



Pricing Regulation of Prescription Drug and Its Analysis across Regulated and Less Regulated Markets

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ABSTRACT

Introduction: Prescription drugs have been an issue that various organizations tried to examine for the years. A few endeavors have been made toward facilitating the burden of drug costs for the nationals. While a great part of the exchange has concentrated on the effect on Medicare and Medicaid, the scan for the wellspring of high physician recommended medicates costs has conceivable advantages for all patients. Present work was done with an intention to investigate the relationship between high cost of prescription drugs and its regulations across regulated and less regulated markets and to discover new modules to lowered down the costs so that the policy makers intends to think for a change. **Methodology:** Anti-diabetic and anti-hypertensive drugs for cost analysis based on pricing regulations in India and USA are selected. The cost analysis of drugs are based on the queering out various data bases of both pharmaceutical market i.e. India and USA along with number of manufacturers, dose of drug, patented drugs, their generic alternates, dose combinations price variation within country between different manufacturers and other factors etc. **Result:** The results of the study reveal the need of extensive research. In addition, the normal cost obviously isn't an exact reason for examination. The drug manufacturers in markets like USA should not be provided monopoly rights for a longer period and the efforts should be made towards easing the process of generic drug approval for its availability in the market for lower down the price of the medicine (drug). **Conclusion:** The study makes the prescriber and people aware about various types of anti-diabetics and anti-hypertensive drugs available throughout the world with their difference in prices in regulated and less regulated markets. This variation in the prices can be reduced by regulating the areas and pharmaceutical companies who actually don't follow it.

Key words: Anti-hypertensive; Anti-diabetic pricing regulation; Prescription drugs

INTRODUCTION

"A prescription drug can be considered as a drug (pharmaceutical) that can be distributed only with a medical prescription. In distinction, 'over-the-counter' drugs are often bought devoid of a prescription by a registered practitioner. Explanation behind this distinction in control of use of substance is the potential extent of misuse, from 'drug-abuse' to practicing medicine with no

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Receiving Date: October 11, 2019

Acceptance Date: November 30, 2019

Publication Date: December 5, 2019

authorization and while not spare education" [1] Drug regulation can be considered as control over use of drugs, by global deal and/or by authoritarian bodies for instance USA "FDA" (Food and Drug Administration), the Japanese "PMDA" (Pharmaceutical and Medical Devices Agency) and the "EMA" (European Medicines Agency).

Important functions of authorities indulged in “Drug regulations” (Drug Regulatory Authorities) are as following:

(i) Pharmacovigilance (ii) Regulation of medical trials (iii) Regulation of homeopathic and herbal drugs (iv) Inspection and maintenance of standard of drug development and production.

Variability of Cost of Prescription Drugs: Different people pay terribly varying expenses for exactly the same "prescribed medication." These differentials in expenses persist across nations and across customer classifications within particular nations at distinct rates. Rule builder contend that “drug prices” should differ more through all nations by reducing expenses in nations with very low salaries to generate greater monetary way in to life-sustaining medicine [2]. Many countries with Low-income require additional “discrimination in price”& significantly reduced rates [2]. In countries like India the pharmaceutical market is well regulated, hence the price of drugs here in India has significant difference from that of USA.

Deciding Cost of a Medicine: The “Committee of Drug and Therapeutics” is accountable and intended for watch full assessment of latest drugs even before it is concluded to the formulas. The mentioned evaluation ought to involve safety, efficacy, standard, and price. This topic discuss about the how the evaluation of cost of a medicine is done, and also the impact of cost on the whole health care system together with the patient. A pharmaceutical's most fundamental cost is reflected in a provider's procurement expenses. Acquisition valuation is one of the most important elements of the cost of shrewd a medicine, but it only starts in the complete assessment. It becomes appropriate to appear the procurement price of a drug on the far side and to procure all rates linked to the use of the drug. There are 3 kinds of prices coupled with drugs in a Medicare system: “direct, indirect, and intangible”. The mentioned 3 forms of overheads, once in use put together, can provide the foremost comprehensive evaluation of actual drugs rate.

