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PRICE CONTROLS IN THE INDIAN PHARMACEUTICAL INDUSTRY

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ABSTRACT

Using AIOCD-AWACS database on drugs sold in the Indian pharmaceutical industry, in this paper we have empirically analysed the impact of price control regulation on sales (units and volumes) of price regulated drugs. The latest drug price regulation, DPCO-2013 has an important limitation that it does not cover all the strengths and dosage forms of a regulated molecule. This leaves some part of the molecule price regulated and some part unregulated. We have utilised this feature of DPCO-2013 in our study. Using 'Difference-in-Difference' methodology we have compared the trend of sales for the price regulated and price unregulated drugs of the same molecule. We find that there is no difference in difference in total units sold of the regulated and unregulated drugs in the pre vs post intervention period. We do find a significant difference in difference in the sales value of regulated and unregulated drugs. The sales value of regulated drugs has declined over time, that of unregulated drugs has increased over time. Hence, price regulation has neither made price regulated drugs more available, nor has it led to their shortage but the sales revenue of firms has declined over time from the regulated drugs and has increased from the unregulated drugs.

Key words: Pharmaceutical Industry, Price Control, DPCO

INTRODUCTION

The Indian pharmaceutical industry, often called the pharmacy to the world, ranks 3rd in terms of volume and 10th in terms of value, globally (McKinsey & Company, 2012). The industry was valued at USD 33 Billion in 2017. The exports from India stood at USD 17.27 Billion. The industry is expected to grow at a CAGR of 22.4% between 2015- 2020 and achieve a market size of USD 55 Billion, of which the domestic generic market is expected

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to contribute USD 27.9 Billion (Nishith Desai Associates, 2019). The industry's typical feature is extreme fragmentation with concentration at the top. That is, it comprises a very large number of small firms and a small number of large firms. The market share of even the largest firms is about 9%, calculated at the industry sales level. This might suggest that the industry is fairly competitive, but such a conclusion is flawed. This is because the actual competition takes place at the level of final drug molecules (Bhattacharjea & Sindhwani, 2014). Pharmaceutical drug molecules are often characterised by a high degree of concentration with high degree of persistence in concentration. Despite the presence of multiple brands for a given molecule, asymmetric information and reliance on doctors, often leads to the consumer buying the most expensive brand of the molecule. This happens because, in India, generics are sold as branded generics and marketing activities of the firms in the industry helps in making the brand leader of a molecule, also the price leader. So, competition in the molecules is often very limited.

Most healthcare expenditure in India consists of 'out of pocket' spending by patients and their families, and a substantial proportion of this is accounted for by the cost of medicines. Such expenses are directly responsible for households falling into poverty or having to sell assets or incur debts, impairing their standard of living. Inability to afford medications leads to morbidity, lost workdays, and low productivity. The cost and availability of drugs is therefore a key development issue, directly impacted by various government policies that affect the degree of competition in the pharmaceutical sector (Bhattacharjea & Sindhwani, 2014). The scope of health insurance extremely limited in India. Both private insurance and social insurance are restricted to hospitalization cases (Planning Commission Expert Group, 2011). There is practically no insurance coverage for out-patients. The fact that these patients themselves are required to bear the cost of medicines with no insurance coverage has led to situations where they are unable to buy the medicines. By 2004, for more than a fourth of out-patient prescriptions, they did not get medicines because they could not afford to buy these medicines (Chaudhuri, 2015).

To provide essential medicines at affordable prices to their citizens, many countries around the world including India, regulate the prices of essential medicines. The latest price control regulation in India, Drug Price Control Order (DPCO)- 2013, which is the subject matter of this study, greatly increased the number of drugs under price control, but several civil society groups continue to argue for a further expansion of the scope of regulation. They demand the

inclusion of substitutable medicines under price control. On the other hand, the pharmaceutical firms and their trade associations argue that price control regulations have led to a significant loss of revenue, that the price control regulations have been ineffective, and that better alternatives, such as bulk public procurement, exist to make medicines more affordable and accessible (Bhaskarbhatla, 2018, Chapter 1).

The downside of drug price regulations, is that it often leads to inefficient outcomes like shortage of drugs in the market. Price control led to the cessation of production of as many as 27 out of 74 bulk drugs, covered by the 1995 DPCO, adversely affecting production of formulations that may be regarded as essential (Bhattacharjea & Sindhwani, 2014). Nautiyal (2014) reports shortage of human albumin, an essential drug price controlled in DPCO-2013, at hospitals, at wholesalers and at retail pharmacies, in cities like Mumbai, Pune, Delhi, Kolkata, Chennai and Gujarat. The National Pharmaceutical Pricing Authority (NPPA) which is responsible for setting prices of essential drugs in the country, has received various complaints of shortages of drugs under price control. It is the responsibility of NPPA to ensure that there are no shortages of medicines that are under price control.

