Counterintuitive Effects of Drug Price Regulation: A Systems Thinking Approach

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Drug price regulation is a subject of intense debate. While prices of drugs are regulated to ensure affordability of essential medicines, opponents of price regulation claim that it reduces a firm's ability to invest in R&D. However, there are more fundamental, counterintuitive effects of price regulation: forced price reduction drives out manufacturers, causing drug scarcity and increased prices; reduction in quality; and evasive measures like change in composition. Using systems thinking approach, and cases from the Indian pharmaceutical industry, we demonstrate the effect of price regulation on firm decision making, and consequently, availability of the drug in the market.

Key words: Drug (Pricing Control) Order (DPCO), pharmaceutical industry, systems thinking

1. Introduction

Economic regulation refers to taxes and subsidies of all sorts as well as to explicit legislative and administrative controls over rates, entry, and other facets of economic activity (Posner 1974). Price regulation is one form of economic regulation. It refers to the policy of setting prices by a government agency, legal statute or regulatory authority (Khemani and Shapiro 1993). It includes setting minimum and/or maximum prices. The debate on the pros and cons of price regulation has long been an active area of research. (Joskow 1974) identifies four main 'academic problem areas' that have received attention. These include understanding why there is government regulation in a particular market, the choice of regulatory instruments, the effects of these regulatory instruments, and the regulatory processes themselves. We situate our paper in the domain of the third question, namely the effects of price regulation. To understand the change in dynamics brought about by the introduction of price regulation, we use the specific setting of the Indian pharmaceutical industry.

1.1 Price Regulation in the Indian Pharmaceutical Industry

Globally, the Indian pharmaceutical industry is the 3rd largest producer of medicines by volume yet 14th in terms of value (Department of Pharmaceuticals 2014). The lower value is due to the fact that Indian medicines are amongst the lowest priced in the world. Despite this, a large part of the population is unable to meet most of its medical needs. Prices are especially important in the Indian context because of the absence of a national medical insurance coverage, or a tax financed scheme. According to a WHO report, for India, the private expenditure on health hovers around 70% of total expenditure on health. Approximately 90% of this is out of pocket expenditure (World Health Organization 2013).

Hence, it becomes imperative that measures are taken to make medicines more affordable to the general population, while at the same time balancing the interests of the industry. It is well known that the variation between the price of the most expensive brand and the cheapest brand of the same drug can be up to 1000% (Srinivasan 1999; Sengupta et al. 2006). Huge inter-brand price differences in branded generics, caused by prescription driven sales (Sen 2005) are perceived to be indicative of market failure. Such market failure, combined with the essentiality of drugs, motivates the government to intervene by regulating prices.

India introduced price regulation after the India-China war of 1962 led to soaring prices. The Drugs (Prices Control) Order of India was first implemented in 1970, and later revised in 1979, 1987 and 1995. The latest version of the Drugs (Prices Control) Order of India into effect in May 2013 (referred to as DPCO 2013). The WHO maintains a model list of essential medicines, which serves as a guideline for each country for compiling its own list of essential medicines. In India, the drugs whose price is to be regulated are included in the National List of Essential Medicines (NLEM). This list is revised periodically, by a committee of experts set up for the same. The latest version of this list, called NLEM 2011, also considered inputs from Indian Pharmacopeia 2010 and the National Formulary of India, 4th edition, 2010 (Bansal and Purohit 2013). NLEM 2011 has 348 medicines and 653 formulations and dosage forms, all regulated under DPCO 2013.

Despite this methodical approach to price regulation, there seem to some unintended consequences. In the past, price regulation has led to unavailability and shortage of the regulated drugs, as the firms stop the production of those drugs as they are no longer profitable. A recent instance of this phenomenon was with regard to human serum albumin, an essential drug brought under price control (DPCO 2013). The price of 100 ml albumin vial was reduced from INR 4000 to INR 1,650 (Nautiyal 2014), resulting in acute nation-wide shortages.

Another course of action for pharmaceutical firms is exploiting the loopholes in DPCO 2013 to escape regulation. For example, chemical analogues of drugs under DPCO 2013 are not subjected to price regulation. This provides the pharmaceutical companies with an escape route, as to they simply stop production of the DPCO drugs, and instead migrate to

other medicines of the same chemical class, or non-standard strengths (Srinivasan, Srikrishna, and Phadke 2013; Srinivasan, Srikrishna, and Aisola 2014). Change in composition is another tactic employed by firms. A recent example is the addition of lactobacillus to norfloxacin to evade price regulation. In the case of Merck's Evion, and Ranbaxy's Revital, changed composition drugs were reclassified as dietary supplements, or over-the-counter drugs (Dey 2009). These consequences defy the basic motive of price regulation, defeating its very purpose.

