Impact of price and trade margin regulation on cancer medicine in India? An interrupted time series analysis

Health Technology Assessment in India
Public Health Foundation of India

Policy Brief

Executive Summary:

In 2016, cancers accounted for 5% of the total Disability Adjusted Life Years (DALYs) and over 8% of total deaths in India. Besides the humongous disease burden, cancer also places significant socio-economic burden on patients and their families. The National Pharmaceutical Pricing Policy, 2012 was notified in order to control prices of medicines including cancer medicines listed on the National List of Essential Medicines using a market based formula. National. In addition, in February, 2019, 42 anti-cancer drugs were brought under 30% trade margin cap.

The objective of the present study was to ascertain the impact of price and trade margin regulation on the sales of anti-cancer medicines in the private retail market in India with the help of Interrupted time series analysis, a quasi-experimental research design. A reference market outside regulation was used as control group to further strengthen our research design.

Our analysis suggests that post intervention (notification of ceiling prices), of total 17 cancer medicines under study, 7 medicines witnessed both an immediate and sustained increase in sales in the post-intervention period, 3 medicines witnessed an immediate increase in sales followed by a sustained decline, 6 medicines witnessed an immediate and sustained decline in sales and 1 medicine witnessed an immediate decline followed by a sustained increase in sales. Our analysis also suggests that post intervention (notification on trade margin cap), of total 26 cancer medicines 2 medicines witnessed both an immediate and sustained increase in sales in the post intervention period, 10 medicines witnessed an immediate increase in sales followed by sustained decline, 5 medicines witnessed an immediate and sustained decline in sales and 9 medicine witnessed an immediate decline followed by a sustained increase in the sales.

Policy Recommendations:

The coverage of price regulation policy must be expanded to include all strengths and dosage forms of medicines under the NLEM including therapeutically equivalent drugs so as to avoid the switch from price regulated to unregulated medicines. Similarly, trade margin regulation should be expanded to other cancer drugs and also therapeutic areas leaving out over the counter drugs.

A system of effective monitoring of availability and sales of regulated medicines must be implemented to ensure that regulated medicines are not gradually phased out of the market.

Background and Literature:

The average out of pocket expenditure for cancer patients is in fact 2.5 times that for other diseases. Borrowings, sales of existing assets and contributions from friends and relatives have been found to be sources of financing cancer treatment of some 40% of hospitalised cases. Impoverishment of households as a result of out of pocket expenditure on medicines in India has been reported in previous studies. Medicine price regulation is therefore imperative.

Literature suggests that while policies involving direct price control are effective in reducing prices and controlling expenditures, they may not lead to a reduction in medicine expenditures in the long run since manufacturers find ways to increase sales of formulations outside regulation. A recent study found that despite the attempts to regulate prices as well as trade margins of some anti-cancer medicines in India, their prices have remained high and that there is considerable variation in the prices of the same medicines marketed by different manufacturers. The studyalso observed that anti-cancer medicines priced lower are not necessarily purchased more. Some pharmaceutical companies are known to have left certain product categories after the implementation of price regulation.

These observations raise questions on the effectiveness of policies aimed at reducing medicines prices and expenditure in increasing consumption as was reported in previous studies

Aims and Objective

This policy brief addresses the policy question of the impact of policies of price and trade margin regulation of select cancer medicines the sales of anti-cancer medicines in the private retail market in India. It summarizes the results of a the impact evaluation study, carried out by the Public Health Foundation of India.

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Methods and Approach

Interrupted time series, a quasi-experimental research design was used to capture the impact of price and trade margin regulation on anti-cancer drug sales in India. A reference market outside regulation was used as control group to further strengthen our research design.

Equation:

$$Y_t = \alpha + \beta 1 \text{ time t} + \beta 2 \text{ intervention t} + \beta 3 \text{ time after intervention t} + \epsilon_t$$

- The dependent variable (Y_t) appeared as 'logarithm of sales volume' of anti-cancer medicines.
- 'Time' appeared as an independent variable.
- Two binary variables were introduced to estimate the immediate level change (variable name: intervention) as well as trend change (variable name: time after intervention) after the intervention in the outcome variable (see equation 1 below).
- The variable 'intervention' was assigned as a binary variable taking the value '0' for the pre-intervention period and the value '1' for the post-intervention period, whereas time after intervention was a continuous variable for the post-intervention period.

Interventions under study:

1. The most recent policy in the country, the National Pharmaceutical Pricing Policy (NPPP), 2012 was notified by the National Pharmaceutical Pricing Authority (NPPA) in order to control prices of 'essential medicines' defined as medicines listed on the National List of Essential Medicines (NLEM) using a market based formula. The market based formula, uses a simple average of prices to retailers (PTR) of brands of a formulation with market share greater than or equal to 1% and allowing 16% retail margin. The Drug Price Control Order (DPCO), 2013 was subsequently notified to implement the provisions of NPPP, 2012 for drugs including those used for cancer treatment on the NLEM, 2011. The NLEM is a dynamic list and was revised in 2015.
2. In February, 2019, the NPPA invoked para 19 of DPCO, 2013 and notified another 42 anti-cancer drugs for 30% trade margin cap through a 'Trade Margin Rationalization Approach'

Results

Impact	Impact of Price Regulation on sales of anti-cancer medicines		Impact of Trade Margin Regulation on sales of anti-cancer medicines	
	Number of medicines	Medicine names	Number of medicines	Medicine names
Immediate increase followed by a sustained decline	3	Bicalutamide, Dacarbazine, Etoposide	10	Bevacizumab, Crizotinib, Sunitinib, Pomalidomide, Azacitidine, Decitabine, Epirubicin, Mitomycin, Exemestane, Cabazitaxel
Immediate increase followed by a sustained increase	7	Capecitabine, Asparaginase, Gefitinib, Mycophenoate Mofetil, Tacrolimus, Trustuzumab, Temozolamide	2	Erlotinib, Pegfilgrastim
Immediate decline followed by a sustained decline	6	Arsenic Trioxide, Chlorambucil, Docetaxel, Letrozol, Methotrexate, Cyclosporin	5	Osimertinib, Carfilzomib, Everolimus, Enzalutamide, Triptorelin
Immediate decline followed by a sustained increase	1	Pegylated Interferon Alpha 2b	9	Irnotecan, Lenolidomide, Regorafenib, Lapatinib, Pemetrexed, Bendamustine, Fulvestrant, Estramustine, Nilotinib
Total medicines under study	17		26	

The preferences of prescribers could have either shifted in the interest of the patient as they would have chosen to prescribe the drugs under regulation instead of equally effective alternatives as they were made available at lower prices leading to an increase in sales- both immediate and sustained or in the interest of pharmaceutical (substitution effect). In order to generate higher revenues for pharmaceutical companies as well as hospitals, higher priced drugs outside regulation may be pushed leading to an immediate as well as sustained decline in sales regulated drugs. Only the dose forms and strengths of molecules identified in the NLEM are price-controlled allowing companies to promote various dosage forms, strengths, and competing molecules, restricting the supply of price-controlled drugs. Some drugs are indispensable for treatment of particular cancers and any price reduction for these drugs led to an immediate and sustained increase in sales (e.g. trastuzumab). Standards of care are routinely updated as a result of drugs with improved effectiveness being made available in the market and may have led to prescription of drugs outside regulation which may have led to an immediate increase followed by a sustained decline in sales of certain drugs. Differences in the effects of the policies may be explained in terms of the type of use for individual drugs i.e. whether a drug is used for curative or palliative care use.