Does Pharmaceutical Price Regulation Result in Greater Access to Essential Medicines?

Study of the impact of drug price control order on sales volume of drugs in India

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W.P. No. 2016-02-01
January 2016

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INDIA

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Introduction

Price regulation in the pharmaceutical industry can be a double – edged sword. While the policymakers typically aim at making the drugs more affordable, price control on drugs may have adverse effects on availability. Firms may exit a category under regulation due to low profit prospects. Lesser profits may also act as a barrier to entry for new firms. Further, firms may shift marketing focus from the drugs under price control, and reduce detailing and promotion efforts for these drugs. These factors may eventually lead to a drop in sales volume for these drugs. While prior studies have examined the impact of pharmaceutical price regulation on delay in launch of new drugs (Danzon, Wang, and Wang 2005**),** pharmaceutical innovation (Vernon 2003) and research and development investments (Vernon 2003), to the best of the authors' knowledge, the impact of price regulation on sales volume of regulated drugs has not been examined. Further, while prior research on pharmaceutical price regulation has been concentrated on drug markets in the US (Abbott 1995; Abbott and Vernon 2007; Vernon 2005) where prices are mostly unregulated and Europe (Mrazek 2002; Puig-Junoy 2010) where prices are either controlled directly (eg. France) or through reimbursements (eg. Germany) or through

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profit controls (eg. United Kingdom) (Vernon 2002), no significant work has been done on price regulation in India, a 'branded generics' market.

Economic theory would suggest no intervention in the generic drugs market (Puig-Junoy 2010). However many governments continue to intervene through some form of price regulation in the pharmaceuticals market. While in the US, the pharmaceutical industry is highly unregulated, in Europe, the governments are actively involved in price regulation (Vernon 2002). The main argument in countries that favor price regulation is that neither the doctor nor the patient takes decisions based on the costs incurred (Green 1998). As these governments typically provide some form of universal healthcare, the governments intervene in an attempt to reduce the healthcare expenses incurred. As a result of strict price regulation, pharmaceutical companies in the European Union attain lesser profits and stock returns, and invest lower R&D amounts compared to their US counterparts (Golec and Vernon 2010). Further, Abbott and Vernon (2007) and Vernon (2002) ran simulations and find that price regulation, if introduced in the US, is likely to result in lowering of R&D investments similar to other countries.

Despite the theoretical attention on price regulation and few studies evaluating the impact on pharmaceutical business and consequently, the welfare of the society (eg. Podnar, Molj, and Golob 2007), there is a lack of strong empirical evidence linking price regulation and drug availability. Examining the effect of price regulation on access and availability of drugs is of utmost importance to both policy makers and managers in the pharmaceutical industry. This is also particularly important in India because the ostensible reason for price regulation is to increase affordability and accessibility in a country that is considered a privatized health economy (Duggal 2007) with around 80% of healthcare expenses being borne privately, with majority being out of pocket expenses (Banerji 2013). In this paper, using a unique dataset and

an event study approach, we report the impact of pharmaceutical price regulation on sales volume of drugs in India.

In May 2013, the Department of Pharmaceuticals (DoP) of India brought 348 medicines under price control by the Drug Price Control Order (DPCO). The list of 348 medicines was taken from the National List of Essential Medicines (NLEM) which was compiled by the Ministry of Health and Family Welfare in 2011. These formulations are considered essential and lifesaving drugs, and address the priority health needs of the country. The objective of the DPCO 2013 was to ensure availability of essential medicines at affordable prices for the poorer masses, while still encouraging innovation and growth in the pharmaceutical industry (DPCO 2013). The order set a price ceiling for these drugs by averaging the existing market prices (of all brands that have a market share of 1% or greater). While the brands priced above the ceiling price were to reduce the prices, the other brands had to maintain the prices at current levels. Further, the order restrained the price increases (optional) to be in line with or below the wholesale price index in any one year period.

Using drug sales data from IMS Health (India) and an event study approach, we empirically assess whether price regulation results in more volume of the regulated drugs (105 oral solids) being sold in India, an emerging economy. We further analyze the event study results of 46 oral solids (which form about 90% of the 105 molecules in terms of sales value), by expressing the volume change induced by regulation, as a function of the absolute price point post regulation, extent of price reduction faced by the market, whether the molecule is prescribed for acute or chronic illnesses, percentage prescriptions from CP/GP (Consultant Physicians / General Practitioners), percentage sales from urban and semi urban (tier-1 and tier-2) cities, industry level detailing efforts for the drug and an interaction between the last two terms. Our results

suggest that while some molecules had an increase in sales volume that can be attributed to DPCO, overall the impact has been negative. Further, we find that the impact of increasing detailing efforts on change in sales volume is moderated by the sales in urban and semi-urban (tier 1 and tier 2) cities. We also find that the post regulation price level (relative expensiveness of the molecule) and the type of molecule (acute vs. chronic illnesses) also have marginally significant impact on the change in sales volume.

The rest of the paper is organized into four sections. First, we provide a brief overview of the Indian Pharmaceutical Market (IPM) and explain how it differs from the US and European Markets. We also briefly explain the details of the Drug Price Control Order 2013 and its objectives. Second, we empirically examine the impact of DPCO on the 105 oral solid molecules using a modified event study approach. Third, we analyze the results of the event study using market level data and identify few factors contributing to the increase (decrease) in sales volume of molecules. Finally, we discuss the policy and marketing implications of our findings.

