Commitment of Indian Pharmaceutical Companies Today To Their Primary Calling of Curing Diseases - A Study

Citizen consumer and civic Action Group (CAG), Chennai November-December, 2017

Table of Contents

1. The Commercialized Global Pharma Industry Today		3
2. What is "Drug Promotion"?		5
3. 2 Pharma-Related Regulations		5
4. Pharma-Related Consumer Guidance		6
5. 4 Pharma-Related Surveys		6
6. Pharma Sector Market Snapshots (Global, USA, and India)	9	
6.1 Global Pharma Sector		9
6.1.1 Total Global Pharma Revenue	9	
6.1.2 Total Global Spending on Medicines	10	
6.1.3 Per Capita Pharmaceutical Spending - Country-Wise Ranking	10	
6.1.4 Total Global Pharmaceutical R&D Spending	11	
6.1.5 Top 10 Global Pharma Companies by R&D Expenses and Presc	ription ('F	₹x')
Sales (2016)11		
6.1.6 Total Global Pharmaceutical Marketing Spending	12	
6.1.7 R&D Expenses Vs. Marketing Expenses of World's Largest Phar	ma Firms	3
(2014)13		
6.2. USA's Pharma Sector		13
6.2.1 Market Size	13	
6.2.2 Market Share	13	
6.2.3 Growth Rate	14	
6.2.4 Total Nominal Spending on Medicines (2002-2016)	14	
6.2.5 R&D Expenditure of U.S. Pharma (1995-2015)	14	
6.2.6 Average R&D Expenses as % of Total Revenue	14	
6.2.7 Total Spending on Medicines by Americans	15	
6.2.8 Marketing Expenses of the U.S. Pharma Sector	15	
6.2.9 Average Profit Margins of U.S. Pharma Companies in 2013	18	
6.3 Indian Pharma Sector	18	8
6.3.1 Indian Pharma Industry Facts	18	
6.3.2 Indian Pharma Sector Landscape		
6.3.3 Overall Indian Pharma Sector's Market Size	18	
6.3.4 Growth Rates ('CAGR')	19	
6.3.5 Total Indian Pharma Exports	20	
6.3.6 Total R&D Expenses of Indian Pharma Sector	20	
6.3.7 Average R&D Expenses as % of Total Turnover	21	
6.3.8 Total Marketing Expenses	21	
6.3.9 Overall Profit Margins	22	

6.3.10 Total Health-Related Out-of-Pocket Expenditure ('OOPE')	22
7. Comparison of Marketing Expenses Vs. R&D Expenses of the Top 7	Indian Pharma
Companies (FY10 - FY17)2	22
7.1 Summary of Expenses of Top 7 Indian Pharma Companies (FY10 -	-
FY17)	.22
7.2 Average R&D Expenses (FY10-FY17)	23
7.3 Average Marketing Expenses (FY10-FY17)	23
7.4 Averages of Marketing Expenses to R&D Expenses Ratio (FY10 -	
FY17)	24
7.5 Summary of R&D Expenses Vs. Marketing Expenses	24
7.6 Recommendations	25
7.7 Estimate of OOPE Savings on Reducing Marketing Expenses	26

1. The Commercialized Global Pharma Industry Today

During the recent years, there have been many reports of drug manufacturers worldwide, especially from USA - offering cash, gifts, sponsoring conferences¹, etc. to tempt and retain healthcare professionals (HCPs) to prescribe drugs from among their brands to their patients. Reports show that 9 out of 10 big American pharmaceutical companies spend far more on marketing than on research.² According to a statement issued by market research firm 'The Law Firm', the largest pharmaceutical companies in the U.S. spent US \$3.49 billion in just over a year (between August 2013 and December 2014) in disclosed payments to doctors, hospitals and other companies!³

Indian pharmaceutical companies are becoming unduly profit-centred in the not-for-profit mission of developing vital medical cures and distributing life-saving medicines for all. There had been exposés of deep-rooted corruption in the Indian pharmaceutical

¹ "Why there is a problem with pharma companies sponsoring medical conferences in India", Priyanka Vora, Jan 05, 2017,

https://scroll.in/pulse/825813/why-there-is-a-problem-with-pharma-companies-sponsoring-medical-conferences-in-india

² "Big pharmaceutical companies are spending far more on marketing than research", Ana Swanson, February 11, 2015,

https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.84ae49919e66

³ "Why there is a problem with pharma companies sponsoring medical conferences in India", Priyanka Vora, Jan 05, 2017,

https://scroll.in/pulse/825813/why-there-is-a-problem-with-pharma-companies-sponsoring-medical-conferences-in-india

industry.⁴ Additionally, extremely high-prices of branded drugs with large fluctuations of prices between company brands has resulted in drugs unaffordable by the Indian majority - already struggling with socio-economic and nature-related large-scale changes - including high-indebtedness, Goods and Services Tax (GST), demonetization, stagnant unemployment, climate disasters and crop failures.

On June 20, 2016, the Government of India approved of a 74% FDI limit in pharma industry allowing foreign companies to acquire upto 74% ownership of Indian pharma companies without requiring review by the government. The pharmaceutical industry caters to the life-saving domain and therefore sufficient government oversight is definitely needed to analyze undue consequences of MNC acquisitions that could adversely impact Indian drugmakers as well as result in high prices for consumers. Moreover, after such acquisitions, the Indian pharma sector may employ aggressive sales marketing strategies adopted abroad - to the disadvantage of the unsuspecting Indian consumer.