HISTORY OF PRICE CONTROLS IN INDIA

India began regulating the prices of medicines in the year 1963 under the Defence of India Rules, following the India-China war. Since then the government has issued various DPCOs: DPCO-1966, DPCO-1970, DPCO-1979, DPCO-1987, DPCO-1995 and DPCO-2013. According to Chaudhuri (2015):

"The Drugs Prices (Display & Control) Order, 1966 provided for selective increases in drug prices on prior approval of the government. But the government was not empowered to reduce the prices of any drugs. By an amendment in 1968, firms were allowed the freedom to fix, with prior government approval the prices of new drugs. But no guidelines were issued and hence manufacturers were practically free to fix the prices of new products as if there were no price control. Under the Drug Prices Control Order (DPCO), 1970 the government acquired for the first time the right to fix the maximum selling prices of bulk drugs. Government fixed the prices of 18 bulk drugs and froze the prices of other bulk drugs, prices could not be increased without the approval of the government. For formulations, a formula was announced for fixing the prices based on material cost, conversion cost and packaging

charges. Unlike under DPCO, 1970, which practically covered the entire drug industry, since DPCO, 1979 a selective approach has been adopted. The basic structure of the DPCOs remained practically unchanged between 1979 and 2013. The DPCOs differ from each other basically with respect to the number of scheduled drugs (i.e., those listed in the DPCO for the purpose of price control), the degree of mark- up over cost permitted for formulation pricing and the rate of return allowed for bulk-drug pricing. The degree of mark-ups and the rate of return permitted have been enhanced and the span of control has been diluted over the years."

Under DPCO-1995, the prices of bulk drugs and formulations falling under these bulk drugs, were fixed. The prices of bulk drugs (74 in number) were fixed on the basis of actual costs plus a mark-up and the prices of of formulations (final drugs) were fixed on a cost-based formula, as follows[1]:

$$RP = (MC + CC + PM + PC) \times (1 + MAPE/100) + ED$$

In DPCO-1995, essentiality of drugs was considered, instead of the economic criteria of turnover of drugs; number of producers and market share. Because of this, the number of bulk drugs decreased from 142 under DPCO-1987 to 347 under DPCO-1979 to 74 under DPCO-1995. The proposed Pharmaceutical Policy, 2002 attempted to liberalize the span of price control further, which would have reduced the number of drugs to less than 35 (Selvaraj et al. 2012). The Supreme Court rejected this policy and asked the government to "formulate appropriate criteria for ensuring essential and life-saving drugs not to fall out of price control". Thereafter, the government announced the National Pharmaceuticals Pricing Policy (NPPP)- 2012, which made three important changes to the price control regulations:

1) Drugs under price control are to be decided by essentiality of the drugs and not by the economic criteria. The National List of Essential Medicines, 2011 (NLEM) is to be used for the purpose.

2) Only the prices of formulations will be regulated and not the prices of bulk drugs.

[1] where, RP = retail price, MC = materials cost, CC = conversion cost, PM = packing material cost of formulation, PC = packing cost of shipment, MAPE = maximum allowable post-manufacturing expenses, ED = excise duties.

3) The prices of formulations will be regulated through "market based pricing" rather than the earlier "cost based pricing".

The government introduced DPCO-2013 to implement the NPPP-2012 policy, the provisions of which are as follows[2]:

1) Government will fix the ceiling prices of the 348 drugs (only formulations) listed in the NLEM. The ceiling prices will be fixed on the basis of the market based data provided by the IMS Health, a private sector market research company.

2) The ceiling prices will be the simple average of the prices of the all the brands with market share of 1% or above. Market share will be calculated on the basis of moving annual turnover.

3) The ceiling prices fixed will be allowed an annual change depending on the changes in the Wholesale Price Index.

RESEARCH OBJECTIVE

The three main features of NPPP 2012 are that it covers essential medicines, it covers only formulations and the pricing of drugs is market based. One important limitation of NPPP 2012 and for which there is no written justification in the policy is that, it is partial in nature. This means that, not all dosages and forms of a molecule are covered by the order. The span of price control is as per the dosages and strengths listed in NLEM-2011. For example, the 500mg tablets of the paracetamol molecule are under price control whereas the 650 mg and 1000 mg tablets are not. Many authors believe that this will cause the firms to shift production and sales from the regulated to the unregulated versions of the same molecule. "In the Indian context, the selective coverage of the policy led to concerns regarding the shift of sales from price-controlled medicines to those outside price control but within the same class of medicines as a result of change in marketing priorities of the companies who would have an incentive to market medicines outside price control" (Selvaraj et al, 2019).