Although there have been studies that compare allocative efficiencies of various kinds of regulation (price, quantity, and hybrid regulatory instruments (Hepburn 2006)), a detailed understanding of how the structure of the system as a whole determines the outcomes is yet to be obtained. In this paper, we attempt to understand how price regulation can lead to the various situations discussed above. The paper is organized as follows. In the next section, we discuss the modelling approach used in the paper, and why it is the appropriate methodology for our endeavour. This is followed by the actual causal model itself, along with a discussion on the interplay between the various factors. We conclude by discussing the implications of our model, and scope for future work.

2. The Modelling Approach

The dynamics of pharmaceutical price regulation arise out of a complex interaction between different factors, interesting feedback effects and significant delays. A systems thinking approach (Senge 1995; Sterman 2000) can be adopted to delve deep into the underlying mechanisms and understand the dynamics. It implies a philosophy of understanding system behaviour by examining it holistically, rather than by analysing the parts. This stems from the belief that the behaviour of a system is a result of the behaviour of the constituent parts, as well as their interactions. It involves the development of a causal loop structure based on an extensive literature survey and expert opinions. It is a method that enhances causal thinking, and enables us to identify the various sub-systems having circular causality. This helps us in deciphering the exact dynamics at play and allows us to take cognizance of the effects of feedbacks and delays inherent in the structure of the system.

Delays are a complex part of the system, as the longer the delay between cause and effect, the more likely it is that a decision maker will not perceive a connection between the two. System dynamics distinguishes between two main types of loops, the balancing loop (denoted by B), and a reinforcing loop (denoted by R). A reinforcing loop is a positive loop where a given change activates a set of changes that cascade through other factors so as to amplify the original change, whereas a balancing loop is a negative loop where dampening occurs. A system may consist of any number of these loops, and the final state of the system can be determined by analysing the various loop dominances (Sterman 2000).

A detailed understanding of the various mechanisms, not only allows us to ascertain the unintended consequences of certain actions but also how they are manifested. Correctional measures can then be devised for the same. In the subsequent sections, we attempt to use a soft systems modelling approach to understand how price regulation gives rise to intended and unintended consequences.

3. A Causal Model of Pharma Price Regulation

We propose the causal model in Figure 1 to explain the dynamics of price regulation of a single drug. The same dynamics are assumed to occur for all other drugs under price regulation.

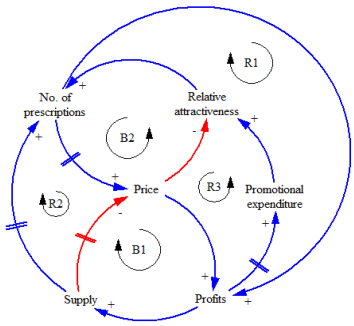

Figure 1 *The Causal Model Pharma Price Regulation*

In several paragraphs below we present the various mechanisms that contribute to this dynamics.

In the pharmaceutical industry, the doctor, and not the end consumer decides the product to be consumed. Hence, the *Relative Attractiveness* of a drug should be viewed through the eyes of prescribing doctors (Paich and Valant 2011). *Relative Attractiveness* itself can be seen as a function of price and clinical attributes of the drug, and the promotional expenditure of the firm (Paich and Valant 2011; Sen 2005). The World Health Organisation defines drug promotion as 'all informational and persuasive activities by manufacturers and distributors, the effect of which is to influence the prescription, supply, purchase or use of medicinal drugs'. Hence, high *Promotional Expenditure* makes a drug relatively more attractive to the prescribing doctors and leads to an increase in the number of prescriptions of that drug, translating into increased sales and therefore higher profits for the firm. This motivates the firm to spend more on promotion, hence forming a reinforcing loop, R1 (Sen 2005). Moreover, a basic microeconomic view of the system would imply that as the firm sees increasing profits from a drug,

it will produce more of it. Assuming that there is enough demand, this translates into greater sales, and hence higher profits, giving rise to another reinforcing loop, R2. This initial causal loop structure is depicted in Figure 2.

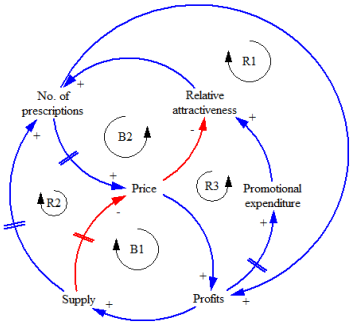

Figure 2 *Drug Adoption Loop*

Microeconomic theory also stipulates that an increase in demand prompts an increase in the *Price* of the drug; generating higher profits which are then used for further promotion. This in turn would make a drug relatively more attractive to the prescribing doctors, forming a reinforcing loop, R3 (Figure 3).