Background

Indian Pharmaceutical Market

The Indian pharmaceutical industry in 2015 was a $22 billion industry and stands 3rd in the world in terms of sales volume of medicines and 13th in terms of revenue. From humble beginnings in 1969, when 95% of medicines sold in India were sold by multinational pharma firms, Indian firms, subsequent to the promulgation of the process patent act in 1969 had reverse engineered many molecules (Bannerji 2009) and grown to become known as suppliers of inexpensive medicines to the world. The Indian Pharmaceutical Market (IPM) shot to worldwide fame when

they supplied AIDs cocktail drugs to many countries around the world at a price that was 5-10% of the price of the same therapy being supplied by large Western pharmaceuticals.

By the time, a WTO agreement to bring back product patents in India took effect in 2005, India had become home to the largest number of US Food and Drug Administration approved plants in the world; these plants, mostly owned by Indian entrepreneurs who had grown over time, supplied medicines to India and to markets around the world. Cipla. Sun, Lupin, Wockhardt and DRL were the five largest firms in India.

The Indian pharmaceutical market itself was a $10 billion market (most firms exported a substantial proportion of their production to both regulated markets like the USA and to unregulated markets in Africa). The IPM recorded a growth of 10% for the 12 month period ending May 2013 over the same period in the previous year (Chemical Business 2013). The growth slightly dropped to 9.3% in April 2014 and was attributed to the price control order (Business Standard 2014).

Unlike developed markets, 95% of sales of medicines in India were of pharma molecules that were off patent (known as generic drugs). Both unbranded generic molecules (amoxycillin, paracetamol, etc.) and branded generic drugs (e.g., Augmentin - a branded amoxycillin) were sold in India. While the scale of the market in revenue terms was relatively small compared to developed markets, (for example, Augmentin, a branded generic antibiotic had annual sales of INR 2 billion (USD 28 million) in 2014, the volumes were substantial as the prices in India were a lot lower as compared to developed markets.

India is considered a privatized health economy (Duggal 2007) and around 80% of healthcare expenses are borne privately, with majority being out of pocket expenses (Banerji 2013); in this,

India is quite different from the USA where insurance pays for more than 90% of health related expenditure and the UK, where a National Health Service covers majority of costs incurred. As per capita income in India was also low ($1800 in 2014), and neither universal healthcare nor universal insurance were available, affordable access to medicines was considered a key policy goal of the Indian government. Thus, cheaper generic alternatives to expensive medicines were widely available in India which in turn, reduced the likelihood of high priced therapies launching successfully (Subramanian, Mutyal, and Nechamkin 2014). Given the low per capita income and the lack of universal health care provision and the privatized health care access, the Drug Price Control order came into existence to fulfill a key policy goal of the Indian government - to provide increased access to medicines to people at an affordable price.

DPCO and Aftermath

The Department of Pharmaceuticals, under a revision of the earlier order, released the Drug Price Control Order in May 2013, regulating the prices of 348 drugs (borrowed from the National List of Essential Medicines) in the Indian market. The order's primary objective was to ensure that the essential and lifesaving medicines are readily available and are at affordable prices. Further, the order authorized the National Pharmaceutical Pricing Authority (NPPA) of India to regulate the medicine prices of NLEM and monitor price increases of medicines which are not part of NLEM (non-NLEM) (Subramanian, Mutyal, and Nechamkin 2014).

The price ceilings for NLEM are set using 'market-based' mechanisms. For most drugs, the price ceiling is the simple average of the prices of all brands in the market with market share of at least 1%. While the brands priced higher than this average are to reduce the prices at or below the ceiling price, those priced below were to maintain their current price levels. Further, if there is

only one drug in a particular category, then the price is based on a fixed percentage derived from price reductions in similar categories. While price increases of NLEM were restricted to be in line with or below the wholesale price index of India, the non-NLEM were allowed a maximum price increase of 10% in any one year period. The price ceiling set by the DPCO refers to the price to the retailer. The retailer margin is then fixed at 16% for NLEM. While firms were allowed to exit from a given category with a six months' notice, the NPPA reserved the right to mandate continued production of up to 12 months (DPCO 2013).

As noted earlier, the impact of DPCO on social welfare, in terms of increased access, availability and affordability of the essential medicines have not been examined in detail. While few independent agency reports have attempted to address this issue (eg. IMS Consulting Group 2015), a number of methodological flaws and confounds make the findings inconclusive. An independent study by Wan (2013) reveals that the molecules under price regulation account for about 60% of the pharmaceutical market in India and the DPCO was expected to erode the value of the IPM by about $290 million annually (2.2% drop of the entire market). Launches of new drugs have also declined from 270 drugs in 2008 to 56 in 2014 (FRPT-Research 2015). Another independent study by IMS Health comparing the sales growth of few NLEM and non-NLEM molecules post the DPCO reveals that the growth rate of NLEM molecules (select few) were lesser than that of their non-NLEM counterparts (IMS Consulting Group 2015). The report further suggests that the DPCO has not resulted in increased access of essential medicines to rural areas. The study used CAGR (cumulative annualized growth rate) of NLEM and non-NLEM molecules (select few) as an indicative measure of access and availability. Comparison of the CAGR for NLEM and non-NLEM molecules across different town classes reveals that post DPCO, the CAGR of non-NLEM grew by 7% in rural areas whereas the CAGR of NLEM

declined by 7%. The report concludes that the DPCO was ineffective in reaching rural areas (IMS Consulting Group 2015, p.15). However, using non-NLEM as a base of comparison might lead to confounding results. Specifically, the increase in sales volume of non-NLEM molecules may be attributed to the increased marketing efforts by pharmaceutical companies to increase their share of the price unregulated segment. Further, the pharmaceutical firms may have also reduced the marketing efforts of the regulated drugs in an attempt to cut costs. We use a robust methodology to isolate the impact of DPCO on sales volume of molecules. Further, we use the entire family of oral solids brought under DPCO in May 2013. In the next section, we explain the empirical strategy followed in the study.