Therefore, in this study we are going to study the effect of price control regulation on sales

[2] These are taken from official documents of NPPP-2012 and DPCO-2013 from the NPPA's website: http://www.nppaindia.nic.in/en/

(volume and value) of drugs under price control. Our analysis will be for all the drugs that came under price control under the DPCO 2013 regulation. Our hypothesis is that sales of regulated formulations (strength and dosage form of a molecule) will decline because of the price control regulation. This is because of the partial nature of DPCO 2013, which controls some formulations of the molecule and leaves some formulations uncontrolled. We utilise all the drugs that came under price control. Some recent studies that have studied the impact of DPCO-2013 on sales of regulated drugs do it for a small set of molecules (Selvaraj et al (2019), Bhaskarbhatla (2017)). Our study is the first of its kind to test the impact of DPCO-2013 on all the molecules (as available in the dataset) covered under it. This we are going to test using difference in difference (DID) methodology.

LITERATURE REVIEW

In this section, we briefly summarise the studies that have empirically analysed the impact of DPCO-2013. Mohapatra and Chatterjee (2015) study the impact of price control on access to drugs in India's malarial market and find that lower prices lead to lower consumer welfare, as costs of making a drug available in a regional market are high enough to induce exit of products in response to lower prices. Sahay and Jaikumar (2016) study the impact of drug price regulation on sales volume and find that there has been an increase in sales volume for 37 molecules while for 52 molecules there has been a decrease in sales volume. Overall, they find a decrease in sales volume. The highest fall in sales volume has been for Paracetamol molecule and the maximum gain has been for Metformin molecule. Bhaskarbhatla et al (2017) study the impact of partial price control on metformin molecule sold in India and find evidence that firms coordinated selectively in the regulated metformin market to raise their prices in anticipation of a ceiling price being imposed on the basis of prevailing prices, so that a higher ceiling price is set by the government.

A related issue, advanced by many critics of the new market-based price control formula, (Selvaraj et al 2012; Selvaraj and Farooqui 2012; Srinivasan and Phadke 2013) is that for many drugs, the firms with high market shares (whose prices would determine the controlled price) were the ones with higher prices. Bhaskarbhatla (2018, Chapter 3) indeed finds that the prices charged by the market leaders are several times more than the minimum price prevailing in the market. Bhaskarbhatla (2018, Chapter 6) finds an adverse impact of price regulation on introduction of new varieties of regulated medicines. Bhaskarbhatla (2018,

Chapter 7) calculates the share of regulated dosages in partially regulated medicines for the years before and after the DPCO-2013 regulation. He finds that the quantity shares of the regulated medicines as a share of the total medicine, did not decline substantially overall. Selvaraj et al (2019) find that the sales of the price-controlled formulation of atorvastatin relative to other statins increased after the price regulation, on account of increased affordability.

DATA AND METHODOLOGY

We have used PharmaTrac dataset which is the sales audit date from AIOCD-AWACS. The dataset provides monthly pack-wise sales (units and values) in the Indian market for nine years 2007-2016. The data is collected from a sample of 18,000 stockists across 23 different regions of the country and then projected to reflect the overall sales in the private sector in the country. These sales are from the stockists to the retailers. PharmaTrac dataset classifies pharmaceutical medicines into five levels of therapeutic classification viz. Therapy, Supergroup, Class, Group, and Subgroup (referred to as Molecule in this study) based on EphMRA classification- Therapy being the broadest and Subgroup being the narrowest level of therapeutic classification. There are 17 therapies, 20 supergroups, 98 classes, 373 groups and 3205 subgroups[3]. Further down, there are around 58,000 brands and over 1,00,000 drugs (which they call SKU- stock keeping unit) sold in the Indian market[4].

To give an example of how a particular medicine subdivides at different levels of classification – 'Crocin', one of the most commonly known medicines belongs to the 'Central Nervous System' Therapy, 'Pain/Analgesics' Supergroup, 'Analgesics' Class, 'Non-Narcotics and Anti-Pyretics' Group and 'Paracetamol' Subgroup. Within the 'Non-Narcotics and Anti-Pyretics' Group, there are a total of 12 subgroups. Example of subgroups apart from Paracetamol are Paracetamol+Tramadol, Paracetamol+Tramadol+Domperidone. These subgroups are substitutable in a limited way depending on the patient's condition. Within the 'Paracetamol' subgroup there are 350 brands of 'Paracetamol' sold in India. These are

[3] While the number of therapies, classes and supergroups remain the same over years, the number of groups and subgroups increase overtime in the dataset.

[4] The difference in number of brands and drugs is because within a brand there are different drugs according to strength and dosage form.

perfectly substitutable within their type- oral, topical, injectable etc. Within the brand of 'Crocin' there are multiple medicines sold, that differ in their strength, drug type and pack size.