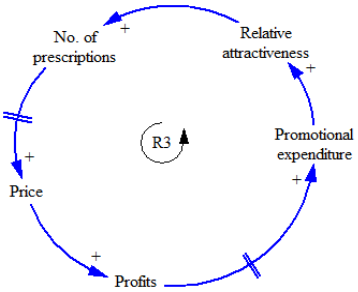

Figure 3 *The Price Increase Loop*

Such a cycle of continually increasing *Price* is of grave concern for the end consumers, especially in the pharmaceutical industry. As discussed above, the government intervenes by regulating *Price* to make the drugs more affordable. In India, this is done by announcing ceiling prices of the essential drugs based on inter-brand price variation and essentiality of the drug. One of the causes behind high inter-brand variation is varying amounts of *Promotional Expenditure* (Sen 2005). The government expects this reduction to translate to a reduction in the *Promotional Expenditure*, thereby re-establishing similar profit margins as before. The effect on *Relative Attractiveness* by reduction in promotional expenditure is expected to be offset by reduction in *Price* (R3). The increase in *Relative Attractiveness* cause by the price reduction would also activate R2, leading to volume based *Profits* for the pharmaceutical companies (Figure 4).

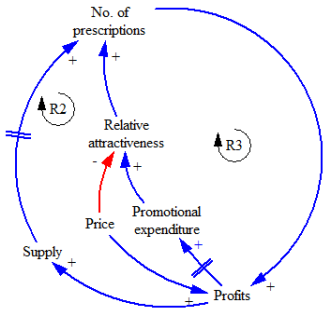

Figure 4 *Regulator's Mental Model behind Price Regulation*

Pharmaceutical companies, perceive *Promotional Expenditure* not as extraneous to the cost of the drug, but an integral part, are unable to reduce it beyond a certain extent. Expecting low (or no) profits, they reduce supply of the drug to the market (Figure 5), as discussed above.

To arrive at the outcome of the effect of price regulation, it is essential to understand the influences of each loop and identify the dominant one(s). For example, one interesting implication is the effect of R2 on the behaviour of the system. The response of R2 to price change depends on two parameters, namely *Relative Attractiveness* and *Profits*. Taking these two

effects together, the net change in the *Number of Prescriptions* caused by price reduction could be either negative or positive. This can be explained as follows. In a price sensitive market, *Price* reduction increases *Relative Attractiveness*, thereby setting in motion the positive amplification of profits, if the supply is not decreased. In an alternate scenario where the dominant effect of *Price* reduction is a decrease *Profits*, the firm decides to reduce/ stop production and the supply decreases, setting in motion a vicious cycle. As has been already discussed, due to the rigidity in *Promotional Expenditure*, the firms resort to stopping the production of the drug.

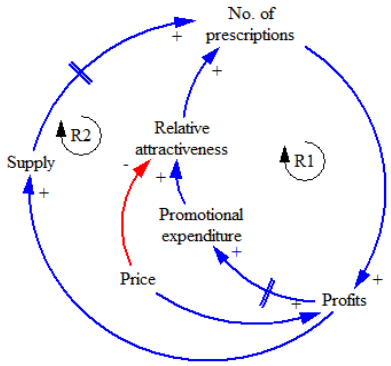

Figure 5 *Response by Pharmaceutical Companies*

4. Conclusions and Future Work

In countries like India, where a majority of expenditure on health is out of pocket expenditure, it is imperative for the government to make medicines affordable to all. Price regulation has been the historically favourite means to that end. However, we have demonstrated that this can indeed have counterintuitive consequences, which can be understood by deciphering the underlying structure and dynamics of the system. The systems thinking approach helps up to delineate ways in which these counterintuitive effects can be identified, and curbed or better still, avoided.

Our model also extends the body of literature on price regulation and opens up new areas of research. Rigidity of promotional expenditure and the effect of change in price on relative attractiveness of the drug need to be explored further. The evasive measures, some of which were discussed above, and their effect on availability and affordability of the drug, need to be incorporated into the model. (Sen 2005) suggests that to ensure that medicines are affordable to the entire population, price regulation is only a part of the strategy. The report recommends several other policy changes in tandem with price regulation, which include higher involvement of Public Sector Undertakings (PSUs), and assistance to small scale pharmaceutical manufacturers. The effect of these measures on the availability and affordability of drugs can be analysed using systems thinking approach, before being implemented.

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