*Original Article*

# Pharmaceutical Market and Drug Price Policy in India

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**Abstract**

Drug prices and cost of healthcare are two major concerns globally. This entails to examine the structure and performance of domestic pharmaceutical industry and Indian market's pricing policy of drugs. This article contributes to the debate around regulation of drug prices in India from the perspectives of the healthcare of the poor and affordability.

**Keywords**

Pharmaceuticals, medicine, India, drug market, drug prices

## Context

Cost of healthcare and drug prices are major concerns in developed and developing countries. Prices of pharmaceuticals (drugs/medicines) affect the healthcare cost accounting for a large part of healthcare expenditure. In many developing countries, public healthcare expenditure is minimal and coverage under health insurance is limited, as most people are engaged in informal and unorganised sector with no social security. The coverage of private health insurance market is limited largely due to lack of information and affordability-related issues for the vast majority of the population. The epidemiological transition (communicable to chronic, non-communicable diseases) shifted the burden of healthcare from public health to individuals (Indian Council of Medical Research et al., 2017), and health expenditure is largely met with household out-of-pocket (OOP) expenditure,

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especially in developing countries. OOP healthcare expenditure is one of the major causes for large number of households falling into poverty (Krishna, 2010). Hence, not only otherwise impending losses due to morbidity and premature death but also expensive healthcare and essential life-saving drugs have major repercussions for the poor.

The growth and structure of pharmaceutical industry and related policy, regulations and pricing have impact on healthcare and related expenditure. However, the economic perspective of pharmaceutical industry seems to downplay such adverse implications and expect to have unregulated pricing regime because of its innovation-intensive, essential and life-saving nature (Kremer, 2002; Lakdawalla, 2018; RAND, 2008). The main objective of this article is to critically review the arguments around price regulation of pharmaceuticals from the perspective of social welfare, especially of the poor, besides examining structure and performance of domestic pharmaceutical industry and market in India and its pricing policies. The sources of information for the analysis are Annual Survey of Industries (ASI), Directorate General of Commercial Intelligence and Statistics (DGCI&S), Centre for Monitoring Indian Economy (CMIE), CRISIL Research, Reserve Bank of India (RBI), India Brand Equity Foundation (IBEF), Organisation of Pharmaceutical Producers of India (OPPI), national accounts for Private Final Consumption Expenditure (PFCE) and gross domestic product (GDP) along with National Health Accounts (NHA).

## Indian Pharmaceutical Industry: Performance

Indian pharmaceutical industry has grown remarkably, overhauling the country from import dependence in medicine (until the 1970s) to self-reliance by 1980s, catering to a large extent of domestic market demand and to becoming a major exporter after 1990. The Indian Patent Act, 1971, which shifted patent compliance from 'product to process patents', became a watershed moment in the turnaround of pharmaceutical industry. The policies of early 1990s provided further impetus for Indian pharmaceutical industry's growth, imputable to its cost-effective, competent, skilled manpower and low-cost manufacturing. The Indian pharmaceutical industry, employs nearly 700,000 people directly in manufacturing, contributes more than 5 per cent of the country's commodity exports and has enjoyed double-digit growth in the last few decades. Its growth rate was almost twice that of national GDP. Pharmaceutical industry attracts large foreign direct investment (FDI), and such inflow has increased post-2000s (Figure 1). Recent policy allows 100per cent FDI in pharmaceuticals.

Certain concerns have been raised, however, in respect of compliance with the World Trade Organization's (WTO) Trade-related Aspects of Intellectual Property Rights (TRIPS) agreement, which makes compliance mandatory with product patent (Das, 2003; Lalitha, 2002; Subramanian, 2004; 't Hoen, 2002). Although compulsory licensing provisions and import–export in addressing public health crisis were made explicit in the Doha declaration, concerns of developing

countries remained unaddressed. What is the impact of such intellectual property rights (IPR) regime on the competitiveness, growth and sustenance of Indian pharmaceutical industry, which had for three-and-half decades leveraged the process patent? How have changes in the global market (especially price pressure and erosion in the USA) for pharmaceuticals affected India's pharmaceutical exports and industry? Another lookout is the impact of Indian pricing policy coupled with demonetisation and goods and services tax (GST). Also, investment in research and development (R&D) is a supply-side concern. Additionally, in India, with economic growth and increasing old-age population and epidemiological transition (IBEF, 2019), there is growth in healthcare expenditure, healthcare awareness, needs and facilities. Under these circumstances, availability and accessibility of medicines at affordable price for the needy, especially the poor, is a major policy concern.

## *Industry Structure and Performance: Growth in Output, Value Added and Employment*

The Indian pharmaceutical industry consists of multinational corporations (MNCs), publicly- and privately-held companies of foreign and Indian origin and public sector undertakings of India. They can be divided into three categories by size and activities. First, large MNCs and firms of Indian origin, involved in R&D developing new drugs/formulations, and producing originator and branded-generic drugs. Second, medium and small firms producing patented and generic drugs as well as into contractual research and manufacturing services (CRAMs). Third, small firms producing generic drugs (Centre for Trade and Development, 2010). The diversity and concentration of the industry are apparent through firms' specialisations in product segments of the value chain (intermediaries, bulk drugs and formulations) and therapeutic classes (such as anti-infection and cardiovascular). Drug intermediaries are used as raw materials in producing bulk drugs (active pharmaceutical ingredients [APIs]), which are then used in formulations (final consumable products). Intermediaries and bulk drugs are produced to captive consumption and/or to market (domestic and export). It is noteworthy that CRAMS and biotechnology-based pharmaceuticals (bio-pharma producing biologics/biosimilars) are an emerging industry in India (IBEF, 2019).