Empirical Analysis of the Impact of DPCO 2013

Overview

We use a novel event study approach to examine the impact of DPCO 2013 on sales volume of drugs. Event studies are commonly used in finance (MacKinlay 1997) and marketing (eg. Jaikumar and Sahay 2015) to estimate the impact of an event on stock returns. In this study, we adapt the event study to fit the objectives of the research. The event study used in this paper consists of three stages: estimating a SARIMA function (with or without drift) using historic sales volume (number of pills) data, creating a baseline using the forecast function for the period immediately following the event (termed the event window) and comparing the actual sales volume with the baseline to isolate the impact of the event. Specifically, we estimate the residuals of the forecast function (termed as 'abnormal change') for the period following the event and test for direction and statistical significance. While majority of the event studies focus on stock returns recorded in the financial markets (eg. Jaikumar and Sahay 2015), to the best of

the authors' knowledge, this is the first study to use event study mechanics on forecasts based on seasonal ARIMA.

Timeline

The specific timelines and definition of 'event window' are listed in Table 1. The estimation period is from May 2009 to April 2013, a total of 48 months. Monthly sales volume data from this period is used to fit a forecast function. The announcement of DPCO in May 2013 is considered the 'event'. This is followed by what we term a 'implementation period' (May 2013 to June 2013). While the announcement was made in mid-May 2013, firms were given a period of 45 days to implement the price change as per regulation. During this 'implementation period', many pharmaceutical firms tried to move their old stock (at pre regulation prices) and also 'recalled' large quantities of stock in an effort to 'relabel' the prices. Hence this period is not considered a part of the event window. The enforcement of NLEM 2013 was complete by end June 2013 and the event window is taken as the one-year period from July 2013.

Table 1: Timeline for the event study

Estimation period	May 2009 to April 2013
Event (announcement of DPCO 2013)	May 2013
Implementation period	May 2013 to June 2013
Event Window	July 2013 to June 2014

Data

The data used in this study are extracted from IMS Health (India) database. IMS primarily records secondary data, i.e., sales data from stockists to retailers. All the oral solids (105 molecules) that come under the DPCO regulation are included in the analysis (few very low

volume oral solids that are under NLEM 2013 are not covered by IMS due to insignificant data). As each molecule has multiple SKUs (stock keeping units) depending on pack size and strength, we take sales volumes of the largest selling SKU for each molecule as representative of that molecule. We extracted monthly MAT (Moving Annual Total) sales volume (number of pills) for all these SKUs from May 2009 to July 2014. As noted earlier in Table 1, data from May 2009 to April 2013 is used for estimation while the data from July 2013 to June 2014 is used to estimate the 'abnormal change' (residuals) due to the event.

Event Study Methodology

Stage 1: Estimate the Forecast Function

We apply the 'forecast' methodology proposed by Hyndman and Khandakar (2008) using R statistical software to estimate the forecast function using historic sales data. The forecast package has been used in a number of research papers to fit forecast functions (eg. Ahrens, Kovandzic, and Vieraitis 2015; Hassani et al. 2015). The forecast package finds the best fitting seasonal ARIMA model using the algorithm developed by Hyndman and Khandakar (2008). Specifically the package identifies an ARIMA (*p, d, q*) (*P, D, Q*) [*m*] model where *p* and *q* refer to the autoregressive and moving average models respectively, *d* refers to the degree of differencing, *P, D* and *Q* refer to the autoregressive, differencing and moving average terms of the seasonal component of the model and *m* refers to the length of seasonality (eg. 12 months in one year). The specification of the seasonal ARIMA (*p, d, q*) (*P, D, Q*) [*m*] process is presented in (1).

(1) $$\Phi(B^m)\,\phi(B)\,(1-B^m)^D(1-B)^d y_t = c + \Theta(B^m)\theta(B)\varepsilon_t$$

where $\Phi(z)$ and $\Theta(z)$ are polynomials of orders *P* and *Q* respectively (both contain no roots in the unit circle), $\phi(z)$ and $\theta(z)$ are polynomials of order *p* and *q* respectively (both have no roots for |z| <1), *c* is the drift term and if c ≠ 0, then it implies a polynomial of order *d* + *D* in (1). B refers to the backshift operator, ε_t denotes the white noise process and $y_t$refers to the time indexed variable of interest. The objective of the forecast package is to identify the appropriate *p, d, q, P, D* and *Q*. An overview of the steps followed (Hyndman and Khandakar 2008) to fit the seasonal ARIMA model is explained below:

1. The value of *D* is first chosen based on Canova-Hansen test. This test checks whether seasonal pattern changes significantly over time to warrant a seasonal unit root.
2. The value of *d* is chosen by using a successive KPSS (Kwiatkowski et al. 1992) unit root rests. The test is applied on seasonally differenced data if $D \neq 0$ and on original data if $D = 0$.
3. If $d + D < 2$, then the drift term *c* is included in the model.
4. A step-wise algorithm is then used to evaluate different models (for detailed steps of the algorithm refer Hyndman and Khandakar 2008, p.11).
5. The values of *p, q, P* and *Q* are chosen by minimizing the AIC (Akaike Information Criteria).

