REVIEW ARTICLE

Drug Pricing Pattern in India, China, and Canada

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ABSTRACT

Objective: In 2018, the Indian government proposed to launch a national health-care pricing reform with purpose of improving the quality and health-care expenditure. The objective of this study is to describe the mercurial drug pricing policy of India.

Methods: The author conducted a thorough research on the drug pricing pattern using Indian health authority websites, pharmaceutical websites and blogs, press releases, and discussion forums.

Results: A systemic design and clear regulations must be set up with adequate policies. Drug prices must be carefully regulated by the government to increase access to the poor citizens.

Conclusion: Price regulations have a long history in India, China and Canada. They are used to increase affordability, accessibility and quality of the medicine. However, with increasing need many reforms have been made over the past decade. There should be a proper balance between price ceiling and local condition for better access of the medicine. The government regulations must evolve over the time.

Key words: Co-payment, Formulary, Line extension, Patent act, Price freezes, Re-imbursement, Tendering system

INTRODUCTION

In the recent decades, the Government of India has been dealing with the issue of growing health-care expenditure. In spite of the exponential growth of health-care expenditure, the patients are not satisfied with the quality of care and accessibility.

To address the above issue, the government had proposed various reforms over the decades. Since pharmaceutical sales constitute a major portion of health-care expenditure, it is important to analyze the potential impact of drug pricing paradigm. India's dominancy as a "worldwide pharmacy" for developing and underdeveloped countries cannot be challenged. It has scaled from net importer (1970s) to net exporter. However, due to increasing population along with poverty, most medications are either out of stock or costly. This led to private sector dominancy in the health-care sector. Adding to the misery, the health insurance does not include drug reimbursement in its coverage.

Indian drug price which was one of the highest in the world, 1970 has taken a reverse route in the wake of government policies, patents, and drug price control orders (DPCOs).

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Despite multiple drugs being approved by the government (for example, diabetes, hypertension, etc.), Indians lack access to essential medicines.

The pharmaceutical market of India, China, and Canada shows assortment in pharmaceutical pricing mechanisms. We have undergone detailed evaluation of pharmaceutical policy reforms.

PHARMACEUTICAL PRICING POLICIES

India

India is the third-largest producer of medicines in the world; it is called the pharmacy of the world, not only in terms of production but it also reflects the advantage of prices. It is eleventh in terms of pharmaceutical exports while the export prices being the cheapest.[1]

The pharmaceutical policy environment is a huge success in India making it capable to compete strongly with the global leaders. This environment has been updated through several "reforms" over the past three decades, which include intellectual property, manufacturing, trade, and prices.

In India, drug prices are directly guarded by the DPCO under The Essential Commodities Act. The act authorized the government to fix price for essential bulk drugs and their formulations. There was no regulation until 1962. In 1970, The Patent Act was introduced to recognize "process patents and product patent." It was a crucial landmark,

which granted companies to patent their product in alternative ways. It brought the advantage of entry of new medicines into the Indian market along with low prices. It was modified in 2005, pre- and post-grant opposition, compulsory licensing and data exclusivity. In recent times, the US and EU are pressurising India to deregulate the above and sign the free trade agreements which will lead to extend the breadth of product patent. In 1997, the National Pharmaceutical Pricing Authority was introduced to regulate price of scheduled and availability of drugs.

The information imbalance creates market concentration and market failures leading to decreasing access to life-saving medicines. Price control mechanisms have a pivotal role in improving accessibility to help grow the pharmaceutical industry. In the 1980s period, reforms extended to pre-tax profits, strategies based on degree of essentiality and quality. By the end, 90% market share and 342 drugs were under price control. The following decades had capitalizing measures, thereby reducing the government control. Now, 17% is under price control.[2,3]

The NPPP, 2012 was a major breakthrough that converted cost based to market based, the ceiling prices are determined on the basis of average price of all brands of medicines. Studies have shown that cost-based pricing has brought down the price by 4 times for selected medicines. The practice in India is that doctor writes brand names of generic product which must be stopped. The revision includes 50 CVS and anti-diabetic drugs.

Recently, media report suggests that DPCO, 2013 will further amend to cap the trade margins debited by chemists and stockist along with the NLEM list being expanded.

Medicine prices have played a pivotal role in pushing citizens toward poverty.

China

National Development and Reform Commission (NDRC) is responsible for setting price for drugs and medical devices under government program of planned supply also known as government pricing. The maximum retail prices of Category A drugs, which were definitive ceilings for retail pharmacies and public hospitals, were determined by the NDRC at the national level. Prices were set for each active ingredient and dosage form on the basis of declared costs by manufacturers multiplying by some mark-ups to account for profits as well as costs of research and development. For drugs in Category B, although their guiding prices were set by the NDRC at the national level, the price ceilings were determined by the governments at the provincial level, usually established through a local tendering system.