Direct prices: Such prices which are straightly linked to supply utilize allied along with a “facility in trading with a medical institution” involvement and it also consist of Lab services, supplies and tools to control medicine, transportation, acquisition price of drug etc.

Indirect prices: is the price connected to “missing capacity of production” and comprises of- lost time from work for the caregiver and patient.

Intangible prices: such prices that are linked with suffering and pain.

CEA- Cost Effective Analysis is a type of trade and industry assessment that compare the cost and outcome of health treatments or programs when involvement contains an ordinary “health outcome” that vary in efficacy. Wellbeing results are evaluated in natural units (e.g., life saved, years gained, instances of disease prevented) or shifts in functional status (e.g., blood pressure “units in hypertension”, hypercholesterolemia cholesterol). Outcomes of a cost effective analysis (CEA) are usually shown as price per unit of impact. This sort of assessment is hard and is also carried out at domestic level alone. It requires cost assessment by specified (impact) assessable medical outcome for each and every drug.

International differences in Prices of Prescription Drugs

According to a research conducted by the Australian Commission on Productivity (Production Commission, 2001)the National Drug Cost Regulation System is a closely executed assessment. Australia subsidizes the acquisitions of prescription drugs by all citizens and continuously

regulates and guides the cost it receives for drugs from a solitary resource. The Australian "PBS" (Pharmaceutical Benefits Scheme) focuses at thorough assessment of the medical efficacy and price of new drugs compared to products previously on the marketplace in order to set a price to subsidize consumer purchases. It also checks commonly with nearby therapeutic competitors the prices of present drugs. A chain of studies in the beginning of 1990s by the "U.S.A. General Accounting Office" (GAO) (Officer, US General Account, 1992) centered on distinctions in factory prices between the Canada and U.S. also the prices between the UK and US for samples of often dispensed branded medicines. The technique underlying these (pair-wise) price comparisons differed in significant ways in the U.S. with other developed nations, but prices in the U.S.A. were much greater than in other developed nations for a full set of branded drugs tested in all studies. The un-weighted average cost of a market bucket composed of 121 often prescribed branded drugs marketed in both countries in Canada (as illustrated by the Province of Ontario) was 32 % smaller than in the U.S. The U.S. and GAO comparison shows that the 1993 factory price of a market bowl of 77 top brand-name drugs, weighed (weighted) by a greater amount of use in the U.S. than in the United Kingdom (US Gen. Account Officer, 1994). The study of the United Kingdom is intended; it is therefore restricted to a comparatively small and biased sample of 77 top branded drugs. The "GAO" evidence for such drugs is strong enough that the manufacturers' transaction prices in the U.S.A were higher than in the United Kingdom. [3] He proposed a accurate sample of studies on whether clients in one nation could acquire a distinct market bucket of drugs at a reduced or enhanced price than they could if they were capable to acquire drugs at the expense of other nations [4] The research represents the outcomes that U.S. weights usually led in a greater price ratio for each nation than comparison nation weights and rates were usually greater in comparison nations than U.S. drug expenses in two instances, Canada and Germany. Overall, differences in worldwide price literature indicate price discrimination occurs at the producer level. Some nations seem to have greater costs than of others for distinctive types of medicines. However, as mentioned earlier, the actual distinctions are expected to be lower than those created in this study due to differences in the list prices used, especially in crowded therapy categories for older multi-source drugs and drugs. Furthermore, producers' expenses are mainly inaccurate as a reason for contrasting the generally available drugs, mainly at the time when USA is one of the comparators. In that event of new pioneering medicines, where manufacturers' costs are probable to be fewer prone to large concession and reductions, rates in the U.S. are higher than in other nations, confirming discrimination in expenditures. As an example of a nation governing solely the entry prices of new drugs, Australia act to be capable to make important reductions in the "US" to the prices of these drugs relative to customers [2]. Prescription drug prices vary across different countries because Vendor has domination (monopoly), diverse consumers are ready to forfeit diff range of costs for the product and consumers cannot deal bought before products among themselves [5].

