated) in ATC group $J$ can be obtained by subtracting equation 9 from equation 8. Similarly, the result of subtracting equation 11 from equation 10 corresponds to the change in non-regulated (control) drugs before and after the implementation of the price-cap regulation, in ATC group $J$. Thus, the impact of regulation on ATC group $J$ is expressed by the difference between these two differences, represented in this model by parameter $\beta_{7J}$. In conclusion, the parameters of interest are contained in vector $\vec{\beta_7} = [\beta_{7,1}, \cdots, \beta_{7,18}]$, which measures the average effect on prices due to the implementation of the price-cap regulation, in each of the 18 ATC groups.

# 5 Data

The main data source is the Medicine Prices Information System (SISMED), a database consolidated and managed by the Colombian Ministry of Health and Social Protection (MSPS). This database systematizes information regarding all medicines marketed nationwide, including: sales prices, units sold, CUM code, ATC group code, whether the medicine is included in the social health insurance benefits plan, among other variables. This database is built from the mandatory reports generated by all institutions in the social protection system that purchase or sell pharmaceuticals.[16] Although there is a legal mandate to report this information, sub-reporting remains to be relatively

[16]These institutions are: Local Health Directorates (DTS in Spanish - *Direcciones Territoriales de Salud*), Health Maintenance Organizations (EPS in Spanish - *Empresas Promotoras de Salud*), Health Service Providing Organizations (IPS in Spanish - *Instituciones Prestadoras de Servicios de Salud*), Family Welfare Organizations (CCF in Spanish - *Cajas de Compensación Familiar*) and pharmaceutical companies. These institutions have to report prices according to official regulatory decrees (*Circular* 1 and 4 of 2004 and 2006, respectively). Reports are generated each trimester and must include the total value of drug purchases and sales, quantities, maximum and minimum prices, for the most specific ATC group code.

high in Colombia (IADB, 2011). Thus, it is important to briefly address how self-reporting may compromise the quality of this self-reported data. All agents have incentives to act strategically under the potential risk of being regulated by the State thanks to the information provided. For instance, a private organization may have strong incentives to misreport price data when this information could trigger a price-cap scheme. We believe these incentives potentially generate biases on the impact estimates of the price-cap regulation only if regulated drug prices are systematically misreported or, if only unregulated drug prices are misreported. However, if all prices are misreported in the same proportion (regardless of the drug's regulatory status), and thus measurement error is homogeneous across treatment and control groups, then impact estimates -*i.e.* average price changes attributable to the regulation- should be unbiased.

According to the MSPS, data in the the SISMED is consistent and comparable across time since 2010. Fortunately, this data restriction does not limit our capacity evaluate the impact of the PMVP scheme, given that it is possible to compare price changes before and after the implementation of the regulation, for both treatment and control groups. However, not having price data series before 2010 limits our ability to analyze the trends during the pre-regulation periods.

Additionally, an original database was built using official regulatory decrees that report the precise periods in which all pharmaceutical products were subject to the PMVP scheme. This data set defines variable $D_i$, which takes a value equal to 1 when drug $i$ (defined by a specific CUM code) is regulated during the period 2011-2014 (and 0 otherwise); and variable $T_{it}$, which is equal to 1 if drug $i$ is regulated during month $t$. Also, using this source of information, a binary variable was constructed to classify all drugs between generic (equal to 0) or brand-name (equal to 1).[17]

The final analytical data set is an unbalanced panel due to missing observations caused by the fact that drugs enter the market at different times. Indeed, it has been documented that, in many cases, regulation itself alters market entry rates (Bardey *et al.*, 2010 and 2016). The database is built at the most specific CUM code level available and contains a total of 48 periods,

[17]This variable was constructed following the following rule: whenever the name of the pharmaceutical corresponds to its active principle, it is assumed that it is a generic drug.

corresponding to the months in a 4 year period (2011 to 2014).

As explained above, the impact evaluation study includes only 18 ATC groups and 2,422 drugs, which correspond to 2.13% of the total drugs registered.[18] The selected 18 ATC groups satisfy three criteria: (i) all include treatment and control drugs (at least 1 of each), (ii) all contain more than 20 drugs (in total), and (iii) all have observations for pre- and post-regulation periods. The decision to use a threshold of 20 drugs is grounded on the fact that, when relaxing of this requirement, an insignificant number of drugs or ATC groups were included in the analysis. Table 2 shows how, as the minimum drugs per ATC requirement changes, the total number of ATC groups and drugs included in the study changes.[19]

Table 2: Minimum required number of drugs by ATC, and corresponding number of ATC groups and drugs included in the study

| Drugs per ATC | ATC groups included | Drugs included |
|---|---|---|
| 25 | 17 | 2402 |
| 20 | 18 | 2422 |
| 15 | 22 | 2492 |
| 10 | 28 | 2516 |
| 5 | 34 | 2557 |
| 3 | 35 | 2581 |
| 1 | 46 | 2714 |

The proposed empirical strategy assumes that, within ATC groups, regulated (treatment) and unregulated drugs (control) are comparable given that they have the same therapeutic use, and exhibit the same chemical composition. Nevertheless, we observe differences in the average price for the treatment and control drugs, during the periods prior to treatment (*i.e.*, before the implementation of the price-cap regulation). Table 3 presents the

[18] In Colombia, in December 2015, there were a total of 113,727 registered drugs classified into 1,238 ATC groups. From these 1,238 ATC groups, only 46 had regulated drugs. These 46 ATC groups included 2,714 drugs.

[19] As a robustness check, we ran the estimation with all of the 46 ATC groups that have drugs in control and treatment groups, that include 2714 drugs. Our results do not vary, but we are concerned about our prediction capacity within the ATC groups that have a small number of drugs.

results for the statistical tests evaluating the statistical significance of mean differences in the the natural logarithm of sale prices of regulated versus non-regulated drugs, by ATC group. Results show that, for most ATC groups, there is a statistically significant difference in the trend of sale prices, before treatment. These differences can be explained by two main reasons. First, because of the different level of competition presented within each of the ATC groups. In particular, competition is lower for non-regulated drugs. Second, because there are more brand-name drugs in the treatment group than in the control group, and it is known that generic drugs have systematically lower prices.