The forecast function specified in (1) was estimated for each of the 105 molecules using 48 months of sales volume data. Seasonal ARIMA models were successfully identified for all the 105 molecules using the steps specified above (details of all the models presented in Appendix A).

Stage 2: Predict Sales Using the Forecast Function

The models identified for the 105 molecules are then used to forecast sales from July 2013 to June 2014. We use the 'forecast' function part of the 'forecasts' package in R to estimate point forecasts and confidence intervals around the forecasts (at 80% and 95% level of significance). The confidence interval (upper and lower limits at 95% significance) is then used to compute the standard error of the point forecasts. All the monthly point forecasts for each of the 105 molecules were tested for statistical significance. We eliminated 7 molecules from further analysis as the point forecasts did not reach statistical significance ($p>.05$).[2] The results of the forecast stage are presented in Appendix A.

Stage 3: Cumulative Abnormal Change - Compare Actual and Predicted Sales

The forecasts of sales volume for the period July 2013 to June 2014 indicate the sales volume that would have been attained in the case of non-event (i.e., DPCO not being enacted). Hence the difference between the actual sales volume and the forecasted volume may be attributed to the event, DPCO 2013. We compute the difference for each of the 98 molecules for the 12 month period. The differences over the 12 month period is then added for each molecule to arrive at 'cumulative abnormal change' (CAC) for that molecule. This value denotes the impact of DPCO on that molecule's sales volume in the 1 year period.

The cumulative abnormal change for the 98 molecules is presented in Appendix A. The CAC values of 89 molecules are found to be statistically significant ($p < .0001$). Statistical significance was tested based on standard event study procedures (refer Brown and Warner 1985; Corrado and Zivney 1992). A positive value indicates an increase in the sales volume due to DPCO and

[2] A molecule was included for further analysis if and only if, all the 12 monthly point forecasts for that molecule were statistically significant ($p<.05$).

vice versa. For instance, the sales volume of *Acetazolamide* decreased by 33,653,525 units over the 12 month event window. The values range from -1,018,575,362 units for *Paracetamol* to 693,960,869 units for *Metformin*. Overall, the mean of the CACs is found to be -33,931,992 units, i.e., overall, there is an average decrease in the number of units sold that can be attributed to DPCO. A summary of the results is presented in Table 2.

Table 2: Results of event study: Effect of DPCO on sales volume of molecules

Overall statistics	
Mean CAC (Δ sales volume)[a]	-33,931,992
Median CAC	-3,936,971
Minimum CAC (*Paracetamol*)	-1,018,575,362
Maximum CAC (*Metformin*)	693,960,869
Molecules with increase in sales volume	
No. of Molecules	37
Mean Increase[b]	70,215,165
Molecules with decrease in sales volume	
No. of Molecules	52
Mean Decrease[c]	-108,036,700

- a,b,c: significant at p<.0001
- CAC: Cumulative abnormal change due to DPCO (over 12 months)

Factors Affecting Change in Sales Volume

While the event study results clearly suggest a negative effect of DPCO on social welfare (in terms of sales of essential medicines), the analysis does not shed light on the drivers for the observed results. We use the results of the event study (CACs) of 46 of the molecules (highlighted in Appendix A) and explain them using few market factors. These 46 molecules form about 90% of the total value of the 105 molecules (in terms of sales value as of June 2014). The CAC is converted into percentage change in sales volume (relative to total sales volume

recorded in the 12 month period). The percentage change in sales volume due to DPCO is then expressed as a function of:

i) absolute price point as per DPCO 2013

ii) price reduction faced by the market - weighted average price cut of top 5 brands per molecule with their market shares as weights,

iii) whether the molecule is prescribed for acute or chronic illnesses (dummy variable),

iv) percentage prescription from CP/GPs,

v) percentage sales from urban and semi-urban cities,

vi) a proxy for the overall detailing efforts for a molecule[3], and

vii) an interaction term between sales from urban and semi-urban cities, and detailing efforts.

Specifically, we estimate the coefficients of Equation (2).

(2) $$\%CAC_i = \beta_0 + \beta_1 Pri_i + \beta_2 PriRed_i + \beta_3 Acu_i + \beta_4 CPRx_i + \beta_5 T1T2_i + \beta_6 Det_i + \beta_7 (T1T2_i x Det_i)$$

where the subscript *i* refers to the molecule, *%CAC* refers to the percentage change in sales volume due to DPCO, *Pri* refers to the price of the molecule as per DPCO 2013, *PriRed* refers to the price reduction experienced by the market, *Acu* is the dummy variable indicating whether the

[3] To obtain a proxy for the detailing efforts, two industry experts were consulted. The industry experts ranked the top 5 brands of each molecule based on the estimated position (page number) in the detailing booklet carried by the firm's medical representatives (post DPCO 2013). For instance, if the medical representatives of a company carry a booklet in which brand x usually appears in the first 4 pages, then it is an indication that the firm gives high priority to that brand. Hence the detailing efforts for brand x is marked as high. Similarly, if the brand appears in the fifth to eighth pages of the detailing booklet, the detailing effort is marked as moderate and the rest are considered to have low detailing efforts. A detailing effort index was built by estimating weighted average of the scores (high, moderate or low efforts, with the brand's market share as weights) for the top 5 brands of each of the 48 molecules. The measure is an indication of the overall relative marketing effort for a molecule.

molecule *i* is prescribed for acute illnesses, *CPRx* refers to the percentage of prescriptions from CP/GPs, *T1T2* refers to the percentage of sales from urban (tier-1) and semi-urban (tier-2) cities, *Det* refers to the relative detailing efforts for the molecule post DPCO and *T1T2xDet* refers to the interaction between the last two terms.