Apart from these, in the PharmaTrac dataset, there is data on brand launch date, subgroup launch date, whether the formulation is a plain or a combination drug, whether the drug is used for acute or chronic illness, the company that manufactures the drug, type of the company (Indian or MNC), drug type (tablet, injection, topical etc.), drug strength (10mg, 50mg etc.), pack size and SKU launch date. Also, there is data on price control status of a drug, i.e. whether a particular drug is price controlled or not. The dataset covers 3 major price control orders that came for the pharmaceutical industry in India which are DPCO-1995, NLEM-11 and NLEM-15.

As explained earlier, in this study, we are going to analyse the impact of partially controlling the molecules on effectiveness of the regulation. The effectiveness of the regulation is expected to be affected significantly by the partial nature of the regulation. This is because firms can move out of the regulated formulations, towards unregulated formulation and also mitigate the impact of price control in regulated formulations by increasing prices of the unregulated formulations.

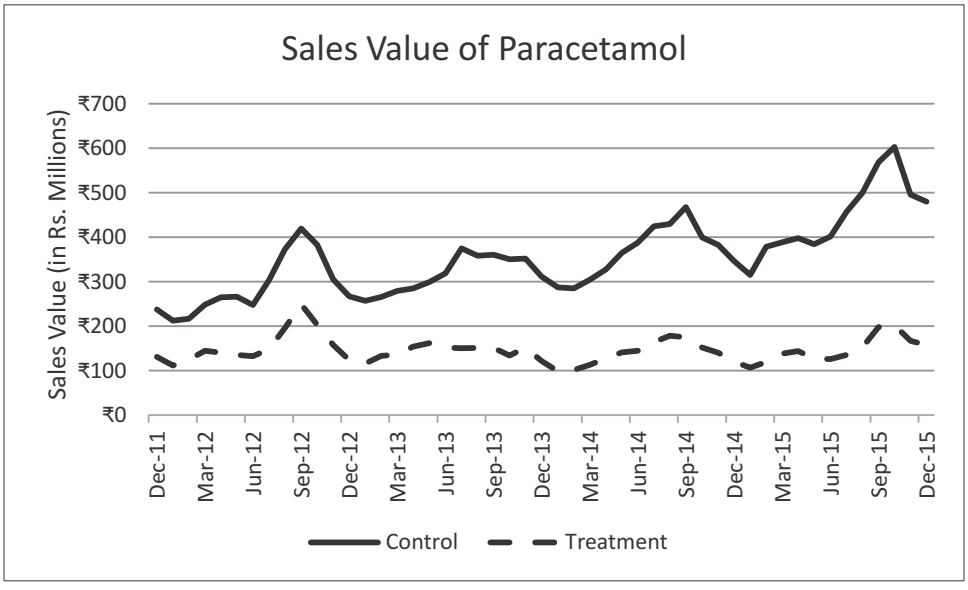
The unit of analysis will be the regulated and unregulated formulations (strengths and dosage forms) of pharmaceutical molecules that came under DPCO-2013 regulation. A total of 348 molecules came under price control in DPCO-2013. However, the PharmaTrac dataset has data on 261 molecules that were price regulated under DPCO-2013. Out of these, 34 molecules were under price control under the DPCO-1995. These will be dropped from our analysis as we are interested in only those molecules that were not under price regulation earlier and came under DPCO-2013 price regulation. This leaves us with 247 molecules, out of which there were 33 molecules that were entirely under price control, i.e., all the formulations of these molecules were covered under DPCO-2013. Since, our research question is to see the impact of partial price control on the effectiveness of the DPCO-2013, we are going to work only on the 214 partially controlled molecules. For these molecules, we are going to assess the impact of DPCO-2013 on their sales and prices.

The period of analysis will be the 49 months' period from December 2011 to December 2015.

DPCO-2013 was notified in May 2013 and a period of 45 days were given to firms to revise the prices of regulated drugs. So the period from December 2011 till June 2013 will be the 'pre-intervention' period and the period from July 2013 to December 2015 will be considered as the 'post-intervention' period. We do not take the months after December 2015, as NLEM was revised in 2016 with some new drugs and some existing drugs were removed.

For econometric analysis, we are going to use 'Difference in Difference' methodology that requires a treatment and a control group. The price regulated formulations of each molecule will belong to the 'treatment group' and the price unregulated formulations of each molecule will be in the 'control group'. The difference in difference, also called a double difference estimator is defined as the difference in average outcome in the treatment group and control group after the intervention minus the difference in average outcome in the treatment and control group before the intervention. The basic condition to get an unbiased DID estimator is that the pre-treatment trend of the treatment and the control group is similar. This ensures that any post-treatment difference in the trend of the treatment and the control group can be attributed to the treatment. The assumption is that without the intervention, the treatment group would have grown the same way as the control group. The unregulated part of each molecule serves as a good control for its regulated counterpart, because their sales and prices are expected to grow similarly before the intervention. There is no reason to believe that sales of 500mg paracetamol and 1000mg paracetamol are going to be different in terms of overall trend, as they are perfect substitutes of each other. Their levels may be different depending on their respective requirement in the overall patient population, but on average they are expected to grow similarly, at least in the pre-intervention period. The below graph for sales value of regulated (treatment) and unregulated (control) formulations of Paracetamol, shows that in the pre-intervention period (before June-2013), the sales value of the treatment and control group paralleled. However, in the post intervention period (after June-2013) the sales value of regulated paracetamol (treatment) began to decline, while that of unregulated paracetamol (control) rose sharply. Their difference widened with time. Looking at the graph (Figure 1), one may be able to say that there is a significant difference in difference in the sales value of regulated and unregulated formulations of paracetamol, in the pre vs post treatment period.