The performance of Indian pharmaceuticals is analysed using ASI data from 1998–1999 to 2017–2018. ASI classifies industries based on National Industrial Classification (NIC), which is revised from time-to-time. The pharmaceutical industry is configured with four-digit Code 2423 of NIC-98 and three-digit Code 210 of NIC-2004 and NIC-2008. The ASI values in current prices are deflated with the wholesale price index (WPI) of manufacturing products to get constant prices, with 2011–2012 as base year. This two-decade period is divided into three subperiods—(a) pre-TRIPS subperiod from 1998–1999 to 2004–2005, (b) post-TRIPS period from 2005–2006 to 2010–2011 to provide insights on industry performance during IPR regime immediately after TRIPS implementation in 2005

and (c) post-TRIPS subperiod from 2011–2012 to 2017–2018 to capture industry performance in post-IPR regime, along with impact of changes in regulatory practices in domestic and global markets. The last subperiod witnessed domestic legislations, regarding prices of drugs and medical devices, and changes in the global market.

In all three subperiods, the domestic pharmaceutical industry grew in terms of number of factories and employment, values of capital, output, value added and profits. While the absolute value of output (2011–2012 prices) in pharmaceuticals industry increased five-fold from ₹494.3 billion (1998–1999) to ₹2,506.7 billion (2017–2018), fixed capital witnessed a six-fold expansion in this period. Employment increased by 3.5 times from around 214,000 to around 740,000. For real value of profits in the industry between 1998–1999 and 2017–2018, its value has multiplied by nine times, and its share in output increased from 11.6 per cent to 20 per cent.

The annual average growth rate in output (gross value of output) accelerated from pre-TRIPS subperiod to that immediately after TRIPS. It decelerated in the subsequent subperiod but was almost double than that of pre-TRIPS subperiod (Table 1). A similar trend is observed for growth rate in value added (gross/net), net income, wage expenditure (emoluments) and employment. The value added continued to register double-digit growth in the third subperiod. Although the growth rate in profits decelerated from pre-to post-TRIPS subperiods, it continued to register double-digit growth. This reflects increasing labour costs (growth rate in wage expenditure is higher than that of profits). Overall, despite slowdown, the Indian pharmaceutical sector performed better in the post-IPR regime phase. The pharmaceutical industry witnessed stable growth in the post-IPR regime until 2013–2014.

Decelerated growth in pharmaceutical sales and exports in the last three years might be due to demonetisation and GST along with global factors affecting exports. Pharmaceutical market research and intelligence organisations, such as All India Origin Chemists & Druggists and Advanced Working, Action and Correction System (AIOCD–AWACS), IQVIA and ICRA have observed a drop in sales of drugs, decelerated growth in annual turnover of pharmaceutical firms and decline in their stock prices. The National Pharmaceutical Pricing Authority's (NPPA) estimate, based on AIOCD–AWACS information for the last five years, shows that the annual growth rate in pharmaceutical sales turnover was lowest ever (3%) in 2017–2018 (Government of India [GoI], 2019). Liquidity or cash flow was also affected by such policies. Also, it was a challenge in the recent past to comply with the destination countries' regulatory framework, especially of the USA's Food and Drug Administration (USA–FDA), as a considerable portion of production was exported. Recent price erosion and pressure in USA pharmaceutical market also affected exports. One could observe that the average growth rate in India's exports during the four years (2014–2015 to 2017–2018) period is less than 5 per cent, sharply decelerating from previous periods.

**Table 1.** Annual Average Growth (%) in Selected Indicators of India's Pharmaceutical Industry

| Details | 1998–1999 to 2004–2005 | 2005–2006 to 2010–2011 | 2011–2012 to 2017–2018 | 2005–2006 to 2017–2018 | 1998–1999 to 2017–2018 | 2014–2015 to 2017–2018 |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Gross value of output | 4.7 | 14.8 | 8.4 | 11.4 | 9.3 | 6.3 |
| Gross value added | 8.9 | 15.1 | 10.5 | 12.6 | 11.5 | 7.9 |
| Net value added | 9.3 | 15.0 | 10.5 | 12.6 | 11.6 | 7.7 |
| Net income | 11.6 | 15.6 | 10.7 | 13.0 | 12.5 | 7.5 |
| Emoluments | 5.4 | 16.2 | 13.5 | 14.7 | 11.8 | 12.5 |
| Profits | 16.3 | 15.7 | 9.5 | 12.4 | 13.6 | 5.1 |
| Employment | 3.9 | 10.1 | 6.9 | 8.4 | 7.0 | 4.7 |

**Source**: The authors' calculations based on ASI data.

**Note**: Constant (2011–2012) prices—WPI for manufacturing products was used to deflate current values.

## *Growth in Pharmaceutical Exports*

According to the DGCI&S and its primary commodity classification, the values of India's drugs and pharmaceuticals exports and imports in 2018–2019 were ₹133.9 billion (US$19.2 billion) and ₹44.4 billion (US$6.3 billion), respectively. In the Indian pharmaceutical industry, from the 1980s, exports have always been exceeding imports. In 2018–2019, pharmaceuticals exports were three times that of such imports, and they formed 5.8 per cent of the total commodity exports from India.

In the export of pharmaceuticals, India was a non-entity before 1970. When the momentum began, exports registered high growth (21.6%) in the 1970s, but its value was 60 per cent of such imports (Table 2). In the subsequent decade (the 1980s), with an accelerated growth, the value of drugs exported exceeded the value of drugs imported. Although growth decelerated since the 1990s, the double-digit growth rate in drug exports continued and was higher than that of imports. The share of drug products in total commodity exports of India increased from < 1 per cent in 1970s to nearly 2 per cent in 1980s and continued to increase. Recently, however, the average growth in pharmaceutical exports decelerated to single digit (8.4%) between 2010–2011 and 2018–2019. It was the lowest ever (3%) between 2014–2015 and 2017–2018, owing to global factors, such as compliance with USA–FDA. Pharmaceutical export growth picked up in 2018–2019 but decadal average was the lowest. However, in 2018, Indian pharmaceuticals were the largest provider of generic drugs, meeting 50 per cent of global demand for vaccines and catering to 40 per cent of generic drugs in the USA and 25 per cent of all medicines in the UK. Over 80 per cent of the global antiretroviral drugs for AIDS that year was supplied by India (IBEF, 2018).