Table 3: Test of difference in average ln(prices)

| | ATC codes | Before the regulation | After the regulation |
|---|---|---|---|
| 1 | A02BC05 | -0,28*** | 0,65*** |
| 2 | A10AE04 | 0,05*** | 0,10** |
| 3 | B02BD02 | -0,95*** | -0,43** |
| 4 | H02AB04 | 0,02 | 0,19*** |
| 5 | J01DH02 | 0,28*** | 0,04** |
| 6 | J01XX08 | 0,93*** | -0,91*** |
| 7 | L01AX03 | 0,66** | 0,22* |
| 8 | L01BC06 | -0,50 | 0,74*** |
| 9 | L02BB03 | 1,06*** | 0,18* |
| 10 | L03AB07 | -0,94*** | 0,10 |
| 11 | L04AA06 | 0,43*** | 0,39*** |
| 12 | L04AD01 | 0,82*** | 0,93*** |
| 13 | L04AD02 | 1,41*** | 0,99*** |
| 14 | N03AX14 | 0,47*** | 0,60*** |
| 15 | N03AX16 | 0,44 | 0,05 |
| 16 | N04BC05 | -0,62*** | -0,08 |
| 17 | N05AH04 | 0,53*** | 0,40*** |
| 18 | N06DA03 | 1,57*** | 0,41*** |

Source: Author estimates using data from SISMED.

Figure 1 gives an idea of the general behavior of prices in the periods included in the study.[20] When interpreting this descriptive figure, it is impor-

[20]It is important to acknowledge that this figure must be interpreted cautiously, since it

tant to note that most of the drugs that have entered the price-cap regulation were regulated in the year 2013.[21] According to Figure 1, at the beginning of the price-cap regulation implementation, there is a general price reduction, but then the difference between the two groups increases.

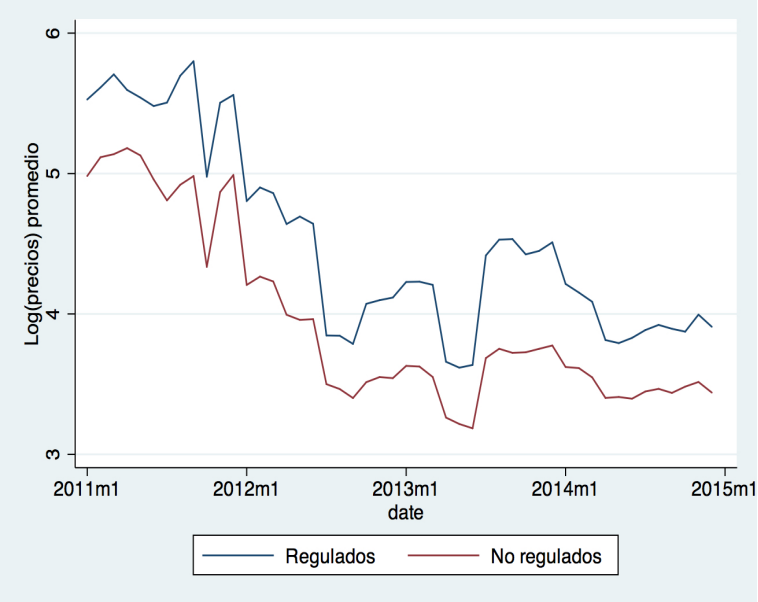


Figure 1: Average prices for regulated and unregulated drugs

An important assumption when identifying the impact of the price-cap regulation in our empirical strategy is that price trends for regulated and non-regulated medicines are parallel during the period prior to regulation, after controlling for observable characteristics at the drug and ATC group levels. To this extent, it must be stressed that the trends presented in Figure 1 do not control for the observable drugs' characteristics. For example, within treatment and control groups there may be proportionally more or less generic drugs. Similarly, the distribution of drugs may be different for each sample at the ATC group level. Hence, to control for pre-existing differences, we include time and drug-specific fixed effects, in addition to three important control variables.

compares unregulated and regulated drugs without controlling by specific characteristics at the ATC group level.

[21] On average, the "treatment" duration was 11 months.

The first control variable is the the *Herfindahl-Hirschman Index* (HHI), which measures market share concentration and that is a good proxy of the level of competition.[22] Table 4 presents the estimated HHI for each ATC group, in years 2011 and 2014 (columns 7 and 8). The results indicate that the HHI contains two important types of variation: between ATC groups and over time (within the same ATC).

The second control variable is a dichotomous variable that indicates if the drug is brand-name or generic. According to the literature, the effect of regulations can be different in this dimension. One could expect a relatively larger number of brand-name drugs within the treatment group, since these usually have greater mark-ups and thus higher sale prices. This explains, at least partially, the difference in price trends between the two groups (see Figure 1). Table 4 shows the total number of drugs in each ATC group ($n$ in column 2), the proportion of brand-name drugs (BN/n; column 3), the proportion of regulated drugs (Reg/n; column 4), the proportion of brand-name drugs over the total number of regulated drugs (BN/Reg; column 5); and the proportion of brand-name drugs in the non-regulated total (BN/UnReg; column 6). Evidently, there is an important variation in these proportions across ATC groups. Only in 3 of the 18 ATC groups, brand-name drugs represent less than 70%. Additionally, the proportion of regulated drugs varies importantly, ranging from a minimum of 1% for ATC A02BC05 and a maximum of 70% for ATC L03AB07. On the contrary, for almost all ATC groups, brand-name drugs are always regulated: in only 4 of the 18 ATC groups the percentage of brand-name drugs included in the regulation fall below 100%. Evidently, it is important to include in the estimation the type of drug (brand-name versus generic) to capture this heterogeneity across groups.

Finally, the model includes the nominal exchange rate between the Colombian peso and the US Dollar as a control variable. This variable is included to take into account the effect exchange rate volatility has on international pharmaceutical markets, given that many of the drugs marketed within the country are imported. Furthermore, many other pharmaceutical products sold in the Colombian market, despite being produced within the national territory, use imported inputs. To this extent, we may expect that the be-

[22] The HHI ranges between 0 and 10,000, where 10,000 indicates a monopolistic structure in the market.

havior of the exchange rate explains part of the variation in prices in the Colombian drugs' market.