Figure 1: Sales Value of Regulated and Unregulated formulations of Paracetamol



We are going to test the impact of DPCO 2013 on sales value and sales units for all the 214 partially price controlled molecules. The theoretical model[5] for estimating the impact of price control on sales of molecules is described below.

Let,

Y_{1irt} = *sales of formulation I at period t if it is under price regulation*

Y_{0irt} = *sales of formulation I at period t if it is not under price regulation*

These are the potential outcomes – in practice, we observe either Y_{1irt} or Y_{0irt} , depending upon whether a formulation came under price control or not. The difference in difference setup assumes an additive structure for potential outcome in the no treatment state, i.e.,

$$E\,(Y_{0irt}\,|r,\,t) = \gamma_r + \lambda_t$$

where *r* denotes regulation (regulated or unregulated) and *t* denotes period (pre-treatment or

[5] This model is derived from Angrist and Pischke (2009).

post-treatment). The above equation says that in the absence of regulation, sales is determined by the sum of an unobserved fixed (time-invariant) formulation effect and a year effect that is common across formulation. Let D_{rt} be a dummy for regulated formulations, where r is for regulated or unregulated. Assuming, that $E(Y_{1irt} - Y_{0irt} | r, t)$ is a constant, denoted by β, we have:

$$Y_{0irt} = \gamma_r + \lambda_t + \beta D_{rt} + \varepsilon_{irt}$$

where $E(\varepsilon_{irt}|r;t) = 0$. From here, we get

$$E(Y_{irt}|r = Unregulated, t = PostTreatment)$$

$$- E(Y_{irt}|r = Unregulated, t = PreTreatment)$$

$$= \lambda_{PostTreatment} - \lambda_{PreTreatment}$$

and

$$E(Y_{irt}|r = Regulated, t = PostTreatment)$$

$$- E(Y_{irt}|r = Regulated, t = PreTreatment)$$

$$= \lambda_{PostTreatment} - \lambda_{PreTreatment} + \beta$$

the population difference-in-differences, β is the causal effect of interest, as is expressed below. This can be estimated by using the sample analogue of the population means.

$$[E(Y_{irt}|r = Regulated, t = PostTreatment)$$

$$- E(Y_{irt}|r = Regulated, t = PreTreatment)]$$

$$- [E(Y_{irt}|r = Unregulated, t = PostTreatment)$$

$$- E(Y_{irt}|r = Unregulated, t = PreTreatment)] = \beta$$

The DID methodology makes use of the treatment variable, the period variable, an interaction variable of treatment and period, along with other covariates. In regression form,

the equation is as below.

$$Y_{irt} = \alpha + \beta(D_r * P_t) + \gamma D_r + \delta P_t + \varepsilon X'_{irt} + \eta_{irt}$$

D_r is the dummy variable that takes value 1 for formulation under price control and 0 for formulation not under price control

P_t is the time dummy that takes value 1 for the post-treatment period and 0 for the pre-treatment period

X'_{irt} is the vector of covariates

η_{irt} is the error term

$\alpha, \beta, \gamma, \delta, \varepsilon$ are the parameters to be estimated and β measures the difference in difference estimate.

Dependent Variable (Y_{irt})

In this study, we are interested in assessing the impact of DPCO-2013 regulation on sales value and sales units of formulations. So, Y_{irt} will be sales value and sales units of formulations in two separate equations. The methodology described above will be applied to all the two Y_{irt} to estimate the difference-in-difference estimators. Sales unit is a real variable while sales value is a nominal variable. Since sales value is a product of sales units and prices, the impact of regulation on sales value will depend both on the change in sales units and the change in prices due to the regulation.

Explanatory Variables (X_{irt})

The main explanatory variables in this study are the treatment dummy, the period dummy and their interaction variable (treatment*period). This variable takes a value of 1 for the price regulated drugs in the post-intervention period and take a value of 0, otherwise. We expect the sign of the interaction variable variable to be negative, as we expect the sales (units and value) to decrease for the price regulated drugs, in the post-intervention period. This is the most important variable in our analysis, as it gives the 'difference-in-difference" (DID) coefficient. The other controls variables included in the regression of the sales value, sales

unit and prices of formulations are as follows: concentration in the market (as measured by HHI), age of the formulation (in months), a dummy for whether the formulation is a plain or a combination drug (Plcom), a dummy for whether the formulation is used for acute or chronic illnesses (Acch) and a dummy for whether the formulation is sold as a prescription drug or as an over the counter drug (RXOTC). Apart from these, formulation fixed effects and year fixed effects will also be controlled for.