We run a simple OLS (Ordinary Least Squares) regression followed by GLS (Generalized Least Squares) regression. The results of the analyses are presented in Table 3. Evidently, the results of OLS and GLS do not vary significantly. The coefficients of NLEM Price (absolute price as per regulation) and type of molecule (acute vs. chronic) are found to be marginally significant (p<.10). Further, the coefficients of tier1-2 sales percentage, detailing efforts and the interaction term are found to be significant (p<.05).

Table 3: Analysis of CACs

Explanatory Variable	Dependent Variable: % Change in Sales Volume (Predicted-Actual)/Actual % (12 months)	
	OLS	GLS
NLEM Price	.002*	.002*
Price Reduction	.051	.051
Acute? (Yes=1)	-.026*	-.026*
CP/GP Rx %	-.047	-.047
Tier1-2 Sales %	-.407**	-.407**
Detailing Efforts	-.388**	-.388**
Tier1-2 x Detailing	.609**	.609**
Intercept	.270**	.270**
Overall Model	F=2.422 (7, 38)	AIC=-155.50

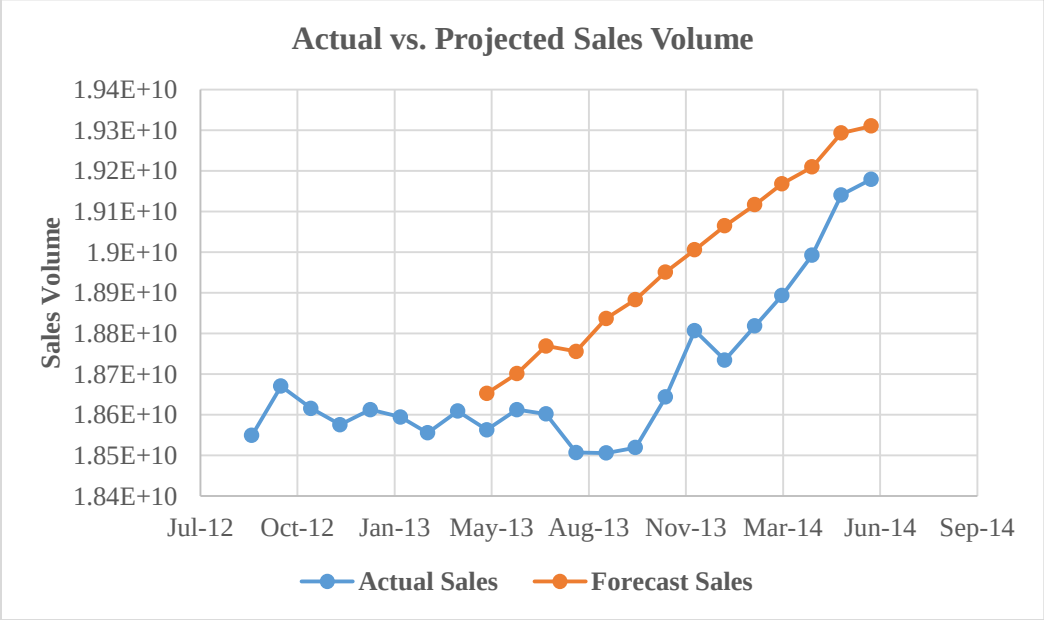
* p < .10, ** p < .05

Results and Discussion

The event study results indicate that, while few of the molecules analyzed (37) had an increase in sales volume attributable to DPCO, majority of the molecules (52) had a negative impact on their

sales volume due to DPCO. Overall, the DPCO may have had a negative impact in terms of sales volume of oral solid molecules, with the average change in sales volume to be -33,931,992 units ($p<.0001$). The total actual and projected sales post DPCO is represented graphically in Figure 1. As illustrated in the figure, the projected sales is consistently higher than the actual sales post DPCO, indicating that the decline may be attributed to the price regulation order. Evidently, the DPCO has not been completely effective in terms of increasing access and affordability of essential medicines.

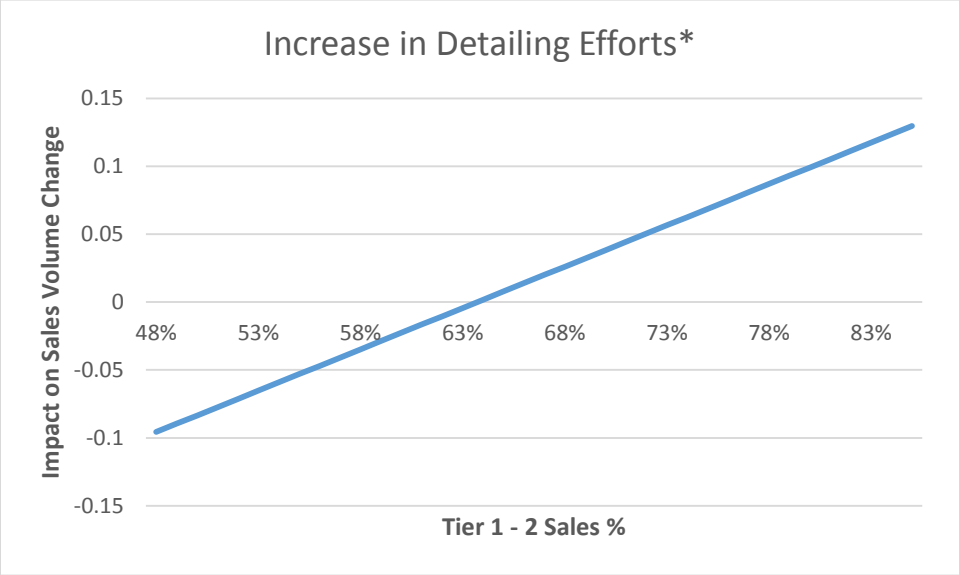
Figure 1: Actual Sales vs. Forecasts – 81 Molecules under DPCO