Table 4: Descriptive statistics by ATC

| | ATC | n | BN/n (%) | Reg/n (%) | BN/Reg (%) | BN/UnReg (%) | HHI 2011 | HHI 2014 |
|---|---|---|---|---|---|---|---|---|
| 1 | A02BC05 | 654 | 78 | 1 | 100 | 78 | 66 | 402 |
| 2 | A10AE04 | 40 | 100 | 63 | 100 | 100 | 10000 | 9988 |
| 3 | B02BD02 | 86 | 83 | 7 | 33 | 86 | 9780 | 1994 |
| 4 | H02AB04 | 107 | 61 | 5 | 100 | 59 | 709 | 1135 |
| 5 | J01DH02 | 181 | 30 | 15 | 100 | 18 | 4 | 1198 |
| 6 | J01XX08 | 48 | 77 | 42 | 45 | 100 | 1 | 70 |
| 7 | L01AX03 | 43 | 93 | 53 | 100 | 85 | 10000 | 9428 |
| 8 | L01BC06 | 25 | 92 | 16 | 100 | 90 | 10000 | 5879 |
| 9 | L02BB03 | 74 | 91 | 47 | 100 | 82 | 4006 | 3296 |
| 10 | L03AB07 | 20 | 100 | 70 | 100 | 100 | 4764 | 5162 |
| 11 | L04AA06 | 62 | 100 | 8 | 100 | 100 | 5542 | 2592 |
| 12 | L04AD01 | 47 | 89 | 19 | 100 | 87 | 5282 | 5467 |
| 13 | L04AD02 | 43 | 63 | 44 | 58 | 67 | 7456 | 7080 |
| 14 | N03AX14 | 187 | 95 | 3 | 100 | 95 | 1163 | 2094 |
| 15 | N03AX16 | 259 | 80 | 22 | 100 | 75 | 0 | 73 |
| 16 | N04BC05 | 48 | 73 | 58 | 100 | 35 | 2067 | 9685 |
| 17 | N05AH04 | 418 | 71 | 38 | 75 | 68 | 3570 | 1999 |
| 18 | N06DA03 | 80 | 100 | 58 | 100 | 100 | 9997 | 9998 |
| | Total | 2422 | | | | | | |

Source: SISMED 2011-2014. Author's calculations.
Notes: Reg=Total number of regulated drugs, UnReg=Total number of unregulated drugs, BN=Total number of brand-name, G=total number of generic, n=Total number of drugs. HHI=Herfindahl-Hirschman Index.

# 6 Results

Before presenting the results of the main econometric model, we briefly discuss two statistical tests that assess the validity of the empirically verifiable assumptions supporting our methodological approach. On the one hand, to asses the validity of the control group (*i.e.* using unregulated drugs within the same ATC group as a counter-factual), we test if the selection of drugs into the treatment group is endogenous or responds to price changes. To do this, we perform a linear regression analysis that evaluates whether, in any of the periods prior to the implementation of the regulation scheme, the variation in the natural logarithm of prices can be explained by the change in the variable that indicates the treatment selection ($D_i$), after controlling for time effects and the previously described vector of control variables (HHI, the generic drug dummy and the US Dollar exchange rate).

The estimates of this regression model, presented in Table 5, indicate that the prices in the market do not correlate with the likelihood of the drug being assigned to the control group. All except one of the coefficients of the interactions between the treatment indicator and period indicator is not statistically different from zero. Thus, we are confident selection into the treatment group is not endogenous, at least for the drugs in the 18 ATC groups included in the study.

On the other hand, to further test the validity of the chosen control group, a falsification test is carried out using only the sample of non-regulated drugs. In this test, we estimate a linear regression model where the dependent variable is the logarithm of average prices, and the independent variables are the *dummy* variable $T_{it}$, the HHI, the *dummy* for generic drugs, and fixed effects of time and drugs. The results of this exercise, presented in Table 6, show that the coefficient associated to $T_{it}$ is not statistically significant, suggesting that entry of the regulatory scheme does not have an effect on the average price trend for unregulated group drugs. This result suggests that the control group is correctly specified in the sense that there is no apparent treatment effect on the price trend of unregulated drugs.

The main results of the impact evaluation exercise are organized in Table 7. Column 1 presents the results of a model specification without controls or

Table 5: Estimated impact in average prices across regulated and unregulated drugs, prior to the regulation (with control variables, fixed effect and cluster of errors)

| | Log(Price) | |
|---|---|---|
| Interaction period 2 | -0.277 | (-1.75) |
| Interaction period 3 | -0.116 | (-0.87) |
| Interaction period 4 | -0.0351 | (-0.24) |
| Interaction period 5 | -0.146 | (-0.53) |
| Interaction period 6 | 0.0147 | (0.07) |
| Interaction period 7 | 0.304 | (1.05) |
| Interaction period 8 | 0.676* | (2.39) |
| Interaction period 9 | 0.438 | (1.74) |
| Interaction period 10 | 0.0500 | (0.11) |
| Interaction period 11 | 0.332 | (1.18) |
| Interaction period 12 | 0.0645 | (0.22) |
| Interaction period 13 | -0.0516 | (-0.20) |
| Interaction period 14 | 0.145 | (0.52) |
| Interaction period 15 | 0.0910 | (0.32) |
| Interaction period 16 | 0.0782 | (0.20) |
| Interaction period 17 | 0.169 | (0.47) |
| Interaction period 18 | 0.0586 | (0.17) |
| Interaction period 19 | -0.403 | (-1.25) |
| Interaction period 20 | -0.464 | (-1.43) |
| Interaction period 21 | -0.380 | (-0.96) |
| Interaction period 22 | -0.182 | (-0.45) |
| Interaction period 23 | -0.0518 | (-0.13) |
| Interaction period 24 | -0.285 | (-0.76) |
| Interaction period 25 | 0.314 | (1.04) |
| Interaction period 26 | 0.197 | (0.59) |
| Interaction period 27 | 0.178 | (0.66) |
| Interaction period 28 | -0.314 | (-1.08) |
| Interaction period 29 | -0.290 | (-0.92) |
| Interaction period 30 | -0.222 | (-0.68) |
| Interaction period 31 | 0.0874 | (0.28) |
| Interaction period 32 | 0.148 | (0.50) |
| Interaction period 33 | 0.144 | (0.45) |
| Interaction period 34 | -0.0257 | (-0.07) |
| Interaction period 35 | 0.0693 | (0.19) |
| Interaction period 36 | 0.130 | (0.37) |
| Interaction period 37 | -0.0139 | (-0.04) |
| Interaction period 38 | -0.179 | (-0.49) |
| Interaction period 39 | -0.200 | (-0.53) |

t-statistics in parentesis $^*p < 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$

Source: SISMED 2011-2014

Table 5 bis

| | Log(Price) | |
|---|---|---|
| interaction period 40 | -0.119 | (-0.32) |
| interaction period 41 | -0.352 | (-0.85) |
| interaction period 42 | -0.179 | (-0.47) |
| interaction period 43 | -0.0997 | (-0.26) |
| interaction period 44 | 0.0175 | (0.05) |
| interaction period 45 | -0.0698 | (-0.20) |
| interaction period 46 | -0.119 | (-0.36) |
| interaction period 47 | 0.475 | (1.07) |
| interaction period 48 | 0.450 | (1.20) |
| HHI | 0.0000627 | (1.10) |
| Brand | 0.966*** | (11.86) |
| Intercept | 3.575*** | (8.69) |
| Observations | 37548 | |

t-statistics in parenthesis $^{*}p < 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$
Source: SISMED 2011-2014.