Regulated Market: A regulated market is a case of the prescription and over-the-counter drug market. Regulated markets provide buyers with clear security. In any case, some argue that there is no point in formal control of business sectors and forces inefficiencies and superfluous spending on business sectors and citizens. These people argue that there are a lot of self-management lessons for company industries [6].

The research promotes the reality that through two channels price regulation can impact cost and performance. It can indirectly influence prices and performance by changing incentives for pharmaceutical companies to participate in fresh drug R & D. It can also immediately impact prices and performance by influencing current drug rates and use. This empirical research discovered adverse effect of price controlling on well-being costs & standard.

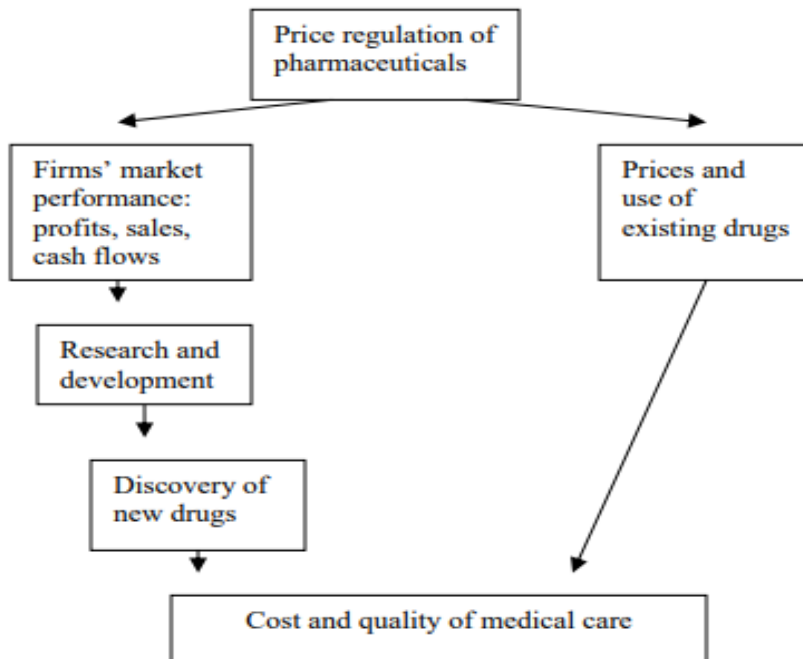


Figure 1: Effects of regulation of price by government on cost and standard of drugs.

Because of the particular authoritative structures, the pharmaceutical business elements differ in India and the U.S. Exact confirmation demonstrates that very controlled low-value markets will in general have less brand and conventional discharges than unregulated markets and longer discharge period [7], while the nonexclusive section is lower, it is probably going to happen in low-evaluated economies and in nations with less guideline. Exact research contrasting huge European nations and the U.S and Canada shows that most European countries, which will in general be more controlled than the U.S., have a nearly greater presence of conventional respondents [8]

The target of medicinal treatment exercises or allotment plans in drug stores might be request side laws and prizes [8] which may incorporate monetary or non-money related prizes. Exact verification has demonstrated that administrative arrangements that urge or expect drug specialists to substitute marked pharmaceutical items bring about a significant ascent in substitute piece of the overall industry [9]. Other interest side estimates, for example, backward pharmaceutical edges and arrangements to endorse doctor direct (for example bills) beneficially affect nonexclusive business stocks [10]. In spite of the fact that the consequences of another investigation were very comparable, a characteristic examination demonstrated that after the presentation of pharmaceutical spending plans in Germany in 1994, the quantity of medical clinic affirmations and hospitalizations expanded essentially [11].

Pharmacoeconomic: It is the branch of pharmaceutical science which deals with description and analysis of cost of different drug formulations available in market.

METHODOLOGY

This study was carried out to assess the “Pricing Regulation of Prescription Drug and Its Analysis across Regulated and Less Regulated Markets.”

Plan of Work:-

- i) Selection of anti-diabetic and anti-hypertensive prescription drugs for cost analysis in India and USA.
- ii) Analysis of drug approval process and pricing regulations in India.
- iii) Analysis of drug approval process and pricing regulations in USA.
- iv) Analysis of impact of pharmacy business management on high cost of drugs in USA.
- v) Analysis of role of insurance provider and payers on high cost of drugs in USA.
- vi) Analysis of “Exclusivity Rights” on drugs and its impact on cost of drug in India and USA.
- vii) Recommendations on policy implementations to lower down the cost of drugs.