**Table 2.** Indian Pharmaceutical Exports and Imports: Annual Average Growth (%) and Ratios

| | | | Rate of Growth (%) | | |
|---|---|---|---|---|---|
| **Period** | **% of Drugs in total Exports** | **Ratio of Drug Exports value to Imports** | **Drug Exports** | **Drug Imports** | **Ratio of growth in exports to imports** |
| **1** | **2** | **3** | **4** | **5** | **6** |
| 1970s | 0.5 | 0.6 | 21.8 | 6.1 | 3.56 |
| 1980s | 1.9 | 1.5 | 22.7 | 11.9 | 1.90 |
| 1990s | 3.7 | 3.1 | 14.5 | 7.3 | 1.99 |
| 2000–2005 | 4.8 | 5.1 | 15.5 | 10.8 | 1.43 |
| 2005–2010 | 4.8 | 4.5 | 12.0 | 18.8 | 0.64 |
| 2010–2019 | 5.2 | 2.9 | 8.4 | 6.1 | 1.38 |

**Source**: The authors' calculations based on DGCI&S.

**Note**: Growth is annual average in constant prices (2011–2012) deflated by GDP deflator.

**Table 3.** Exports and Imports of Bulk Drugs and Formulations

| Year | % of Drug Formulations in Drugs Exports | % of Bulk Drugs in Drugs Imports | Ratio of Exports to Imports | |
|---|---|---|---|---|
| | | | Bulk Drugs | Drug Formulations |
| 1 | 2 | 3 | 4 | 5 |
| 1980–1981 | 75.6 | 90.0 | 0.1 | 3.7 |
| 1991–1992 | 54.4 | 87.0 | 0.6 | 5.8 |
| 2000–2001 | 46.8 | 90.8 | 0.7 | 8.1 |
| 2005–2006 | 67.2 | 89.0 | 0.3 | 6.6 |
| 2010–2011 | 60.2 | 86.1 | 1.4 | 5.4 |
| 2015–2016 | 66.1 | 74.8 | 1.1 | 8.0 |
| 2018–2019 | 75.2 | 61.6 | 1.1 | 7.1 |

**Source**: The authors' calculations based on DGCI&S.

**Notes**: Nominal/current prices; Bulk drugs = Active pharmaceutical ingredient (API).

After the import dependency of the pre-1970s was turned around, the growing domestic industry served the domestic market to a large extent. Although the import of pharmaceuticals in India registered its highest growth during the 2000s (18.8% during 2005–2010), it was always lower than exports. A majority of Indian drug exports are formulations, whereas imports are bulk drugs/APIs (Table 3). Until the 2000s, imports of bulk drugs were higher than exports; thereafter, exports exceeded imports. Formulation exports exceeded such imports by the 1980s (Table 3). The Indian pharmaceutical industry, while exporting certain APIs, also imports certain others for its formulation industry.

Although a majority of imports are APIs, certain branded generics or patented drug formulations too are imported. Demand for imported formulations seems to be increasing with a growing corporate healthcare sector. Also, the emerging market for medical devices is largely import-dependent because of the nascent state of domestic industry. Accelerated decadal growth in imports during the 2000s could be due to imports of medical devices, such as coronary stents and knee implants. Subsequent decelerated growth in pharmaceutical imports could be due to decline in imports of medical devices affected by price regulations. But the major factor is decelerated growth in imported bulk drugs, which could be an effort to reduce import dependence and be self-reliant for bulk drugs or due to slowdown in the formulation export market during the period.

## *Research and Development*

The growth of pharmaceuticals is contingent on R&D investment. The R&D profile of Indian pharmaceuticals includes development of generics, new drug development and delivery systems (Joseph, 2011). As Indian pharmaceuticals are predominantly generic, there is low R&D investment here compared to developed countries.

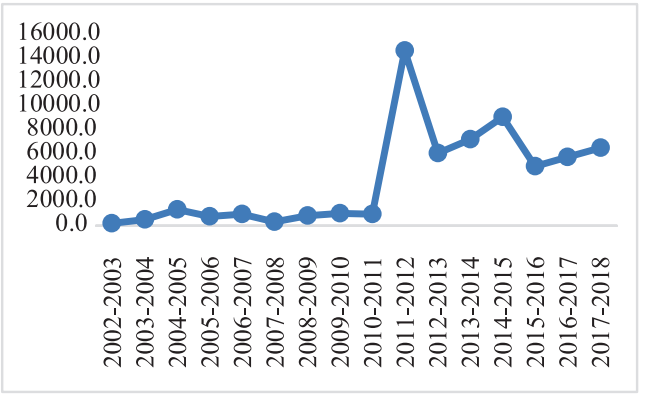


**Figure 1.** FDI in Indian Pharmaceutical Sector (Rs. Crore)

**Source**: RBI%.

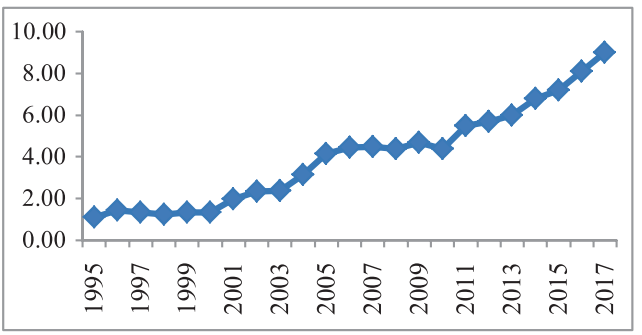


**Figure 2.** R&D Expenditure in Indian Pharmaceutical Industry (% of Sales)

**Source**: CMIE and CRISIL Research%.

A momentum in R&D expenditure in the 1990s was followed by an increase since the turn of the century (Figure 2). The R&D–sales ratio of pharmaceutical companies (proportion of R&D to expenditure in sales) was less than 2 per cent until the end of 1990s, and it increased to 9 per cent in 2017. The momentum in the ratio of R&D to sales in Indian pharmaceuticals slowed in the late-2000s but has picked up since 2011. Also, R&D intensity varies with the size of firms: Large pharmaceutical companies have higher intensity than medium and small firms (Mazumdar, 2013). Also, from CMIE data, one can observe a high and positive correlation ($r = 0.63$) between share of R&D in sales and the market share of the company. Among major pharmaceutical companies, the highest investment in R&D in 2018–2019 was made by Lupin (US$225 million), followed by Cipla (US$173 million), Cadila and Sun Pharma (IBEF, 2019). The CMIE data indicate that in the last 15 years, most pharmaceutical majors displayed an increasing trend in R&D share in sales.