Table 6: Falsification test

| | (1)<br>Log(Price) |
|---|---|
| $T_{it}$ | -0.0959 |
| | (-1.30) |
| $Marca_i$ | 0.913*** |
| | (5.68) |
| $IHH_j$ | 0.0000256 |
| | (0.58) |
| Intercept | 5.018*** |
| | (20.34) |
| Observations | 26247 |
| Fixed time effect | yes |

t-statistics in parenthesis
Source: SISMED 2011-2014.
$^{*}$ $p < 0.05$, $^{**}$ $p < 0.01$, $^{***}$ $p < 0.001$

time fixed effects. The second column presents the estimates of the specification including control variables but excluding time effects. Finally, column 3 presents the complete estimation, *i.e.* the model with control variables and fixed time effects. We focus our discussion on the direction, magnitude and significance of the coefficients presented in the last specification.

As shown below, only three of the eighteen coefficients of interest (those that are associated to the triple interaction between $D_i$, $T_t$ and $G_j$) are negative and statistically different from zero. This indicates that for only these 3 ATC groups the PMVP scheme caused a reduction in average prices of the regulated drugs. Note that the coefficient of interest does not represent differences in price levels across regulated an unregulated drugs, but rather differences in price variation after the regulation, across regulated an unregulated drugs within a particular ATC group. For instance, for ATC $A10AE04$ -which corresponds to Glargine Insulin (used for the treatment of Diabetes Mellitus)-, thanks to the price-cap scheme a reduction of 86.8% in prices was achieved, when comparing regulated and unregulated drugs in this specific ATC group. For ATC $L01BC06$, which corresponds to Capecitabine (used for malignant neoplastic diseases and the modulation of the inmuno-suppressive system), we observe a reduction of 36.2% in average prices, thanks to the regulation. Similarly, for ATC $N06DA03$, that corresponds to drugs for the nervous system the estimated impact is a reduction of 10,4% in average prices.[23]

It is important to highlight some special characteristics shared by the ATC groups in which we observe the expected impact of the regulation scheme (*i.e*, a price reduction). The three ATC groups include treatments for catastrophic and high-cost diseases -such as Cancer, Diabetes, Parkinson's and Alzheimer's-. Evidently, one could hypothesize that the corresponding markets share particular characteristics. For instance, in two of these ATC groups there is relatively little competition (see columns 7 and 8 of Table 4, for ATC groups $A10AE04$ and $N06DA03$). There is no systematic evidence that the introduction of the regulation scheme promoted competition within these ATC groups. On the contrary, as shown in Table 4, competition increased substantially between 2011 and 2014 only within ATC $L01BC06$ -

[23]This ATC group corresponds to a presentation of the drug Rivastigmine that is used to treat cognitive deficit related to Alzheimer's disease and dementia associated Parkinson's disease.

while relatively low levels of competition are persistent in time. These descriptive statistics suggest that, precisely because of low competition levels and the specificity of catastrophic and high-cost disease treatments (where prices were especially high), the price-cap regulation effectively led to a reduction in the average prices (below the equilibrium price of the respective markets).

Moreover, the coefficient estimates presented in Table 7 also show that this regulation scheme led to a statistically significant increase in average prices in ten out of the eighteen ATC groups we study. To better illustrate this unexpected result, we showcase three particular pharmaceutical products. The first one is a "coagulation factor" called *Factor VIII* -used to treat hemophilia-, classified into ATC group $B02BD02$, which is of special interest given that it represents the lion's share of total sales in the study's sample of pharmaceutical products. In particular, the observed importance of this ATC group in total sales is explained mainly by its relatively high price, and not by the quantities sold. For this ATC group, our estimates show an increase of 71.5% in the average prices of the regulated medicines, attributable to the PMVP price-cap regime. For ATC group $J01XX08$, that corresponds to the antibiotic *Linezolid* (used to treat bacterial diseases), we observe an increase of 33.3% in prices. Similarly, for ATC group $L01AX03$ -corresponding to *Temozolomide*, an anti-neoplastic chemotherapy drug-, the impact of the regulation was an increase of 91% in average prices.

We hypothesize that these results are explained by a convergence effect: within an ATC group, prices could gravitate towards a price-cap that was higher than the market equilibrium price (observed prior to the introduction of the regulation). In other words, when the scheme introduces a price-cap that is higher than the free-market price, the price-cap works as a reference point to which firms have clear incentives to converge to. Thus, the PMVP scheme led to and unexpected and unwanted effect in these particular ten ATC groups, for which firms ended up reacting to the policy by increasing drug prices to a marginally lower level than the price-cap.[24]

[24] A simple descriptive analysis shows that, for the aforementioned ten ATC groups, we observe that the price-cap is relatively high, and that it does not affect the market directly by setting an effective maximum price cap that forces a generalized drop in prices (see Appendix A).

Table 7: DDD estimation with fixed time effect and error clusters.