The cost analysis of drugs are based on the queering out various data bases of both pharmaceutical market i.e. India and USA along with number of manufacturers, dose of drug, patented drugs, their generic alternates, dose combinations price variation within country between different manufacturers and other factors etc. The authors searched “Current Index of Medical Specialties -CIMS” and “Indian Drug Review” for the current costs of prescription drugs in the similar quality and dosage form being formulated by various organizations. Also sorted PubMed, ScieneDirect, Google Scholar from 2010 to October 2017, in short, the hunt procedures included cost of a specific medication (cost per tablet) was acquired from MeSH terms (e.g., orange book, Pharmasahidaam, pharmaeconomics analysis, pricing regulations and price regulated and less regulated markets) and keywords (e.g., diabetics, anti-diabetics, hypertension and antihypertensive drugs).

The medications being made by just a single organization or being made by various organizations be that as it may, in different qualities were prohibited. Percentage cost variation within regulated and less regulated market was calculated using this formula (Karve& Chattar, 2014):

% Cost variation

$$= \frac{Maxcost - Mincost \times 100}{Mincost}$$

The price of less regulated market was in US dollars and for the comparison, the authors converted that in Indian rupees by multiplying with 65.02 (1 US dollar = 65.02 rupees). The data analysis was carried out using Microsoft Office Excel, 2017. The various pie charts of individual drug with strength were made to show the variation in prices.

RESULTS

We have evaluated cost of 8 monotherapy anti-diabetics which are available in 23 different strengths and formulated by various companies. Maximum and minimum cost of oral single formulations of anti-diabetics in regulated market (India) in both rupees (INR) and dollars (USD) in which Sitagliptin (50mg) shows maximum price of 38.43 INR (0.5910 USD) whereas Glibenclamide (2.5mg) shows minimum price of 0.26 INR (0.0040USD). Table 5.3 & 5.4 shows maximum and minimum price of oral single formulations of anti-diabetics in less regulated market (US) in both rupees (INR) and dollars (USD) in which Sitagliptin (100mg) shows maximum price of 346.77 INR (5.3333 USD) whereas Glipizide (2.5mg) shows minimum price of 13 INR (0.1999 USD).

DISCUSSION

Dissertation work was conducted with the aim of computing cost and difference in cost among anti-diabetics and antihypertensive drugs across the different brands available in regulated and less regulated market. Our study indicates that the cost of many formulations of the anti-diabetics in less regulated market have higher prices as compared to regulated market that’s not

suitable for patient and it conjointly results in unfair burden on the consumers. There are not even single formulations which have more prices in regulated market. There are different brand names for the same drug with different prices. In regulated market, the drug prices are controlled by drug price controlled order 2013 (DPCO). NPPA established in 1997 and DPCO along with government of India fixes the ceiling price of 11 bulk drugs and make sure that no Indian company should takes advantage of it. The drug prices are revised every year according to wholesale pricing index. The key objective to attain adequate production is Drug Price Control Order, 1970 (DPCO), it also guide to maintain the supply of the drugs and avail it at fair price. It was presented when the greater part of India's medications were under strict price controls.

Regulated markets are the medium for the trading of merchandise or administrations over which an administration body have a control. It might require market members to acclimate the natural measures, drug safety particulars, data revelation necessities and so on. The market for medicine and in addition OTC medications is a case of a regulated market for instance India. Less regulated markets are those on which there is no control of government to fix the minimum or maximum price. They set their price with their own wish. For example- United States. The pharmacist also has a role in the price variation of the drugs. There are some pharmacist that do not give the actual brand written by the prescriber, they change the brand and give some costly drug. Pharmacists are earning from that costlier brand. Pharmacoeconomics should be introduced in the under graduate medical curriculum in which students should learn how to use CIMS or MIMS for selecting the cheapest available formulation of a particular drug.