DESCRIPTIVE STATISTICS

First, we summarise the key variables of interest (dependent variables: sales value and sales unit in the pre and post intervention period, in Table1. The average sales value of formulations, in the treatment group, has declined in the post-intervention period, in absolute terms, while that of the control group, has increased. In percentage terms, there has been a fall of 2.7% in average sales value, in the treatment group in the post-intervention period as compared to the pre-intervention period, while there was a 3% rise in sales value in the control group. The total number of units sold has increased for the treatment group by 3%, while that of the control group increased by 7%. Next, we report the summary statistics for all the dependent and explanatory variables, averaged over the entire 49 months' period, in Table2.

Table 1: Sales Unit[6] and Sales Value[7] of Formulations in the Pre-Post Intervention Period

	Pre-Intervention				Post-Intervention			
	Treatment		Control		Treatment		Control	
Variable	Obs	Mean	Obs	Mean	Obs	Mean	Obs	Mean
Sales Value	4,066	40.1	4,066	17.5	6420	39	6420	21.4
Sales Unit	4,066	1070.08	4,066	474.85	6420	1102.45	6420	509.61

[6] Everywhere in the analysis, the sales units are in units of 1000's to make the coefficients more readable.

[7] Everywhere in the analysis, the sales values are in Rs. Millions, to make the coefficients more readable.

Table 2: Summary Statistics

Variable	Obs	Mean	Std. Dev.	Min	Max
Sales Value	20,972	29.66	78.83	0	1157.84
Sales Unit	20,972	793.02	2025.52	0	25735.79
HHI	20,972	0.42	0.27	0	1
Age	20,972	8262.42	3716.25	944	24075
PlCom	20,972	0.96	0.20	0	1
Acch	20,972	0.59	0.49	0	1
RxOTC	20,972	0.86	0.34	0	1

As the next exercise, we graph the total sales of formulations (unit and value) of the treatment and control group for the entire time period. The key identifying assumption in difference-in-difference (DID) models is that the pre-treatment trends are similar for treatment and control groups. We observe that before the intervention, the trends of the treatment and control group look very similar for both the sales value and sales units. So, the basic DID condition is met in our data. However, post regulation, there is an immediate fall in the sales value of the treatment group as compared to the control group and the difference between the treatment and control group is narrowing (Figure 2). However, for total units sold, the trend in the treatment and the control group looks very similar in the pre-treatment period, as well as in the post intervention period. Hence, one can say that the price regulation has had no impact on the quantities sold of regulated formulations, positive or negative (Figure 3). In the next section, we are going to test this econometrically.

Figure 2: Sum of Sales Values of formulations in Treatment & Control Group

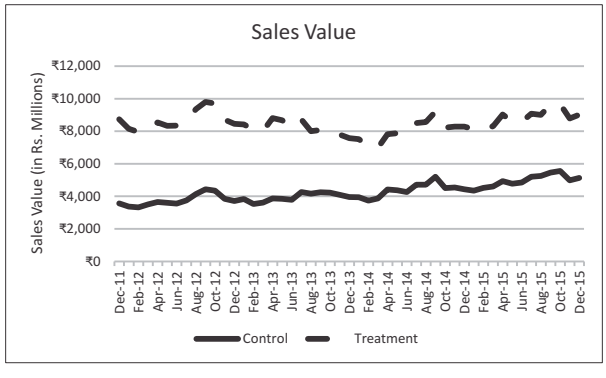
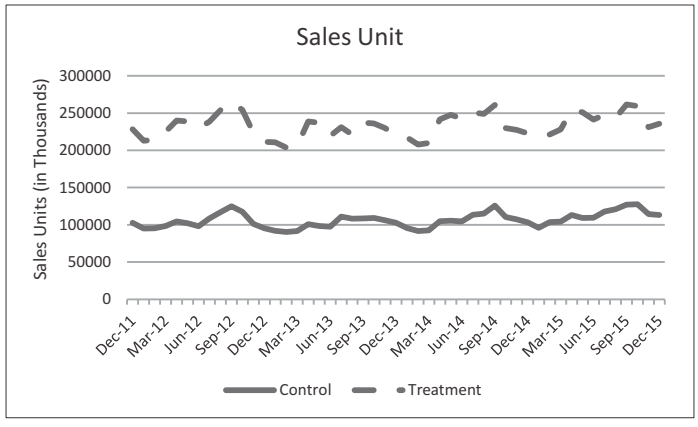