| | (1) | (2) | (3) |
|---|---|---|---|
| | Log(Price) | Log(Price) | Log(Price) |
| D=1*A10AE04*t=1 | -1.595*** | -1.211*** | -0.868*** |
| | (4.86e-13) | (0.0384) | (0.114) |
| D=1*B02BD02*t=1 | 0.428*** | 0.361*** | 0.715*** |
| | (4.86e-13) | (0.0393) | (0.0774) |
| D=1*H02AB04*t=1 | -0.232*** | -0.305*** | -0.0632 |
| | (4.86e-13) | (0.0102) | (0.0613) |
| D=1*J01DH02*t=1 | -0.0363*** | -0.353*** | -0.0794 |
| | (4.86e-13) | (0.0362) | (0.0561) |
| D=1*J01XX08*t=1 | 0.130*** | -0.00676 | 0.333*** |
| | (4.86e-13) | (0.0160) | (0.0508) |
| D=1*L01AX03*t=1 | 0.831*** | 0.653*** | 0.910*** |
| | (4.87e-13) | (0.0222) | (0.0604) |
| D=1*L01BC06*t=1 | 0.402*** | 0.116 | -0.362*** |
| | (4.86e-13) | (0.111) | (0.0822) |
| D=1*L02BB03*t=1 | 0.00574*** | -0.218*** | 0.237*** |
| | (4.86e-13) | (0.0231) | (0.0662) |
| D=1*L03AB07*t=1 | 0.183*** | 0.0586*** | 0.193*** |
| | (4.87e-13) | (0.0123) | (0.0443) |
| D=1*L04AA06*t=1 | 0.0490*** | -0.0826*** | 0.241*** |
| | (4.86e-13) | (0.0183) | (0.0676) |
| D=1*L04AD01*t=1 | -0.111*** | -0.210*** | -0.00490 |
| | (4.86e-13) | (0.0103) | (0.0573) |
| D=1*L04AD02*t=1 | 0.600*** | 0.567*** | 0.761*** |
| | (4.86e-13) | (0.00792) | (0.0752) |
| D=1*N03AX14*t=1 | -0.124*** | -0.197*** | 0.151* |
| | (4.86e-13) | (0.0132) | (0.0715) |
| D=1*N03AX16*t=1 | -0.168*** | -0.213*** | 0.0334 |
| | (4.86e-13) | (0.00820) | (0.0614) |
| D=1*N04BC05*t=1 | -0.0370*** | -0.279** | 0.229* |
| | (4.86e-13) | (0.0850) | (0.112) |
| D=1*N05AH04*t=1 | 0.0530*** | -0.0588** | 0.153** |
| | (4.87e-13) | (0.0183) | (0.0521) |
| D=1*N06DA03*t=1 | 0.302*** | 0.259*** | -0.104* |
| | (4.89e-13) | (0.00780) | (0.0503) |

DDD estimation with fixed time effect and error clusters - bis

| | (1) Log(Price) | (2) Log(Price) | (3) Log(Price) |
|---|---|---|---|
| Intercept | 4.244*** | 4.571*** | 5.195*** |
| | (6.52e-13) | (0.0927) | (0.140) |
| Observations | 37548 | 37548 | 37548 |
| Number of drugs | 2422 | 2422 | 2422 |
| R2 (with-in) | 0.0657 | 0.1064 | 0.24 |
| R2 (overall) | 0.2033 | 0.2216 | 0.3114 |
| Time fixed effect | No | No | yes |
| Controls | No | yes | yes |

Stand errors in parentesis

Source: SISMED 2011-2014, MSPS

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

This result is consistent with the findings of Danzon *et al.* (1996), but apparently contradicts the evidence presented by Brekke *et al.* (2007) for Norway. We believe these contradictory results can be explained by the fact that, in Norway, the price of all drugs within an ATC group were regulated. This meant that, in this country the regulation was intended to cap all prices (within an ATC group), and probably eliminated any space for price-setting strategic behavior.

Finally, it is important to highlight that our economic model explains 31% of the overall variation in prices, and approximately 24% of the variation within ATC groups. Also, it should be noted that the coefficient associated with the dummy indicating that a drug is brand-named is statistically significant and positive, which coincides with the literature in which it is widely documented that these drugs are relatively more expensive (when compared to generic drugs). For this reason, these brand-name drugs are more frequently targeted by regulation frameworks. Indeed, in our analytical sample we find proportionally more regulated brand-name drugs. As mentioned before, by including this dummy variable we hope to control for the pre-existing differences in the distribution of generic versus brand-name drugs among treatment and control groups.[25]

[25]Additionally, we perform additional regression analyses to show that there is a dif-

As an approximation to the overall economic impact of the price-cap implementation, we do a back-of-the-envelope estimation of the net value of drug sales and expenditure, resulting from the changes in prices attributable to the PVMP scheme. In this calculation we use the observed quantities sold during November 2012 - the last month in which none of the drugs included in the study were regulated. We observe that, in this particular month, total sales from the eighteen ATC groups in our sample represented approximately USD 126 million. We estimate that the net economic impact of the price-cap regime on prices implied an increase of 30% in the value of the monthly sales. This means that, if the regulation was implemented in the baseline month (November 2012), total sales would have reached USD 164 million (see Table 8). It is important to highlight that the estimated net economic impact is actually a higher bound, since this static methodology does not consider relevant mechanisms that could mitigate this impact. For instance, even in a very inelastic market, strategic behavior by the firms could result in the reduction of prices of unregulated drugs to avoid future regulations.

From our results, we are able to suggest the specific adjustments to the design of the price-cap regulation. First, price-caps should be lower in ATC groups that represent the lion's share in total sales, or that evidenced a price increase after the price-cap regulation implementation. For instance, ATC groups $L04AA06$, $L04AD02$ and $N03AX14$, which represent 41%, 21% and 22% of total sales in our analytic sample, respectively. Second, for the specific cases in which drugs show extremely high increases (e.g., $B02BD02$, $L01AX03$, $L04AD02$ and $J01XX08$) a much deeper analysis is required to fully understand the market structure, incentives and strategic behaviors from the pharmaceutical firms. These two types of urgent intervention cases are clearly identifiable in Figure 3.

ferential impact of the regulation on drugs, according to whether they are brand-name or generic. We find that, in average, prices in ATC groups $B02BD02$ and $L04AD02$ fell 125% and 43,5%, respectively. These results are statistically significant with type I error probabilities of 1% and 5%, respectively.

Table 8: Monthly sales observed (November 2012) and projected; and price-cap regulation impact

| **ATC** | **Observed (USD)** | **Projected (USD)** | **Impact** |
|---|---|---|---|
| A02BC05 | 40,085 | 40,085 | 0% |
| A10AE04 | 1,859,800 | 245,494 | -87% |
| B02BD02 | 140,509 | 240,972 | 72% |
| H02AB04 | 43,134 | 43,134 | 0% |
| J01DH02 | 2,094,822 | 2,094,822 | 0% |
| J01XX08 | 304,309 | 405,643 | 33% |
| L01AX03 | 2,127,354 | 4,063,247 | 91% |
| L01BC06 | 1,946,603 | 1,241,933 | -36% |
| L02BB03 | 396,926 | 490,997 | 24% |
| L03AB07 | 2,910,334 | 3,472,028 | 19% |
| L04AA06 | 52,189,930 | 64,767,703 | 24% |
| L04AD01 | 548,317 | 548,317 | 0% |
| L04AD02 | 26,841,376 | 47,267,663 | 76% |
| N03AX14 | 27,074,165 | 31,162,364 | 15% |
| N03AX16 | 2,084,758 | 2,084,758 | 0% |
| N04BC05 | 1,679,319 | 2,063,883 | 23% |
| N05AH04 | 2,693,231 | 3,105,296 | 15% |
| N06DA03 | 985,094 | 882,644 | -10% |
| **Total** | **125,960,065** | **164,220,982** | **30%** |