Investigational new drug applications (INDAs) and new drug applications (NDAs) reflect R&D efforts in drugs discovery and development. The USA–FDA has approved 847 of final abbreviated new drug applications (ANDAs) meant for generic-drug development in 2017, along with 175 tentative applications. Of these, 314 final and 66 tentative approvals were claimed by Indian pharmaceutical companies; Zydus group had the largest claims (77), followed by Aurobind (55) and Sun Pharma (22; Singh & Associates, 2018; see also, Food and Drug Administration, 2020). But Indian pharmaceutical companies have few INDAs and NDAs filed and claimed. Although India Patent Office (IPO) granted around 4,000 patents to pharmaceutical products and biologics between 1995 and 2016, most (72%) of them are secondary patents (Ali et al., 2018), reflecting lacunae in R&D beyond generic products, processes and evergreening.

## Indian Pharmaceutical Market: Demand, Supply Chain and Price Controls

With growth in domestic industry and imports (indicating increased supply) and growing public and private expenditure on healthcare (indicating growing demand), the Indian pharmaceutical sector is growing fast with enormous potential to expand further (IBEF, 2019). The supply chain is, however, inflicted with challenges, such as fragmented and unorganised distribution systems, menace of spurious drugs, high trade margins, high drug prices and price controls. On the demand side, the twin problems of access to medicines and their affordability continue to persist. Regulations and price controls have a critical role to ensure safety, efficacy, access and affordability.

### *Growing Healthcare and Medicine Expenditure*

The growth rate in PFCE on health has almost always been higher than of GDP and total PFCE. The percentage of PFCE on health in GDP and total PFCE have increased over the decades, the lowest being < 1 per cent in the 1950s, to 2.3 per cent of GDP and 4.1 per cent of PFCE during the last decade (2010–2019; Table 4).

The NHA takes into account private and public expenditure on health, along with other organisations, including insurance agencies. It indicates that nearly three-fourths of current health expenditure (CHE) is financed by households' OOP expenditure, social insurance contributions and voluntary prepayments. This forms 3 per cent of GDP, whereas public health expenditure constitutes 1 per cent. More importantly, more than one-third of CHE—deducting capital expenditure from total health expenditure—is spent on pharmaceuticals (Table 5). The pharmaceutical expenditure in NHA includes prescribed medicines, over the counter (OTC) drugs and those provided during inpatient, outpatient or any other contacts with a healthcare provider (GoI, 2017). Besides, a considerable proportion of CHE (12% in 2015–2016) is incurred on traditional, complementary and alternative medicine.

**Table 4.** Private Final Consumption Expenditure on Health: Growth Rate and Shares in GDP and Total PFCE—All India

| | Rate of Growth in Value (%) | | | Rate of Growth in Per Capita (%) | | | % of PFCE-H | |
|---|---|---|---|---|---|---|---|---|
| **Period** | **GDP** | **PFCE-T** | **PFCE-H** | **GDP** | **PFCE-T** | **PFCE-H** | **GDP** | **PFCE** |
| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** |
| 1950s | 3.91 | 3.37 | 4.9 | 2.0 | 1.5 | 3.0 | 0.9 | 1.1 |
| 1960s | 3.48 | 2.88 | 8.7 | 1.3 | 0.7 | 6.5 | 1.4 | 1.8 |
| 1970s | 3.32 | 3.04 | 5.2 | 1.1 | 0.8 | 2.9 | 1.7 | 2.2 |
| 1980s | 5.25 | 3.96 | 2.1 | 3.1 | 1.9 | 0.0 | 1.7 | 2.3 |
| 1990s | 5.82 | 4.76 | 8.2 | 3.8 | 2.9 | 6.2 | 1.5 | 2.2 |
| 2000s | 6.62 | 5.26 | 7.5 | 5.1 | 3.9 | 6.0 | 2.0 | 3.4 |
| 2010–2019 | 6.57 | 6.70 | 10.1 | 5.1 | 5.2 | 8.7 | 2.3 | 4.1 |

**Source**: Authors' calculation based on national accounts.

**Notes**: GDP: Gross domestic product; PFCE: Private final consumption expenditure; PFCE-T: Total PFCE; PFCE-H: PFCE of health. Growth rates are based on semi-log model.

**Table 5.** Health Expenditure in India: National Health Accounts

| Sl No. | Indicator | 2004–2005 | 2013–2014 | 2014–2015 | 2015–2016 |
|---|---|---|---|---|---|
| 1 | THE (₹ billion) | – | 4,351.06 | 4,832.59 | 5,284.84 |
| 2 | Per capita THE (₹) | 1,201 | 3,638 | 3,826 | 4,116 |
| 3 | % THE/GDP | 4.2 | 4.0 | 3.9 | 3.8 |
| 4 | CHE as % of THE | – | 93.0 | 93.4 | 93.7 |
| 5 | Household expenditure as % of CHE | – | 72.9 | 71.0 | 69.1 |
| 6 | OOP expenditure as % of CHE | 69.4 | 69.1 | 67.0 | 64.7 |
| 7 | Expenditure on pharmaceuticals as % of CHE | – | 39.5 | 37.9 | 35.4 |
| 8 | Expenditure on traditional, complementary and alternative medicine in CHE | – | 11.3 | 16.0 | 11.9 |

**Source**: National Health Accounts.

**Notes**: '–': Not available; CHE: Current health expenditure; OOP: Out-of-pocket; THE: Total health expenditure; CHE is after deducting capital expenditure from total health expenditure; Current prices.