Figure 3: Sum of Sales Unit of formulations in Treatment & Control Group



ECONOMETRIC ANALYSIS

In this section, we present the econometric results for the regressions of sales units and sales values, as described above. For each of them, we run 4 separate models:

- Y_{irt} regressed on only the explanatory variables (base model)
- Y_{irt} regressed on only the explanatory variables and formulation fixed effects
- Y_{irt} regressed on only the explanatory variables and year fixed effects
- Y_{irt} regressed on only the explanatory variables and formulation and year fixed effects

We run a simple OLS regression on the models described above. The results are summarised below:

Regression of Sales Units

In the base model, the coefficient of treatment variable is positive and significant at 1% level of significance (Table 3). This means that on average the formulations under the treatment have higher sales unit than the formulations under control group. The coefficient of the Period variable is negative, meaning that on average the sales of all the formulations have gone down in the period after intervention. However, this coefficient is insignificant. The estimated coefficient of the interaction variable of Treatment and Period is negative,

meaning that DID coefficient is negative and that sales units of formulations under treatment have fallen in the post intervention period. However, this coefficient is insignificant. Concentration (as measured by HHI) has a significant negative impact on the number of units sold in the market. The Age variable has a significant positive impact on sales units, meaning that older formulations have larger sales as expected. The coefficient of plain-combination dummy is negative and significant, meaning that plain drugs have on average lower sales units than the combination drugs. The coefficient of acute-chronic dummy is positive and significant, meaning that on average, the market for acute drugs is bigger than that of chronic drugs in India, in terms of sales units. The coefficient of prescription-OTC dummy is negative and significant, meaning that on average the prescription drugs are sold in lesser quantities than the OTC drugs.

When formulation fixed effects are accounted for, the coefficient of treatment variable is still positive and significant at 1% level of significance. The period variable is negative but insignificant. The coefficient of interaction variable of Treatment and Period is negative, meaning that DID coefficient is negative and that sales units of formulations under treatment have fallen in the post intervention period. However, this coefficient is insignificant. Concentration has a significant negative impact on concentration. Age has a significant positive on concentration. The coefficient of plain combination dummy has a significant positive coefficient, meaning that plain drugs have on average higher units sold, when the formulation fixed effects are accounted for. The coefficient of acute chronic dummy has a significant positive coefficient, meaning that drugs for acute diseases have on average higher units sold than the drugs for chronic diseases. The coefficient of prescription-OTC dummy is positive and significant, meaning that on average the prescription drugs are sold in greater quantities than the OTC drugs. When the formulation fixed effects are accounted for, the R-squared increases from 0.11 to 0.70.

When only year fixed effects are accounted for, without accounting the formulation fixed effects, the results are very similar to the base model where no fixed effects (formulation or year) are accounted for. Only, the coefficient of the period variable changes and it is positive and insignificant, as compared to the base model. When both the formulation and year fixed effects are accounted for, the coefficients are mostly similar to the coefficients in the regression with just formulation fixed effects, with one difference. The coefficient of period is positive but insignificant.

Table 3: Regression of Sales Units

	Dependent Variable: Sales Unit			
Variables	Model 1	Model 2	Model 3	Model 4
Treatment	607.1***	596.4***	607.1***	596.4***
	(40.74)	(24.32)	(40.73)	(24.31)
Period	-18.68	-14.84	34.93	8.144
	(31.45)	(32.44)	(53.50)	(36.28)
Treatment*Period	-3.468	-2.498	-3.468	-2.498
	(53.40)	(31.34)	(53.40)	(31.33)
HHI	-1,795***	-177.9***	-1,795***	-178.3***
	(49.08)	(22.09)	(49.11)	(22.23)
Age	0.0731***	0.0667**	0.0732***	0.248***
	(0.00364)	(0.0330)	(0.00364)	(0.0782)
PlCom	-345.3***	487.1***	-345.3***	1,094***
	(85.39)	(121.5)	(85.39)	(266.9)
Acch	166.7***	354.5***	166.7***	465.1***
	(24.65)	(54.79)	(24.66)	(69.94)
RxOTC	-436.2***	262.3*	-436.3***	1,068***
	(57.03)	(153.6)	(57.04)	(350.5)
Constant	1,258***	-1,335***	1,281***	-3,601***
	(91.05)	(436.1)	(121.8)	(991.8)
Formulation Fixed Effects	No	Yes	No	Yes
Year Fixed Effects	No	No	Yes	Yes
Observations	20,972	20,972	20,972	20,972
R-squared	0.109	0.702	0.109	0.702