Notes: Observed sales correspond to the total value of sales in November 2012. Projected monthly sales are estimated using average price changes by ATC group, obtained from the of the preferred econometric model specification.
Source: SISMED November 2012, MSPS

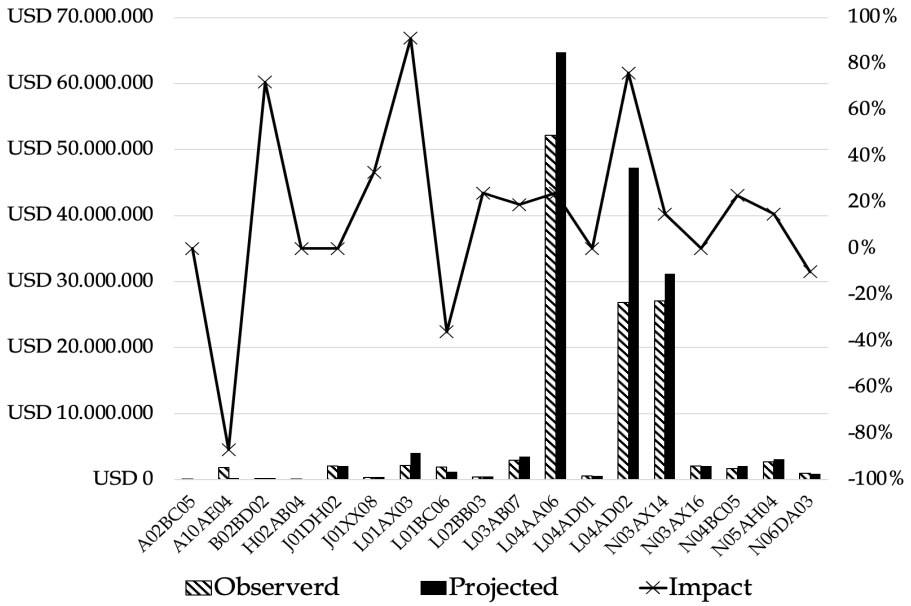


Figure 2: Monthly sales observed (November 2012) and projected; and price-cap regulation impact

# 7 Conclusions and policy recommendations

Pharmaceutical markets exhibit a particular structure, usually described by limited competition, differentiated products, and the inelasticity of demand. These conditions have led countries, to implement diverse regulatory schemes to control sale prices, protect the consumer, contain government expenditures and ensure the sustainability of health insurance systems. Using an econometric estimation of triple differences, this study evaluates the impact of a price-cap regulation scheme implemented during the period 2011-2014 in Colombia. The results of this empirical estimation indicate that, in addition to having only met its objective of reducing prices in just three ATC groups, this regulation had the unexpected and unwanted effect of an average increase in the prices in ten ATC groups.

On the one hand, it should be noted that the price-cap regime succeeded in reducing the prices of drugs used for high-cost and catastrophic diseases such as Cancer, Parkinson's and Alzheimer's. This is a particularly impor-

tant result, since in Colombia high-cost and catastrophic disease patients are subject to special protection from health and financial risks through specially designed public policy mechanisms. Similarly, the regulation caused a reduction in the average price of drugs used to treat Diabetes, which is itself a precursor to high-cost diseases that, in addition of the cost and suffering of patients and their families, they represent a substantial financial burden for the health insurance system.

On the other hand, it is also true that most of the pharmaceutical products in the ten ATC groups for which the average prices increased thanks to the price-cap regulation, are associated to the treatment of high-cost or catastrophic diseases. Without a doubt, this increase in prices has contributed significantly to an imbalance in the Nation's budget and compromises the capacity of the social security system to guarantee the rights of these patients.

Further research is needed to fully understand how the regulation impacts competition and, specifically, the entry of generic drugs to the medicines market. Existing literature shows that, in different regulatory systems, market participation of generic drugs has increased (Aronsson *et al.*, 2001; Dalen *et al.*, 2006; Brekke *et al.*, 2011; Brekke *et al.*, 2015). Furthermore, evidence suggests that reference price systems have a negative effect on the entry of brand-name drugs (Brekke *et al.*, 2009).[26] Bardey *et al.* (2016a) develop a theoretical model to analyze how me-too drugs generate competition within a therapeutic class when regulation by reference prices is applied. While this research focuses on a price-cap scheme -and not reference prices-, their results show competition dynamics depend on the market structure within the therapeutic groups, which corroborates the premise that there is competition within ATC groups. However, the time period of this study does not them to fully investigate the dynamics of market structures.

[26] According to Brekke *et al.* (2009), the reference price scheme increases the number of generics and their participation in the market, and reduces the prices of all drugs. These authors show that regulation by reference prices has better properties than price cap regulations.

# 8 Appendix

Legal set up

| Type | Body | Objetive |
|---|---|---|
| Circular 04 of 2006 | CNPM | Checked freedoom regime for all drugs, except the one that have entered into the regulated freedoom regime or direct control regime. |
| Decree 4474 of 2010 | MSPS | Implementation of maximum value price -VMR- for drugs that do not belong to POS. |
| Circular 04 of 2010 | CNPM | 25 drugs have entered into the VMR scheme. |
| Resolution 4316 of 2011 | MSPS | VMR are modified through international price comparisons (135 drugs). |
| Circular 01 of 2011 | CNPM | 81 medicamentos are regulated through price-cap scheme (PMVP). |
| Circular 02 of 2011 | CNPM | Reference price methodology is designed. Reference price are defined as the median value of sale price within a group of homogeneous drugs (ATC). |
| Circular 01 of 2012 | CNPM | 66 drugs have entered into the PMVP scheme. |