NHA (2014–2015) states that 53.5 per cent of total household-health-expenditure is spent on pharmaceuticals. National Sample Survey (NSS) estimates (71st Round, 2014; 75th Round, 2017–2018) show that a bulk of the expenditure (72% in rural, 70% in urban) on non-hospitalised treatment is for buying medicines, reflecting growing need and demand, besides denting household budgets.

## *Pharmaceutical Market: Size, Structure and Issues*

The total size of Indian pharmaceuticals is estimated considering domestic consumption equivalent to domestic production, less exports, plus imports. The value of the domestic pharmaceutical market is derived by deducting the value of exports (from DGCI&S) from the value of domestic output (from ASI) and adding the value of imports (from DGCI&S).

The estimated value (current prices) of the Indian pharmaceutical market (IPM) increased eight times, from ₹238.3 billion in 1998–1999 to ₹2,089 billion (US$32.4 billion) in 2017–2018. OPPI estimates are far lower than of IBEF, and the deviation increases over the period. IBEF and the authors' estimates are on the same line and trend with certain differences, indicating that the value of Indian pharma retail market is growing remarkably.

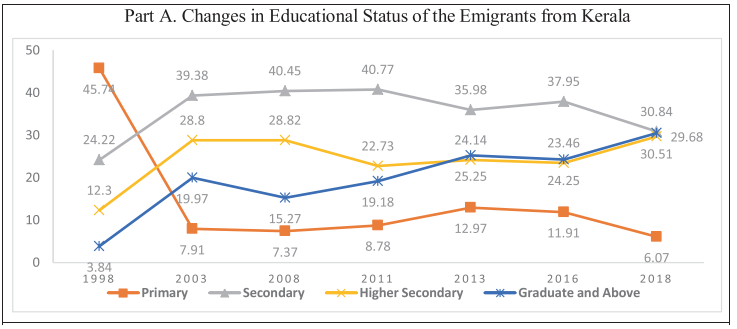


**Figure 3.** Growth of Indian Pharmaceutical Market

**Source:** Authors' estimates along with IBEF and OPPI estimates.

**Note:** Values are in current prices (million).

The ASI data on value of output is not price paid by the end consumer and is based on ex-factory price excluding costs and margins throughout the post-factory supply chain added to ex-factory price. The maximum retail price (MRP) of a drug includes all the manufacturing costs and producers' margin, distribution costs and trade margins. It appears that a large portion of MRP paid by the end consumer is charged and shared in the post-factory supply chain. As observed in the USA, manufacturer's (ex-factory) price is only 16 per cent of the price that the end consumer pays; the rest is charged and shared within the supply chain. Therefore, the actual size of the Indian pharma retail market would be much larger than the estimates based on ex-factory value.

## *Major Players, Therapeutic Classes and Segments*

In the IPM, the major players appear to be largely Indian companies. Among the 22 major players holding more than 75 per cent of the total domestic pharmaceutical sales (during the period 2015–2016 to 2017–2018), a couple of them are MNCs and a few others are private foreign companies (Figure 4). This indicates the large presence of Indian-origin companies in the market.

The Indian pharmaceutical industry consists of privately-held native and foreign firms, along with public companies and public sector undertakings. Private foreign firms accounted for 5–7 per cent of total sales in India during the 2000s (Figure 5), but their share is declining. It could be due to Indianisation of firms, through mergers and acquisitions of native firms by foreign players (for example, USA-based Abbott Lab acquiring Piramal) and of foreign firms by native players (for example, Lupin acquiring American Daiichi and Russian Biocon).

The therapeutic class-wise shares of IPM value indicate that anti-infective is the single largest segment (accounting 16%), followed by cardiovascular (13%) and gastrointestinal therapeutic class. The top five therapeutic classes account for more than 55 per cent of total turnover of the domestic pharmaceutical market (Figure 6).