Further, we shortlisted 46 of the molecules and expressed the percentage change in sales volume induced by DPCO as a function of factors including the regulation price, extent of price reduction, type of molecule (acute vs chronic illnesses), percentage prescriptions from CP/GPs, percentage sales from tier-1 and tier-2 cities and detailing efforts for the molecule. We found the

impact of regulation price and type of molecule (acute vs. chronic) to be marginally significant. Evidently, more expensive the molecule, higher the increase in sales volume due to DPCO. Further, molecules prescribed for chronic illnesses seem to benefit from DPCO. The results suggest the post DPCO, patients under chronic care are likely to have made the switch to regulated molecules whereas doctors either continued to prescribe non-NLEM molecules for acute illnesses or switched to non-NLEM molecules post DPCO. Our results further shed light on focusing the detailing efforts to increase the sales volume post DPCO. Specifically, increasing detailing efforts for molecules with a higher presence in the tier 1 – 2 cities may result in a positive effect due to DPCO. Interaction term between town class sales and detailing is based on the assumption that detailing efforts are proportional to sales volume in cities. As the interaction term is significant, we present the impact of increasing the detailing efforts at different tier1-2 sales % levels in Figure 2 (minimum and maximum tier1-2 sales % chosen from the data). Evidently, in the case of molecules that are above the median level (62%) of percentage sales in tier 1-2 cities, increasing the detailing efforts in these cities for regulated molecules results in an increase in the cumulative abnormal change. However for molecules with a relatively higher presence in the tier 3-4 cities, it may be beneficial to increase the detailing efforts in these cities. In other words, detailing efforts should be increased in the cities in which the molecule already has a higher presence, in order to elicit a positive change in sales volume attributable to DPCO.

Figure 2: Effect of Increasing Detailing Efforts on Sales Volume Change due to DPCO



* - increasing detailing efforts from low to moderate / moderate to high

General Discussion

Our findings have the following policy implications. Since price control is actually decreasing access to the list of drugs that the government considers as essential, it may be time for the government to re-examine the design and operation of price control in India. The mechanism by which the policy appears to be failing is that price control leads to a decrease in the marketing effort by pharmaceutical firms, especially as a reaction to the decrease in the price and profitability of molecules; this would suggest that, assuming that price control is the way to increase access, that the price control mechanism being set up by the government needs to be tweaked. It is worthwhile to note here the drug prices in India are already amongst the lowest in the world and that profit margins for Indian pharmaceutical firms are much lower than that of big pharma firms of the west. Another implication is that GoI may want to consider whether there are other ways of increasing access to drugs for patients in India than through price control.

Indeed, whether there are some positive incentive mechanisms that can be developed to increase access.

Our research also has the following marketing implications. As expected different town classes react differently to price changes. As a corollary, therefore, it seems reasonable to state that sales in the Indian pharma market in urban areas appears to be significantly a function of the marketing effort and less a function of other variables and that the marketing effort elasticity of price is high. Indeed, some firms are known to have exited from some product categories after the price controls came into effect. .

The study has a few limitations. First, this study only examines the impact of DPCO on oral solids and does not consider injectables and oral solutions that are under price control. Second, the Department of Health introduced few minor changes (eg., new molecules being added to the list) during the event window (July 2013 to June 2014). These changes are not taken into account in the analysis. Third, our focus is on the short term (12 months) impact of DPCO. Further research may analyze the long term impact of DPCO and examine whether price regulation results in an increase in sales volume. Finally, we proxy marketing effort using the position of the molecule in the detailing booklet of the firm / division. Further research may assess the changes in marketing expenses for the molecules brought under price regulation. Future research may assess the impact of price regulation at the brand level. Brand level dynamics might be completely different and may provide richer insights for marketers. Further, the nature of the marketing action by the pharma firms and the doctor's perception of price changes of the medicines remains to be explored. Our study used a proxy for the marketing effort and did not take into account any changes in the doctor's perception that is changing the prescription behavior.