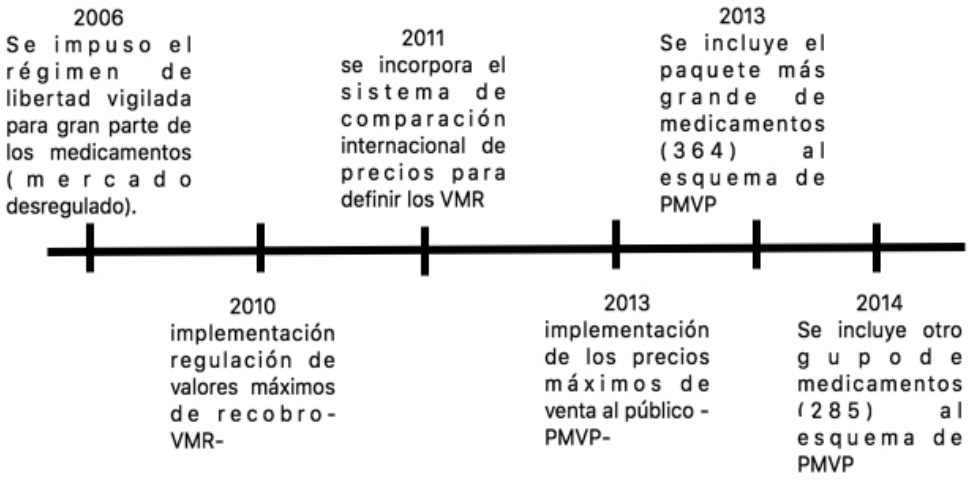


Figure 3: Time line of legal reforms

Legal set up bisl

| Type | Body | Objetive |
|---|---|---|
| Circular 03 of 2013 | CNPM | Design of the methodology for direct price control regime and implementation of price-cap regieme (PMV) for some drugs. |
| Circular 04 of 2013 | CNPM | 189 medicamentos included into the PMVP scheme and 30 drugs into the VMR scheme. |
| Circular 05 of 2013 | CNPM | Modification of PMVP for 189 regulated drugs by circular 04 of 2013. 23 medicamentos included in the PMVP scheme. Modification of price for 9 drugs in VMR scheme defined by Circular 04 of 2013. |
| Circular 06 of 2013 | CNPM | Three drugs (KALETRA) included in PMVP scheme du to their high impact. |
| Circular 07 of 2013 | CNPM | 364 drugs included in PMVP scheme and 252 drugs included in VMR scheme. |
| Circular 01 de 2014 | CNPM | 285 drugs included in PMVP scheme. |

Source: Circulars and Decrees published by MSPS and CNPM.

DDD estimation with time and ATC fixed effect. Standard errors clusters

| | Log(Price) | Log(Price) | Log(Price) |
|---|---|---|---|
| D=1 | 0.333*** | 0.193*** | 0.512*** |
| | (1.58e-11) | (0.0344) | (0.0722) |
| A10AE04 | 0.688*** | 0.296 | 1.120* |
| | (6.54e-13) | (0.587) | (0.504) |
| B02BD02 | 0.128*** | -0.396 | 0.107 |
| | (6.57e-13) | (0.254) | (0.196) |
| H02AB04 | 0.278*** | 0.0390 | 0.533*** |
| | (6.65e-13) | (0.0439) | (0.196) |
| J01DH02 | -0.0637*** | -0.206** | 0.225 |
| | (6.52e-13) | (0.0745) | (0.120) |
| J01XX08 | 2.704*** | 2.602*** | 2.885*** |
| | (6.54e-13) | (0.0347) | (0.0677) |
| L01AX03 | 2.249*** | 1.110 | 1.893*** |
| | (6.54e-13) | (0.613) | (0.464) |
| L01BC06 | 0.623*** | -0.431 | -0.180 |
| | (6.53e-13) | (0.578) | (0.424) |
| L02BB03 | 1.311*** | 0.788*** | 1.315*** |
| | (6.53e-13) | (0.229) | (0.184) |
| L03AB07 | 3.268*** | 2.769*** | 2.847*** |
| | (6.57e-13) | (0.225) | (0.151) |
| L04AA06 | 1.951*** | 1.437*** | 1.928*** |
| | (6.55e-13) | (0.247) | (0.187) |
| L04AD01 | 0.326*** | -0.168 | 0.296 |
| | (6.52e-13) | (0.343) | (0.277) |
| L04AD02 | 2.825*** | 2.058*** | 2.639*** |
| | (6.54e-13) | (0.424) | (0.340) |
| N03AX14 | 0.795*** | 0.727*** | 1.177*** |
| | (6.53e-13) | (0.0444) | (0.0806) |
| N03AX16 | 0.271*** | 0.367*** | 0.899*** |
| | (6.53e-13) | (0.0346) | (0.0919) |
| N04BC05 | 1.713*** | 0.844* | 1.600*** |
| | (6.53e-13) | (0.420) | (0.352) |
| N05AH04 | 0.413*** | 0.201 | 0.624*** |
| | (6.64e-13) | (0.162) | (0.162) |
| N06DA03 | 1.635*** | 1.188* | 1.222** |
| | (6.59e-13) | (0.590) | (0.463) |

DDD estimation with time and ATC fixed effect. Standard errors clusters bis

| | Log(Price) | Log(Price) | Log(Price) |
|---|---|---|---|
| D=1*A10AE04 | 1.527*** | 0.953*** | 0.507** |
| | (1.58e-11) | (0.0630) | (0.160) |
| D=1*B02BD02 | -0.0241*** | -0.0911 | -0.473*** |
| | (1.58e-11) | (0.0838) | (0.131) |
| D=1*H02AB04 | 0.0248*** | 0.174*** | -0.119 |
| | (1.58e-11) | (0.0259) | (0.0613) |
| D=1*J01DH02 | -0.577*** | 0.0488 | -0.291*** |
| | (1.58e-11) | (0.0882) | (0.0871) |
| D=1*J01XX08 | -0.313*** | -0.285*** | -0.570*** |
| | (1.58e-11) | (0.0804) | (0.108) |
| D=1*L01AX03 | 0.266*** | 0.548*** | 0.117* |
| | (1.58e-11) | (0.0333) | (0.0489) |
| D=1*L01BC06 | -0.276*** | 0.0105 | 0.380*** |
| | (1.58e-11) | (0.110) | (0.0659) |
| D=1*L02BB03 | 0.619*** | 0.942*** | 0.474*** |
| | (1.58e-11) | (0.0327) | (0.0650) |
| D=1*L03AB07 | -0.0880*** | 0.00847 | -0.0559 |
| | (1.58e-11) | (0.0308) | (0.0671) |
| D=1*L04AA06 | -1.822*** | -1.694*** | -2.049*** |
| | (1.58e-11) | (0.0362) | (0.0747) |
| D=1*L04AD01 | -0.963*** | -1.008*** | -1.260*** |
| | (1.58e-11) | (0.0115) | (0.0704) |
| D=1*L04AD02 | -0.825*** | -0.820*** | -1.107*** |
| | (1.58e-11) | (0.0396) | (0.0752) |
| D=1*N03AX14 | -0.810*** | -0.824*** | -1.177*** |
| | (1.58e-11) | (0.0238) | (0.0756) |
| D=1*N03AX16 | 1.049*** | 0.956*** | 0.675*** |
| | (1.58e-11) | (0.00891) | (0.0846) |
| D=1*N04BC05 | -0.634*** | -0.267** | -0.841*** |
| | (1.58e-11) | (0.0880) | (0.108) |
| D=1*N05AH04 | 0.483*** | 0.416*** | 0.157* |
| | (1.58e-11) | (0.0206) | (0.0773) |
| D=1*N06DA03 | -1.120*** | -1.526*** | -1.272*** |
| | (1.58e-11) | (0.0475) | (0.115) |