The cost-effective analysis of antihypertensive drugs was studied of same formulation with same strengths. The common most drugs used as monotherapy for hypertension was taken for the study to compare the prices in regulated and less regulated markets. The problem of higher prices of prescription drugs in less regulated market has profound, complicated roots and distributed the reasons in JAMA. The main key findings in the JAMA for the higher price in U.S are as:

i) Active pharmaceutical ingredients (API), recipients, labor and overhead cost based on locality: As per Trading Economics, US is the developed country having the average wages of labor about 1444 INR/hour (22.22 USD/hour) whereas in the developing countries like India, average wage is 34.02 INR/hour (0.52 USD/hour) leads to higher manufacturing cost of pharmaceutical formulations in US market.

ii) Implementation of Pharmaceutical price regulation schemes and price control orders in regulated and less regulated markets: As Indian pharmaceutical market is controlled by DPCO and NPPA so no direct control of prices, however in US, there is no regulation scheme, so it may be one of the leading causes of price variation.

iii) U.S. gives the better quality than the India this may be reason of higher prices also: As USFDA has strict norms related to the quality of the pharmaceutical products, so US pays huge amount for the maintenance and production of drugs that is the reason of charging higher prices than India.

iv) Public and Private Payers Roles: Amid a medication's market selectiveness period, the essential offset against extraordinary estimating is the negotiating power of the payer. Every payer charges differently depending on the different locations that may be the reason of variation of prices in pharma markets.

There is lack of transparency in the margins of the pharmaceuticals to the researchers, health officials and industries. So, the prices of drugs are like a black box. As we reviewed most of the research articles based on the cost effective analysis, less information is available which relates the costs of drugs of various brands exhibit in the world. In this way, we chose to do the examination which covers the pharmacoeconomic investigation of antihypertensive medications in price regulated and less regulated markets.

As the US follows CGMP regulations enforced by the USFDA that assures the identity, strength and quality of the pharmaceutical preparations which is the main factor of high prices of drugs. India follows DPCO and NPPA for the control of maximum and minimum prices of drugs so the manufacturers do not have authority to change the prices of pharmaceuticals by their own. On the other side, there is no regulation scheme in US, so drug manufacturers can set their own price that leads to higher prices of drugs. The cost of labor and material (API, excipients, equipment) is different in regulated and less regulated market like in India; the amount is less for both labor as well as the cost of API whereas in US they pay a significant amount to the labor and for the raw material. There are government and private payers (insurance companies) who imply disparate charges to different individuals and location, so depending on the payer, the cost of particular drug going to be changed leads to higher prices in pharmaceuticals. Some of the pharmaceutical markets based to their earlier structure existence leads to price variation of the drugs depending on the location. As there are many formulations, the prices of which are directly controlled by inventors (patented drugs), leads to fluctuations in the prices in both the markets.

Our study also revealed that the costs of the greater part of the antihypertensive brands which are utilized normally demonstrate the percentage price variation over 100%, which isn't satisfactory circumstance for patients. Of 10 drugs contemplated, the vast majority of which are regularly endorsed, percentage price variation is substantial which prompts out of line trouble on the customer. The prices, brand name and manufacturers name of antihypertensive drugs in the below depicted in the table was taken from "Current Index of Medical Specialties' – CIMS" of regulated market (India) as the prices are keep on updating on regular basis and the prices of same drugs of less regulated market (US) was taken from "GoodRx" and "Online Pharmacies" as Online Pharmacies further contains 20 more pharmaceutical selling companies.

CONCLUSION

Our study makes the prescriber and people aware about various types of anti-diabetics and anti-hypertensive drugs available throughout the world with their difference in prices in regulated and less regulated markets. Therefore, this variation in the prices can be reduced by regulating the areas and pharmaceutical companies who actually don't follow it. This will minimize the health and expenses on drug load of patient and prescriber. The generic drugs can reduce the expenditure of patients on the drugs. So, the changes in the pharmaceutical policies are mandatory and the prices in less regulated area should be controlled in an effective way. Price variation should be controlled in an effective manner by regulatory bodies in order to provide cost-effective drug therapy to the patients. This will help in lessening the load on both patient and medicinal services framework.

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