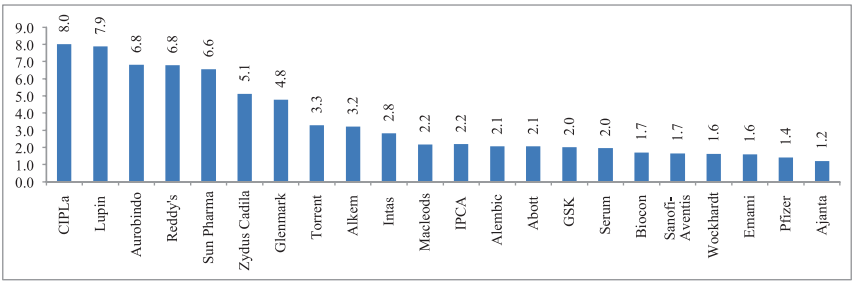


**Figure 4.** Average Share (%) in Sales by Major Players in India (2015–2016 to 2017–2018)

**Source**: The authors' calculations based on CMIE.

**Note**: Companies which have more than 1% share in pharmaceutical sales.

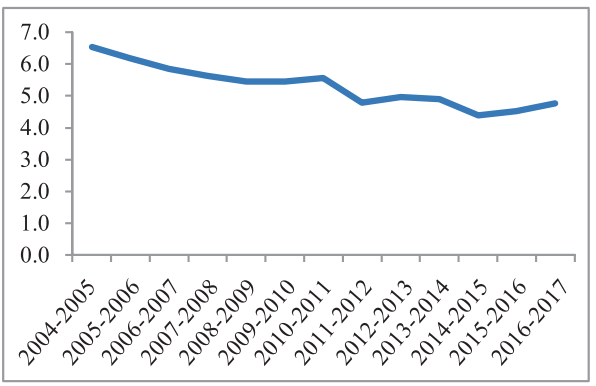


**Figure 5.** Share (%) of All Private Foreign Firms in Pharmaceutical Sales in India

**Source**: The authors' calculations based on CMIE-Prowess.

**Note**: Privately-held pharmaceutical companies excluding MNCs.

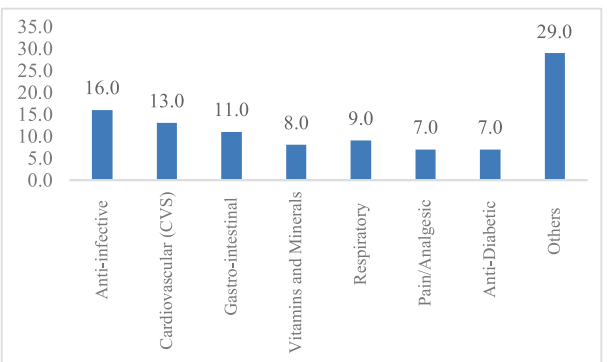


**Figure 6.** Share (%) in Value of Indian Pharmaceutical Market by Therapeutic Class, 2015

**Source**: IBEF (2017).

**Note**: Others including derma, neuro, gynaeco, anti-neoplastics, opthal, hormones, vaccines among others.

India pharmaceuticals, in terms of sales value, is largely dominated by generic drugs (75%), followed by patented/originator branded drugs (25%). Also, India is the largest provider of generic drugs globally, accounting for 20 per cent of global exports in volume (IBEF, 2018). However, the generic market is predominantly of branded generics (80%) and the generic-generics capture only 20 per cent of the total generic market value (RNCOS, 2015). When the drug market is segmented based on sales control, that is, prescription and OTC drugs, the Indian market has considerable (21%) presence of OTC sales (IBEF, 2018).

## *Fixed-dose Combinations and Spurious Drugs*

With an estimated 6,000 fixed-dose combinations (FDCs) in India, the production and marketing of irrational FDCs is a major concern (Gupta & Ramachandran, 2016; Srinivasan, 2018; Srinivasan et al., 2016). About 28 FDCs are included in the National List of Essential Medicines (NLEM). Over 40 per cent of drugs sold in India are FDCs, while they are less than 20 per cent in developed countries (Srinivas, 2014). Following the recommendations of an expert committee (Central Drug Standards Control Organisation, 2015), the Central Dug Standards Control Organisation (CDSCO)[1] banned about 344 FDCs in 2016–2017, considering them unsafe and irrational. When challenged, the Delhi High Court stayed the ban, and later the Supreme Court of India, in December 2017, asked the Drugs Technical Advisory Board (DTAB) of the ministry to review. Finally, the list of FDCs banned was restricted to 328 in 2018 (Raghavan & Rajagopal, 2018).

India might be a leading country in the world for producing spurious or low-quality drugs (Khan & Khar, 2015). Globally, India and China contribute 75 per cent of the counterfeit drugs manufactured (World Health Organization, 2017, p. 18). India's 'National Drug Survey 2014–2016' showed that over 10 per cent of the drugs in government's own supply chain did not meet the quality standard (National Institute of Biologicals, 2016). NITI Aayog has suggested the block-chain technique to deal with this menace (Sen, 2018).

## *Supply Chain: Fragmented/Unorganised and High Trade Margins*

Along with manufacturing and production cost, post-factory supply chain is a critical factor determining drug prices. The post-factory supply chain of drug market begins with distributors–wholesalers and is followed by retailers and consumers. Distributors–wholesalers bear the cost of logistics, inventories, packaging and marketing. Distributors–wholesalers consist of carrying and forwarding agents (CFAs), stockist-cum-distributors and wholesalers or sub-stockists. While CFAs are paid a percentage of the turnover by the manufacturers, others meeting their distribution costs have to set their trade margins. In India, retail pharmacy is largely unorganised, as organised pharmacy and e-pharmacy are nascent (but emerging slowly). E-pharmacies form 0.5 per cent of the Indian market, and there is potential

for its expansion, but prescription verification, safe transportation and ethical practices are important considerations (Singh et al., 2020).

The costs of drug production and producers' profit margins form one segment of the final price (MRP or cost-to-consumer) downstream. Distribution costs, including logistics and inventory, and trade margin in post-factory supply chain are segment upstream. As the NPPA observed in its reports, manufacturers, meeting the demands of post-factory supply chain, usually print inflated MRPs. Sandhu Committee in 2004 and Pant Committee in 2016 (GoI, 2004, 2016) observed high trade margins (10% to 1,000%) and suggested certain cuts in trade margins to reduce drug prices. The NPPA's investigation report in the Fortis case revealed that very high margins were obtained by in-house pharmacies of hospitals, by procuring from manufacturers at a negotiated cheaper price and selling at MRP. Also, the prices of therapeutic equivalents of drugs vary by patent and brand (Srinivas, 2014). Here, along with fixing the ex-factory price itself, policy options are channel consolidation and fixing the trade margins at each point of post-factory supply chain. Also, as most expert groups have recommended, de-branding of generics is necessary. Providing inexpensive and high-quality generic medicines under the Pradhan Mantri Bhartiya Jan-Aushadhi Pariyojna (PMBJP) scheme indicates the possibility of drastic price cuts (Singh et al., 2020).

## *Price Policy*

The Essential Commodities Act, 1955, included life-saving drugs as one of the essential commodities for price control. The policy began with the 'Drug (Prices Control) Order' (DPCO) of 1962 and was followed by orders in 1970, 1979, 1987 and 1995. In 1997, the NPPA implemented a national pharmaceuticals price policy and DPCOs to regulate the prices of scheduled and non-scheduled drugs. The NLEM, first released in 1996, formed the basis for Schedule-I of the DPCO. (It was later revised in 2003, 2011 and 2015.). Through DPCO-2013, the NPPA capped the prices of 871 essential drugs listed in NLEM 2015, besides regulating prices of 642 drugs classified as 'new' ones. Coronary stents and knee implants were also listed in NLEM and are under price control. Exorbitant prices of medical devices prompted the government to extend price policy for the same (Advanced Medical Technology Association & IQVIA, 2018; GoI, 2017).

Such policy, since inception, has attracted criticism from opposite groups—industry bodies as well as those concerned with consumers' access and affordability (Drug prices, 1965; Nair, 1965). Price control orders were criticised for their coverage, inclusion and exclusion in the list (span of control; Joseph, 2016; Rane, 1996, 2002; Srinivasan, 2001). In 1970, most drugs were under price control but the list was reduced to select 349 APIs in 1979, 142 in 1987 and to only 74 APIs in 1995 (GoI, 2005). Changes in DPCO-2013 are the span of control, the method of fixing ceiling price and the form of the drug under price control. The method of fixing price was changed in DPCO-2013 from cost-based price (CBP), in practice since 1979, to market-based price (MBP). The MBP method is different from the

CBP method as well as another method recommended by a task force chaired by Pronab Sen (GoI, 2005).