DDD estimation with time and ATC fixed effect. Standard errors clusters

| | Log(Price) | Log(Price) | Log(Price) |
|---|---|---|---|
| t=1 | -1.294*** | -1.456*** | -0.519*** |
| | (2.34e-13) | (0.0157) | (0.105) |
| D=1*t=1 | 0.130*** | 0.270*** | -0.00187 |
| | (4.86e-13) | (0.0169) | (0.0590) |
| A10AE04*t=1 | 0.411*** | 0.0411 | -0.241* |
| | (2.35e-13) | (0.0408) | (0.102) |
| B02BD02*t=1 | 0.942*** | 1.284*** | 0.905*** |
| | (2.34e-13) | (0.127) | (0.121) |
| H02AB04*t=1 | 1.123*** | 1.207*** | 0.894*** |
| | (2.35e-13) | (0.0157) | (0.0758) |
| J01DH02*t=1 | 1.307*** | 1.291*** | 0.989*** |
| | (2.34e-13) | (0.00534) | (0.0745) |
| J01XX08*t=1 | 0.787*** | 0.923*** | 0.516*** |
| | (2.34e-13) | (0.0134) | (0.0489) |
| L01AX03*t=1 | -0.0769*** | 0.127*** | -0.195*** |
| | (2.36e-13) | (0.0347) | (0.0475) |
| L01BC06*t=1 | 0.576*** | 1.073*** | 1.088*** |
| | (2.35e-13) | (0.223) | (0.164) |
| L02BB03*t=1 | 0.663*** | 0.881*** | 0.506*** |
| | (2.34e-13) | (0.0484) | (0.0851) |
| L03AB07*t=1 | 1.369*** | 1.433*** | 1.295*** |
| | (2.35e-13) | (0.0604) | (0.0600) |
| L04AA06*t=1 | 0.347*** | 0.644*** | 0.284** |
| | (2.34e-13) | (0.0991) | (0.102) |
| L04AD01*t=1 | 0.719*** | 0.878*** | 0.684*** |
| | (2.34e-13) | (0.0316) | (0.0595) |
| L04AD02*t=1 | -0.148*** | -0.0942*** | -0.362*** |
| | (2.35e-13) | (0.00538) | (0.0561) |
| N03AX14*t=1 | 0.541*** | 0.525*** | 0.197* |
| | (2.34e-13) | (0.0703) | (0.0959) |
| N03AX16*t=1 | 1.378*** | 1.442*** | 0.955*** |
| | (2.34e-13) | (0.00880) | (0.0959) |
| N04BC05*t=1 | 1.377*** | 1.213*** | 0.917*** |
| | (2.34e-13) | (0.177) | (0.164) |
| N05AH04*t=1 | 0.739*** | 0.940*** | 0.644*** |
| | (2.37e-13) | (0.0693) | (0.0861) |
| N06DA03*t=1 | -0.365*** | -0.359*** | 0.0742 |
| | (2.38e-13) | (0.00599) | (0.0553) |

DDD estimation with time and ATC fixed effect. Standard errors clusters

| | Log(Price) | Log(Price) | Log(Price) |
|---|---|---|---|
| D=1*A10AE04*t=1 | -1.595*** | -1.211*** | -0.868*** |
| | (4.86e-13) | (0.0384) | (0.114) |
| D=1*B02BD02*t=1 | 0.428*** | 0.361*** | 0.715*** |
| | (4.86e-13) | (0.0393) | (0.0774) |
| D=1*H02AB04*t=1 | -0.232*** | -0.305*** | -0.0632 |
| | (4.86e-13) | (0.0102) | (0.0613) |
| D=1*J01DH02*t=1 | -0.0363*** | -0.353*** | -0.0794 |
| | (4.86e-13) | (0.0362) | (0.0561) |
| D=1*J01XX08*t=1 | 0.130*** | -0.00676 | 0.333*** |
| | (4.86e-13) | (0.0160) | (0.0508) |
| D=1*L01AX03*t=1 | 0.831*** | 0.653*** | 0.910*** |
| | (4.87e-13) | (0.0222) | (0.0604) |
| D=1*L01BC06*t=1 | 0.402*** | 0.116 | -0.362*** |
| | (4.86e-13) | (0.111) | (0.0822) |
| D=1*L02BB03*t=1 | 0.00574*** | -0.218*** | 0.237*** |
| | (4.86e-13) | (0.0231) | (0.0662) |
| D=1*L03AB07*t=1 | 0.183*** | 0.0586*** | 0.193*** |
| | (4.87e-13) | (0.0123) | (0.0443) |
| D=1*L04AA06*t=1 | 0.0490*** | -0.0826*** | 0.241*** |
| | (4.86e-13) | (0.0183) | (0.0676) |
| D=1*L04AD01*t=1 | -0.111*** | -0.210*** | -0.00490 |
| | (4.86e-13) | (0.0103) | (0.0573) |
| D=1*L04AD02*t=1 | 0.600*** | 0.567*** | 0.761*** |
| | (4.86e-13) | (0.00792) | (0.0752) |
| D=1*N03AX14*t=1 | -0.124*** | -0.197*** | 0.151* |
| | (4.86e-13) | (0.0132) | (0.0715) |
| D=1*N03AX16*t=1 | -0.168*** | -0.213*** | 0.0334 |
| | (4.86e-13) | (0.00820) | (0.0614) |
| D=1*N04BC05*t=1 | -0.0370*** | -0.279** | 0.229* |
| | (4.86e-13) | (0.0850) | (0.112) |
| D=1*N05AH04*t=1 | 0.0530*** | -0.0588** | 0.153** |
| | (4.87e-13) | (0.0183) | (0.0521) |
| D=1*N06DA03*t=1 | 0.302*** | 0.259*** | -0.104* |
| | (4.89e-13) | (0.00780) | (0.0503) |
| Constant | 4.244*** | 4.571*** | 5.195*** |
| | (6.52e-13) | (0.0927) | (0.140) |
| Observations | 37548 | 37548 | 37548 |

Standard errors in parenthesis

Source: SISMED 2011-2014, MSPS

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

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