RECENT REFORMS INCLUDE

Drug Price Advancement, June 2015. Manufacturers can set market prices, until the drug is included in the health insurance formulary (HIF). Before June 2015, the pricing of reimbursable drugs was under direct control of the government. Each active ingredient and dosage form had pre-defined prices which were derived from the manufacturer's costs (development, manufacturing, etc.). Local governments could adjust the maximum prices. Products with better quality can have the price higher than the maximum retail prices indicated by GGP (i.e., "individual" pricing or pricing "privilege"). Local tenders set the actual price. Selected manufacturers were allowed to provide their products to hospitals at prices established through a bidding process (i.e., local procurement prices). There was no standardized reimbursement price – drugs were reimbursed based on their actual price.[4]

In 2015, China introduced changes in the current protocol with the core being abolishing the GGP including Category A and Category B, thereby introducing the "reimbursement standards" to guide the price of drugs included in HIF. The Ministry of Human Resources and Social Security played a pivotal role in this process. However, this led to the Chinese local administration to gain autonomy over the methodology to fix the price before national level introduction of regulations happen.

The medicines with no market competition/in-patent will not be included in the system. The prices will be fixed by transparent and multilateral negotiation mechanism involving industry, stakeholders, and retailers.[5]

NDRCs Academy of Macroeconomic Research suggests that drug quality, drug costs, and winning tender prices should also be included into the definition of reimbursement standard, there was no conclusive guidance provided.

For biological products, the prices are set according to the tenders negotiated. Specific framework has not yet been announced.

New Pricing Mechanism

	With market competition	Without market competition
Drugs included in HIF	Reimbursement standard	Multilateral negotiation
Biological products	Tenders and multilateral negotiation	

Projects

- Scanning: Introduced June, 2014. The reimbursement standard is set at the procurement price of the cheapest generic from the group and patients are

liable to cover an excess amount in addition to any other applicable copayment.
- Advantage: Increasing the use of generics, reducing malpractice and overprescription, and optimizing the use of the health-care budget.
- Chongqing: Introduced January 2015. Procurement price of a given drug is to be compared with the national average procurement price (NAPP). The NAPP is calculated based on the previous year's procurement prices for all drugs across China with the same active ingredient and dosage form.
- Shaoxing: Introduced January 2015. Second price negotiation which allows hospitals to negotiate discounts directly with suppliers. Local procurement prices obtained through the tendering process serve as both price caps in negotiations and reimbursement standards. Hospitals hand out obtained discounts to the provincial Bureau of Finance. This money is to be further invested in hospitals.

Challenges

- The reform lacks systemic design and adequate supporting policies.
- Clear regulations for introduced changes and coordination mechanisms between responsible bodies are not established.
- The quality of generic drugs is not ensured.

To address growing health-care expenditure accompanied by the issue of quality and accessibility to care, in 2009, the Government of China launched a reform program under which a universal health-care system is to be established by 2020. The program targets different health-care sectors and aim to provide all citizens with affordable and quality health care covered by health insurance.[6]

Canada

Common drug review under Canadian Agency for Drugs and Technologies in Health assess the clinical effectiveness and cost-effectiveness of products and the federal responsibility for drug price control rests with the PMPRB, an independent, quasi-judicial body.[7]

Governments in Canada have established mechanisms planned to control drug prices. It contains:
- The federal government establish the semi-judicial body to control factory-gate prices and other measures at the local level such as:
  - Formulary management
  - Use of generics
  - Reference-based pricing
  - Price freezes.

These measures to a large extent have been effective in control of price.