In CBP method, the retail price is fixed based on material and conversion costs, packaging material costs and packaging charges, along with maximum allowable post-manufacturing and excise duty. The MBP is based on market data and current market prices of a drug formulation of a therapeutic class. It takes a simple average of price-to-retailer of all branded-generic and generic versions of a formulation with a market share of 1 per cent and above and adds a national retailer margin of 16 per cent to it. The MRP of a formulation under price control should not exceed ceiling price plus taxes. However, the inclusion of branded-or traded-generics can influence prices as per this price-fixing method. Moreover, taking the average price-to-retailer and fixing only the retailers' margin leaves out the control on trade margins charged and shared by distributors–wholesalers. NITI Aayog suggested price-fixing based on drug formulation, by taking price-to-distributor and fixing the margins of distributors and retailers.

Fixing the price of a formulation instead of API appears to have some leverage for industry. The formulation involves mixture of API and in-active ingredients (excipients), in different dosages (200mg/300mg) and forms (pill/tablet/capsule/syrup/solution) for different administration routes (mouth/intravenous/skin). Industry may lobby for the least demanded formulation (dosage form) under price control, and the other formulations will remain out of price control. Also, the prescribing physicians are incentivised to advise high-price, branded, non-scheduled formulations, as NPPA (2018) observed from its analysis of prices charged in four private hospitals in Delhi. Eventually, the MBP method encountered severe criticism and was challenged in the Supreme Court. The All India Drug Action Network filed a petition showing the instance of NPPA's referential simple average price being higher than the price of a market leader and procurement prices. The profit margin was still in the range of 10–1,300 per cent. The supreme court, in a verdict on 15 July 2015, questioned the method and directed the government to review it.

The industry opposes any price control (Nair, 1965; Sood et al., 2009), while consumers and civil society expect all essential drugs to be brought under price control, reducing exorbitant prices. Although there is equal chance for a covert stand by the regulating authority, depending on the influence of either side, the industry–regulator nexus prevails more often (Mulinari, 2016).

## *Emerging Alternatives: Bulk Procurement, State-run Outlets and Sliced Trade Margin*

An emerging alternative to price control mechanism is price-negotiated bulk procurement and distribution. The sale of medicines at subsidised prices through public sector outlets or public healthcare centres is an option. In developed countries, insurance agencies do such price negotiations and bulk procurement

(Lakdawalla et al., 2009; RAND, 2008). In India, exemplary cases have been observed in Tamil Nadu and Rajasthan, where the state government engages in price negotiations with drug manufacturers and dealers–distributors–wholesalers (Lalitha, 2008). The drug procurement of Tamil Nadu Medical Services Corporation was considered a successful model, based on the principles of centralised procurement and decentralised distribution (GoI, 2004, 2005). The Sandhu Committee also suggested price negotiation at the launch of a new patented drug as one of the measures to make drug prices reasonable (GoI, 2004).

This may, however, have limited scope in India for individual patients, who may not have a negotiating capacity such as a state, large organisations or insurance companies. The percentage of utilising healthcare services of public hospitals is low and varies across states. Private sector is the primary source of healthcare (for 56% in urban and 49% in rural, according to National Family Health Survey-4). This could be attributed to the complete absence of, or poor, public healthcare facilities. With minimal insurance coverage, Indian insurance companies have not shown interest in such negotiated prices for their clients.

The Pradhan Mantri Bhartiya Jan Aushadhi Kendras (PMBJAK) are intended to ensure availability of affordable quality medicines through Jan Aushadhi outlets. The scheme's plan shows that medicines available in the open market are 2.5–10 times higher than in stores, but there are several bottlenecks in its implementation (Public Health Foundation of India, 2012). Only 50 per cent of the prescribed medicines are available in public hospitals. As these stores are meant for dispensing generics, doctors (public and private), when prescribing, advise for branded generics, thus making it difficult to identify a cheaper generic substitute in stores.

Rationalisation of trade margin, although prompted as another alternative (Advanced Medical Technology Association & IQVIA, 2018), must be considered necessary for policy action. The MBP method rationalises only the retailers' trade margin, not that of the entire supply chain. The Sandhu (2004) and Pant (2016) Committees, which observed high trade margins in post-factory supply chain, recommended capping of trade margin in generics (branded/traded/general); the NITI Aayog too has endorsed this.

## Social Welfare or Development Perspective

As a policy instrument, many countries are implementing regulations and price controls on drugs. RAND (2008) examined the regulations in respect of pharmaceutical industry and their impact on industry revenue in 19 countries (OECD and USA) for the period 1992–2004. It showed that not only did regulations exist in these countries prior to 1992 but also that some adopted new regulations too (Sood et al., 2009). Hence, regulations on pharmaceutical industry are found to be normal rather than an exception across countries but the intensity and extent of regulations vary.

## *Markets: Competition, Information Asymmetry and Power Relations*

Theoretical assumptions underlying market economics—such as perfect competition, no information asymmetry, availability of effective substitutes in the market, or that consumer choice and price competition will result in price reduction—are missing in the pharmaceutical sector. The players in the pharmaceutical market are far from competitive (Mehta et al., 2016). Certain anti-competitive practices prevail because of inelastic demand, patent protection monopoly, information asymmetry, skewed power relations between buyer and seller, and nexus between manufacturer (or supply chain) and the drug-prescribing doctor (Bhattacharjea & Sindhwani, 2014; Centre for Trade and Development, 2010; Gadre & Sardeshpande, 2017; Mondal & Pingali, 2015). Under such circumstances, market forces fail to reduce drug prices.