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Appendix A

No.	Molecule	Seasonal ARIMA Model	Cumulative Abnormal Change	% Change in Sales Volume[a]
1	Acetazolamide	ARIMA(2,1,0)(1,0,1)[12] with drift	-33,653,525	-6.65%
2	Acyclovir*	ARIMA(0,1,0) with drift	2,721,320	0.94%
3	Albendazole*	ARIMA(0,1,0) with drift	-20,336,470	-2.83%
4	Allopurinol*	ARIMA(0,2,1)(0,0,1)[12]	44,647,411	2.44%
5	Alprazolam*	ARIMA(1,2,0)	-86,227,030	-1.15%
6	Amiodarone*	ARIMA(0,1,0)(1,0,0)[12]	-10,191,456	-2.86%
7	Amitriptyline	ARIMA(0,2,1)	-29,431,468	-2.68%
8	Amlodipine*	ARIMA(2,0,0)(1,1,0)[12] with drift	-493,114,964	-3.28%
9	Amoxyclav*	ARIMA(1,1,0)(1,1,0)[12]	25,803,346	0.45%
10	Amoxycillin*	ARIMA(0,2,1)(0,0,1)[12]	287,557,364	6.18%
11	Ampicillin	ARIMA(0,2,1)(0,0,1)[12]	-519,077 [b]	-0.19%
12	Androgens Simicomb	ARIMA(0,2,2)	4,945,399	6.55%
13	Antifilarials	ARIMA(0,1,0)	-72,323,800	-21.08%
14	Antithyroid Preparations*	ARIMA(0,1,0)(0,0,1)[12] with drift	60,157,802	5.21%
15	Atenolol*	ARIMA(1,2,0)	-22,826,275	-0.39%
16	Atorvastatin*	ARIMA(1,1,2)	53,884,881	0.63%
17	Azathioprine*	ARIMA(0,1,0)(0,0,1)[12] with drift	-25,832,339	-6.90%
18	Azithromycin*	ARIMA(1,2,1)(0,0,1)[12]	-70,619,228	-3.52%
19	Bisacodyl*	ARIMA(1,2,1)(1,0,0)[12]	-54,375,682	-1.61%
20	Bromocriptine	ARIMA(1,2,0)	653,456	1.53%
21	Cardglycosides Plain*	ARIMA(1,0,0)(1,0,0)[12] with non-zero mean	129,714,785	5.81%

22	Cefixime*	ARIMA(0,1,0)(0,1,1)[12]	-670,752,010	-7.56%
23	Cephalexin*	ARIMA(1,0,0)(1,0,0)[12] with non-zero mean	-41,896,194	-5.11%
24	Cetirizine*	ARIMA(0,2,2)(0,0,1)[12]	-149,807,646	-1.31%
25	Ciclosporin	ARIMA(0,1,0)(0,0,1)[12] with drift	1,073,774	9.65%
26	Clindamycin*	ARIMA(3,1,0) with drift	16,973,120	6.96%
27	Clomifene Citrate	ARIMA(1,2,0)(1,0,0)[12]	-35,965,131	-11.55%
28	Clopidogrel*	ARIMA(1,2,1)	56,319,928	1.15%
29	Colchicine	ARIMA(0,1,0)(0,0,1)[12] with drift	-5,238,854	-2.65%
30	Cyclophosphamide	ARIMA(0,2,1)(0,0,1)[12]	Insignificant Forecasts (Jun '14): p>.05	
31	Danazol	ARIMA(0,1,0)(0,0,1)[12] with drift	-2,182,827	-2.93%
32	Diazepam	ARIMA(1,2,0)	-6,480,681	-0.76%
33	Diclofenac*	ARIMA(0,2,1)(1,0,0)[12]	-280,394,470	-7.56%
34	Diltiazem	ARIMA(1,2,1)	-4,672,520	-0.55%
35	Domperidone*	ARIMA(1,0,0) with non-zero mean	-137,119,019	-7.42%
36	Efavirenz	ARIMA(0,1,0)(1,0,0)[12]	-1,104,998	-43.98%
37	Enalapril*	ARIMA(1,2,1)	-65,108,322	-2.92%
38	Ethambutol Comb	ARIMA(0,2,1)(0,0,1)[12]	775,562 [b]	0.12%
39	Ethinylestradiol Levonor	ARIMA(0,1,0) with drift	-11,949,675	-0.48%
40	Fluconazole*	ARIMA(1,2,1)(0,0,1)[12]	63,750,220	5.78%
41	Fluoxetine	ARIMA(1,2,1)	28,408,078	3.21%
42	Glibenclamide*	ARIMA(0,1,0)(1,1,0)[12]	129,679,261	3.61%
43	Hydrochlorothiazide	ARIMA(0,2,1)(0,0,1)[12]	-8,284,856	-1.36%
44	Hydroxychloroquine*	ARIMA(1,0,0)(1,1,0)[12] with drift	-17,406,601	-1.16%
45	Hyoscine*	ARIMA(1,2,1)	-3,936,971	-0.36%

46	Imatinib	ARIMA(2,2,0)	169,806 [b]	0.62%
47	Imipramine	ARIMA(0,2,1)(0,1,1)[12]	27,965,940	5.39%
48	Indinavir	ARIMA(0,1,0)(0,0,1)[12] with drift	1,457,240	23.80%
49	INH	ARIMA(0,1,0)(0,0,1)[12] with drift	-30,023,848	-20.23%
50	Isosorbide Dinitrate	ARIMA(1,1,0)(1,1,0)[12]	Insignificant Forecasts (Jun '14): p>.05	
51	Isosorbide 5 Mononitrate*	ARIMA(0,2,2)	14,171,752	0.97%
52	Lamivud Stavud Nevirap	ARIMA(0,2,3)(0,0,1)[12]	128,702 [b]	0.22%
53	Lamivudine	ARIMA(0,2,2)	649,162	1.28%
54	Lamivudine Stavudine	ARIMA(0,1,0)(1,0,0)[12] with drift	-391,724	-3.65%
55	Leflunomide*	ARIMA(3,1,1)	10,731,137	6.68%
56	Levothyroxine*	ARIMA(1,1,0)(1,1,0)[12]	-566,948,678	-3.27%
57	Lithium Carbonate	ARIMA(0,1,0)(0,0,1)[12] with drift	-12,709,598	-4.41%
58	Losartan*	ARIMA(2,2,0)	69,114,129	1.41%
59	Medroxyprogesterone*	ARIMA(0,1,1) with drift	-36,715,526	-4.84%
60	Mefloquine	ARIMA(0,1,0) with drift	-1,495,840	-7.77%
61	Metformin*	ARIMA(2,0,0)(0,1,0)[12] with drift	693,960,869	4.06%
62	Methotrexate	ARIMA(1,1,0)(1,0,0)[12] with drift	-24,445,807	-10.21%
63	Methylergometrine*	ARIMA(1,2,1)(0,0,1)[12]	12,131,160	2.00%
64	Metoprolol*	ARIMA(1,0,0)(0,1,0)[12] with drift	-80,657,412	-1.46%
65	Mifepriston	ARIMA(0,2,1)	Insignificant Forecasts (Apr '14 - Jun '14): p>.05	
66	Nifedipine	ARIMA(1,2,1)	-1,641,889 [b]	-0.07%
67	Nitrofurantoin*	ARIMA(1,1,0) with drift	-26,240,023	-3.25%
68	Norethisterone*	ARIMA(1,2,1)(0,0,1)[12]	-168,717,864	-5.20%