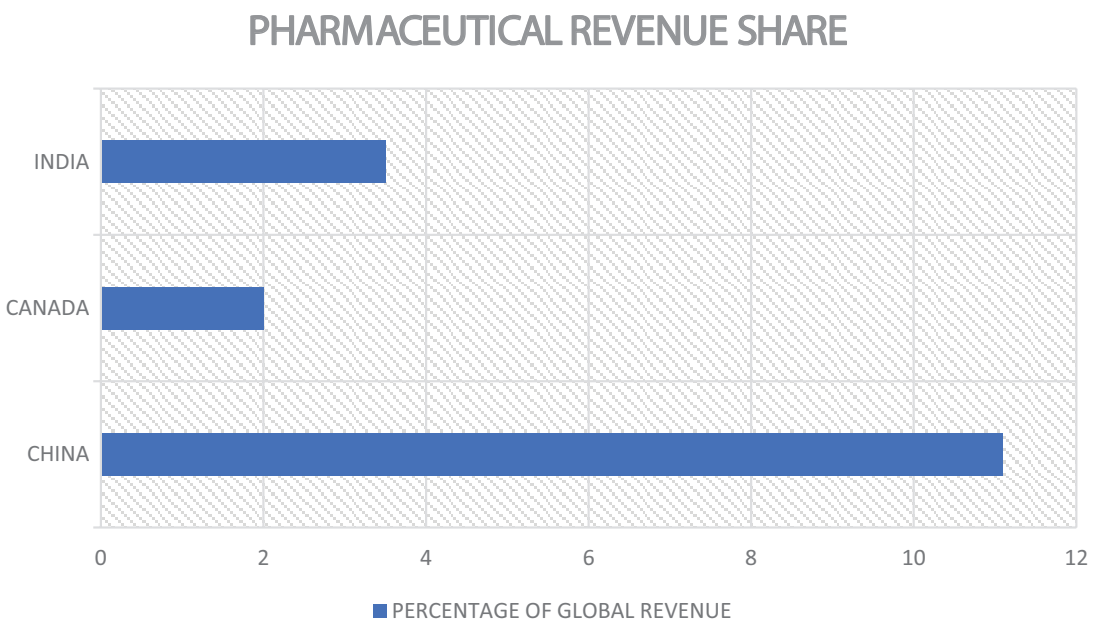
ACTS AND BILLS

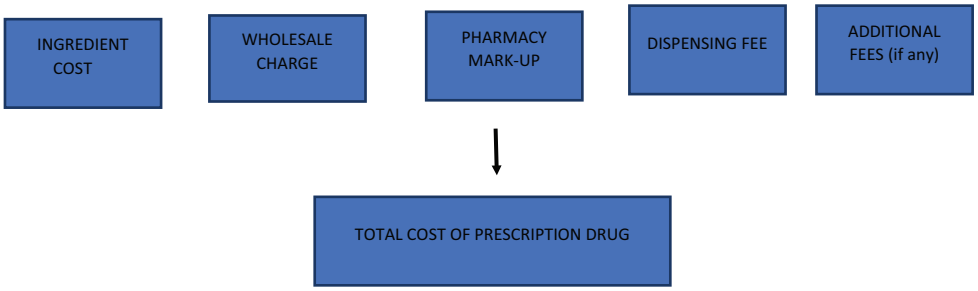
- The Canadian government's Hospital Insurance and Diagnostic Services Act,1958
- Medical Care Act, 1968
- Canada Health Act
- Patent Act, 1923
- Bill C-91, 1991

The PMPRB does not set prices. Instead, it reviews factory-gate prices of individual products to determine if they are excessive.[8]

Process is

- Category 1: A new drug product that is an extension of existing or comparable dosage form of an existing





medicine, usually a new strength of an existing drug ("line extensions")
- Category 2: The first drug to effectively treat a particular illness or that provides a substantial improvement over existing drug products, often referred to as "breakthrough" or "substantial improvement."
- Category 3: A new drug or dosage form of an existing drug that provides moderate, little, or no improvement over existing drugs ("me-too").

Manufacturer submits the data

(price+reviews of the product in recognized journals + results of two to five well-controlled trials + reviews of the drug)

PMPRB:
- Manufacturers are supposed to file price and sales information each year that the drug remains patented.
- These figures are then reviewed by board staff.
- If it is established that a price is excessive, the manufacturer can make what is called a voluntary compliance undertaking to adjust the price and take remedial action
- The board also can initiate formal proceedings and hold a public hearing.

GOVERNMENT APPROACHES

- Formularies
- Generic substitution
- Reference-based pricing: The "reference product" in each category is that with the lowest price.
- Price freezes: Manufacturer is prepared to provide a price reduction for a different drug so that the change is cost neutral to the drug program.
- Controls on mark-ups: Local governments can limit mark-ups so that prices of drugs bought under the provincial drug program will be controlled.
- Dispensing and risk sharing: Governments have started to negotiate with companies to reach agreements aimed at limiting total expenditures on specific drugs.

After a new drug has received approval to be marketed and sold in Canada, the manufacturer makes a submission to local government to have the drug covered by a particular drug program.

The program reviews effectiveness of a new product in relation to its costs and determines whether it has a therapeutic advantage over products already on the formulary.[9]

Trends

Since 1994, average prices have actually dropped. This is on average true for the prices of non-patented single-source drugs as well, while for non-patented multiple source drugs, this trend of annual price decreases began in 1993.

The issue of pricing needs a holistic solution generated by the synchronized efforts of stakeholders, pharmaceutical companies, and health-care professionals to catalyze equity in access to health care.

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