Moreover, healthcare and pharmaceutical industries have the phenomenon of induced demand, which is influenced by supply, not demand proper (Fuchs, 1986; Johnson, 2014). Such an induced demand prevails '…when the physician influences a patient's demand for care against the physician's interpretation of the best interest of the patient' (as quoted in Johnson, 2014, p. 77). Certain incentive mechanisms and physician's self-interests may tailor treatment beyond the best interest of the patient (Fuchs, 1986; Johnson, 2014). Such practices, particularly in private healthcare, are evident in India (Centre for Trade and Development, 2010; Gadre & Sardeshpande, 2017) and explainable through 'pharmaceuticalisation'—the 'translation or transformation of human conditions, capabilities, and capacities into opportunities for pharmaceutical intervention' (Mulinari, 2016, p. 75).

## *Impact of Healthcare/Pharmaceuticals Expenditure: Falling Into Poverty*

Insurance coverage among the population is low (14.1% in rural areas and 18.0% in urban areas, according to National Family Health Survey-4), so is public expenditure. OOP expenditure has become predominant, and a large part of it is spent on medicines. Hence, prices of pharmaceuticals and cost of healthcare adversely impact households' living standards. In the NSS 71st Round, 25 per cent of people in rural and 18 per cent in urban areas reported 'borrowing' as the source for healthcare expenditure. Many households on the margin, just above the poverty line, are at one-disease-distance to slip into poverty (Krishna, 2010).

A study based on NSS 71st-Round health survey (2014) observed that more than one-third of inpatients reported distressed financing of their healthcare expenditure (Kastor & Mohanty, 2018). OOP expenditure incurred on pharmaceuticals and certain disease conditions contribute significantly to financial burden and poverty (Selvaraj et al., 2018). Selvaraj et al. (2018), based on NSSO's Consumption Expenditure Survey, observed that the expenditure on medicines formed 4.5 per cent of households' total consumption expenditure in 2011–2012, whereas expenditure on healthcare formed 6.8 per cent. Expenditure on medicine in particular and healthcare, in general, was catastrophic to 11.2 per cent and 17.9

per cent households, respectively. Alarmingly, OOP medicine payments pushed about 38 million persons into poverty (Selvaraj et al., 2018). Hence, a policy measure that regulates costs of healthcare and prices of drugs is necessary.

## *Justifying Price Regulation*

Growth of pharmaceutical industry with advancement in medical technology is critical for saving lives and relieving many from morbidity (Kremer, 2002). Economic theory suggests that an innovation-intensive industry, such as pharmaceuticals, needs intellectual property protection through patents and market exclusivity as an incentive to undertake R&D for innovations (Lakdawalla, 2018). In this regard, the increasing costs of innovation and capital, and risks owing to low transition rates of different phases of drug development, are causes for concern (DiMasi et al., 1991, 2016; International Federation of Pharmaceutical Manufacturers and Associations, 2017). Regulations and price control may affect the zeal of innovation and availability of effective drugs in future (RAND, 2008). The concern is about losing exclusive market—to not only cover costs but also make profits for the innovator having patents—as an incentive for furthering R&D investment. But evergreening of patents is an abuse that the pharma industry has been implicated in. Ali et al. (2018) showed that 72 per cent of the patents granted for pharmaceuticals in India were secondary patents, which were granted for marginal improvements over previously known drugs already having primary patents. The risks and innovation cost of generics are very low compared to that of innovator drugs. The Indian pharmaceutical industry is predominantly generic-based. There are huge variations in the prices of patented, branded and generic drugs, and medical devices in each of the therapeutic classes. It is so without any differences in their pharmacopeia/chemical properties and standards (Srinivas, 2014). Prices of patented drugs are several times higher than of their counterpart generics, and prices of branded-generic drugs are higher than of trade-generic and other-generic.

As noted earlier, high trade margins in the supply chain (GoI, 2004, 2016; Selvaraj, 2007), huge profit margins of pharmacies attached to hospitals (Mudur, 2017), and costs of promotion (for example, advertisements) and marketing (Mulinari, 2016) are causes of concern. The social relevance of aggressively promoting drugs and related costs in the case of life-saving drugs is questionable. The incentive mechanism tailored in drug promotion creates induced demand over and above the optimum demand of the patients. It manipulates the actual demand for cheaper substitutes in each therapeutic class.

Regulation is, therefore, necessary for social welfare. Emerging alternatives such as bulk procurement and dispensing through public healthcare centres (state-run outlets under PMBJAK) may not be sufficient because of vested interests of hospitals and doctors. Patients are not educated enough to search for the therapeutic-equivalent in generics. Hence, state regulations and price controls are essential as a correcting mechanism to ensure the safety and efficacy of drugs, besides ensuring their accessibility and affordability.

## Conclusion

Our analysis of the Indian pharmaceutical industry shows that performance in the post-TRIPS period was more impressive than in the pre-TRIPS period. But, in the post-TRIPS period, growth slowed down compared to the period immediately after TRIPS. The recent slowdown might be attributable to the impact of demonetisation, GST and global factors that resulted in declining exports. For pharmaceutical exports, a decelerating growth rate was observed with increasing share in the total commodity exports of India. During the last four years, it registered a very low growth rate owing to global factors such as compliance with USA–FDA regulations and pricing pressure/erosion in the USA.

While examining the pharmaceutical sector, the post-factory supply chain is observed to be affecting drug prices through high trade margins, after covering acquisition, distribution and dispensing costs. This article reviewed the discussion on regulations and price controls on drugs in India. Changes in the recent price policy are found to have certain leverage for the industry rather than affecting it. In the interest of social welfare, given its critical nature in the existence of the human race, drugs—while protecting, maintaining and restoring health of human beings— must be regulated to ensure their safety, quality and effectiveness. With induced demand and an inadequate competitive environment, the pharmaceutical industry fails to reduce prices. Supply-chain trade margins are very high. Hence, government intervention through price control of essential and life-saving drugs is a necessity for India.

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### Note

1. Following the Drugs and Cosmetics Act, 1940, each FDC has to get the approval of CDSCO. Then a State Licensing Authority (SLA) can allow the manufacturing and marketing of such FDCs. But there are instances of SLAs issuing licenses for FDCs without CDSCO approval (Gupta & Ramachandran, 2016).

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