69	Oestro Progestogen Comb	ARIMA(0,1,0)	226,026 [b]	0.37%
70	Oestrogens Simi Comb	ARIMA(0,1,0)(0,0,1)[12]	-9,121,944	-17.42%
71	Ofloxacin*	ARIMA(1,1,0)(1,1,0)[12]	-349,611,119	-6.29%
72	Olanzepine*	ARIMA(0,2,2)	24,978,690	2.57%
73	Omeprazole*	ARIMA(2,2,0)(1,0,0)[12]	620,528,365	7.27%
74	Ondansetron	ARIMA(1,2,0)(1,1,0)[12]	-13,107,962 [b]	-0.47%
75	Oth Anti Hiv Prep	ARIMA(0,1,0)(1,0,0)[12]	-1,500,129	-10.57%
76	Oth Cns Drugs	ARIMA(0,2,1)	1,604,200	7.12%
77	Oth Gonadotrophins	ARIMA(0,1,0)(0,0,1)[12] with drift	-733,374	-6.24%
78	Oth Alkylating Agents	ARIMA(2,0,0)(1,0,0)[12] with non-zero mean	51,665	3.90%
79	Oth Antimetabolites	ARIMA(1,0,0)(1,0,0)[12] with non-zero mean	607,898	4.17%
80	Oth Antineoplastics	ARIMA(1,0,0) with non-zero mean	292,297	38.30%
81	Oth Hormo Contracep Nonto	ARIMA(1,2,1)(0,0,1)[12]	-1,380,657	-6.10%
82	Other Anti Hist Plsol	ARIMA(0,1,0)(0,0,1)[12] with drift	-350,039,595	-31.35%
83	Other Antiinf Leprost	ARIMA(0,1,0)(1,0,0)[12] with drift	-153,362,066	-14.77%
84	Other Penicillines Orals	ARIMA(1,1,0)	921,527	3.38%
85	Others, Plain Folic Acid*	ARIMA(1,2,0)	-204,122,225	-2.75%
86	Paracetamol*	ARIMA(1,1,0)(1,1,0)[12]	-1018,575,362	-5.91%
87	Pheniramine	ARIMA(0,1,0)(0,0,1)[12] with drift	8,677,715	4.08%
88	Phenobarbitone	ARIMA(0,1,0)(0,0,1)[12] with drift	-20,642,149	-1.34%
89	Phenytoin*	ARIMA(0,1,0)(1,1,0)[12]	-99,058,688	-0.91%
90	Primaquine	ARIMA(0,2,0)(0,0,1)[12]	Insignificant Forecasts (Dec '13 - Jun '14): p>.05	
91	Promethazine	ARIMA(0,1,0) with drift	-38,253,238	-3.53%

92	Propranolol	ARIMA(0,1,0) with drift	2,021,541 [b]	0.09%
93	Psychostim Neurotonics	ARIMA(1,2,1)(0,0,1)[12]	Insignificant Forecasts (Dec '13 - Jun '14): p>.05	
94	Pyrazinamide Plain*	ARIMA(0,1,0)(0,0,1)[12] with drift	-45,275,716	-10.40%
95	Pyridostigmine	ARIMA(0,1,0)(1,0,0)[12] with drift	-6,896,149	-5.75%
96	Quinine	ARIMA(0,1,0) with drift	-4,422,654 [b]	-1.73%
97	Raloxifene Comb	ARIMA(0,1,0)(1,0,0)[12] with drift	-9,756,663	-33.53%
98	Sodium Valproate*	ARIMA(1,2,0)(1,0,0)[12]	15,912,413	0.64%
99	Tamoxifen	ARIMA(0,2,1)(0,0,1)[12]	Insignificant Forecasts (Jun '14): p>.05	
100	Terbutaline	ARIMA(1,2,0)(1,0,0)[12]	Insignificant Forecasts (Oct '13 - Jun '14): p>.05	
101	Tramadol	ARIMA(0,2,1)(0,0,1)[12]	20,297,287	5.41%
102	Trihexyphenidyl*	ARIMA(1,2,1)(0,0,1)[12]	143,965,007	4.61%
103	Warfarin	ARIMA(0,1,0)(1,0,0)[12] with drift	18,294,141	3.88%
104	Zidovudine	ARIMA(1,0,0)(1,0,0)[12] with non-zero mean	4,629,707	41.10%
105	Zidovudine Lamivudine	ARIMA(0,2,1)	728,668	1.94%

- a: CAC / Actual Sales (during event window)
- b: CAC is insignificant (p>.05)
- *: Shortlisted molecules for further analysis