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Regression of Sales Values

For the second regression (Table 4), where the dependant variable is the sales value, in the base model, the coefficient of Treatment dummy is significant and positive, meaning that on average formulations in the treatment group have significantly higher sales value than the formulations in the control group. The coefficient of the period dummy is positive and

significant, meaning that sales value of formulations on average have gone up in the post-intervention period. The estimated coefficient of the interaction variable of Treatment and Period is negative and significant. This means that on average the sales value of formulations under treatment group have gone down significantly in the post intervention period. This is the DID estimate. HHI has a significant negative impact on sales value. Age has a significant positive impact on sales value, meaning that older formulations have larger sales value as expected. The coefficient of plain-combination dummy is negative and significant, meaning that plain drugs have on average lower sales value than the combination drugs. The coefficient of acute-chronic dummy is positive and significant, meaning that on average, the sales value for acute drugs is bigger than that of chronic drugs in India. The coefficient of prescription OTC (RxOTC) dummy is positive and significant, meaning that on average the prescription drugs have higher sales value than the OTC drugs, in India.

When formulation fixed effects are accounted for, the coefficient of treatment variable is still positive and significant at 1% level of significance. The coefficient of period dummy is negative, meaning that overall sales value has gone down in the post intervention period, but the fall is insignificant. The estimated coefficient of the interaction variable of Treatment and Period is negative and significant. This means that on average the sales value of formulations under treatment group have gone down significantly in the post intervention period. HHI has a significant negative impact on sales value. Age has a significant positive impact on sales value. The coefficient of plain-combination dummy is positive and significant, meaning that plain drugs have on average higher sales value than the combination drugs. The coefficient of acute-chronic dummy is positive and significant. The coefficient of prescription OTC (RxOTC) dummy is positive and significant.

When only year fixed effects are accounted for, without accounting the formulation fixed effects, the results are very similar to the base model. Only, the coefficient of the period variable changes and it is still positive but insignificant, as compared to the base model. When both the formulation and year fixed effects are accounted for, the coefficients are mostly similar to the coefficients in the regression with just formulation fixed effects, with one difference. The coefficient of period becomes positive, but still insignificant.

Table 4: Regression of Sales Value

	Dependent Variable: Sales Value			
Variables	Model 1	Model 2	Model 3	Model 4
Treatment	23.14***	22.61***	23.14***	22.61***
	(1.550)	(0.906)	(1.550)	(0.905)
Period	3.738***	-0.927	2.334	0.213
	(1.043)	(1.262)	(1.973)	(1.397)
Treatment*Period	-5.043**	-4.996***	-5.043**	-4.996***
	(2.059)	(1.182)	(2.059)	(1.182)
HHI	-80.38***	-1.719**	-80.46***	-1.748**
	(2.139)	(0.692)	(2.142)	(0.698)
Age	0.000224**	0.00642***	0.000205**	0.0132***
	(0.000101)	(0.00129)	(0.000101)	(0.00311)
PlCom	-50.65***	21.57***	-50.63***	44.25***
	(7.042)	(4.566)	(7.041)	(10.52)
Acch	0.951	4.713***	0.950	8.846***
	(1.037)	(1.633)	(1.037)	(2.379)
RxOTC	4.209***	16.29***	4.203***	46.39***
	(1.434)	(5.892)	(1.434)	(13.88)
Constant	93.45***	-81.70***	93.72***	-165.3***
	(6.630)	(16.91)	(7.364)	(39.39)
Formulation Fixed Effects	No	Yes	No	Yes
Year Fixed Effects	No	No	Yes	Yes
Observations	20,972	20,972	20,972	20,972
R-squared	0.111	0.716	0.111	0.716

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

SUMMARY AND POLICY IMPLICATIONS

We assessed the impact of DPCO-2013 on the sales value and sales units of the price regulated formulations. Using difference in difference methodology, we compared the trend of sales units and sales value of the price regulated formulations with that of the unregulated formulations. Graphically, we saw that the trends of the sales unit for the regulated and the unregulated formulations looked parallel in the pre-intervention and post-intervention

period. There was a fall in the sales value of regulated formulations immediately after the intervention, for almost a year. Thereafter, the sales value started to increase. For, the unregulated formulations, there has been a rise in the sales value in the entire post-intervention period. So, the difference in sales value between the regulated and unregulated formulations has narrowed. Looking at their graph, one may be able to say that there has been a significant difference in difference in sales value but not for sales unit.

We tested this econometrically and found that there has been no significant impact of the intervention on the number of units sold of the formulations that came under price regulation. Though, there has been a significant negative impact of the intervention on sales value of the formulations under price regulation. Sales value is a product of sales unit and prices and there has been no significant change in the sales unit, so one can say that this change in sales value is coming from the change in price. This means that on average the prices of regulated formulations have gone down in comparison to the price of unregulated formulations.

In nutshell, there has been no real impact of DPCO-2013 to make essential formulations more accessible. Their prices may have gone down, making the drugs more affordable but that is not leading to any increase in their quantities sold, as compared to the pre-intervention period. Hence, partial control of molecules under DPCO-2013 has seriously limited the impact of the policy.

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