The interactions between Indian pharmaceutical companies and medical practitioners is increasingly under scrutiny. A recent study revealed that medical representatives have a lot of undue influence on physicians in prescribing drugs and that these salesmen over-emphasize benefits and suppress any mention of risks in their medicines. Studies by the Reserve Bank of India (See RBI Report, dated 24.08.2017) reveal that medical emergencies expenditure are usually the second-largest reason for debt in India. Consumer organizations have been analyzing problems of unethical drug promotions and high prices of drugs to see if drug companies allot sufficient budgets for drug research so as to develop good quality and safe drugs affordable by the poor and the middle classes.

On December 18, 2017, the National Pharmaceutical Pricing Authority ('NPPA') (i.e., the government regulatory agency formed 29th August, 1997 to control the prices of pharmaceutical drugs in India; http://www.nppaindia.nic.in) fixed/revised ceiling prices/Retail prices of 65 scheduled formulations under the Drugs (Price Control) Order.

⁴ "Pharma industry has a deep culture of corruption", THE HINDU BusinessLine, December 3, 2013, http://www.thehindubusinessline.com/opinion/pharma-industry-has-a-deep-culture-of-corruption/article541 8237.ece

⁵ The new pharma FDI policy undermines Indian generics, which may make drugs more expensive "June 28, 2016,

https://scroll.in/pulse/810499/the-new-pharma-fdi-policy-undermines-indian-generics-which-may-make-drugs-more-expensive

⁶ "Risky Medicine: Why FDI in India's Generic Drugs Industry Could be a Bad Idea", 20/07/2016, https://thewire.in/51899/domestic-global-risks-eased-direct-foreign-investments-indias-generics-industry/

⁷"A study on the interactions of doctors with medical representatives of pharmaceutical companies in a Tertiary Care Teaching Hospital of South India", Sandeep Kumar Gupta, Roopa P. Nayak, and R. Sivaranjani, Journal of Pharmacy & Bioallied Sciences, 2016 Jan-Mar; 8(1): 47–51, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4766779/

<u>2013</u>.⁸ Similar price controls earlier were opposed by the Indian pharma companies - who bypassed capping measures by preparing drugs with different combinations and thus moved away from the purview of DPCO. Such irrational combinations, with adverse effects, flourished in the Indian Pharma market.

The main priority of policy analysts and pharma industry supporters is to insure an economic environment favorable for investors. Reducing health-related financial debt of Indians is of low priority with mainstream analysts' reports. As expected, the pharma industry supporters are predicting negative consequences from the recent price control - including reduction in medicines' supply, decrease in quality and increase in dependency with China - when, in reality, this drug price relief could be of interim help to the people struggling after the GST and demonetization shocks.⁹

This article summarises salient recommendations from four market surveys that analyzed drug promotional practices in the Indian pharmaceutical industry, including a survey by Citizen consumer and civic Action Group (CAG) (Download pdf). Further, this study calculates the Marketing expenses of seven leading Indian pharmaceutical companies and their Research and Development (R&D) expenses for the recent 8 years (FY 2009-2010 to FY 2016-2017) from Annual Reports of these seven companies (56 reports totally) and estimates their Marketing Spend to R&D Spend ratios.

2. What is "Drug Promotion"?

Drug promotion broadly refers to "all the informational and persuasive activities by the pharmaceutical industry, the effect of which is to induce prescription, supply, purchase, and use of medicinal drugs. Drug promotion includes activities of medical representatives, drug advertisements to physicians, provision of gifts and samples, drug package inserts, direct-to-consumer advertisements, periodicals, telemarketing, holding conferences, symposiums and scientific meetings, sponsoring of medical education and conduct of promotional trials". ¹⁰

https://health.economictimes.indiatimes.com/news/pharma/nppa-notifies-prices-of-65-essential-formulations/62127564 and http://www.nppaindia.nic.in/wh-new-2017/wh-new-64-2017.html

⁸"NPPA notifies prices of 65 essential formulations - NPPA has fixed/revised ceiling prices/Retail Prices of 65 scheduled formulations under Drugs (Prices Control) Order, 2013," the regulator said in a statement", PTI, December 19, 2017,

⁹"Beware price controls on medicines: It will deter pharma industry and choke the supply of quality products", December 16, 2017, Ritesh Singh, TOI,

https://blogs.timesofindia.indiatimes.com/toi-edit-page/beware-price-controls-on-medicines-it-will-deter-ph arma-industry-and-choke-the-supply-of-quality-products/

¹⁰Lal, Avtar. (2001). "Pharmaceutical Drug Promotion: How it is being Practiced in India?", The Journal of the Association of Physicians of India. 49. 266-73,

3. 2 Pharma Promotion-Related Regulations

- A. Code of Ethics Regulations from the Medical Council of India: This code called Code of Ethics Regulations (Professional Conduct, Etiquette, and Ethics Regulations, 2002) (amended upto 8th October 2016) from the Medical Council of India is legally binding on medical practitioners. (See Code of Ethics Regulations, 2002). This regulation describes the duties and responsibilities of physicians, ethics of their conduct to patients, other physicians, to the public and allied medical professionals (pharmaceutical companies and device manufacturers). Section 6.4.1 ("Rebates and Commission") restricts medical practitioners from accepting gifts from pharmaceutical companies.
- B. Uniform Code of Pharmaceutical Marketing Practices (UCPMP): This code, issued by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers (Government of India), is voluntary in its present form, but the Government has been debating on and off whether to make it compulsory or notif not effectively implemented by pharmaceutical companies after 6 months from the date of issue, i.e., 01.01.2015. This code stipulates that a drug must not be promoted without prior marketing approval from the competent authority authorizing its sale and supply. It instructs drug companies to provide accurate, balanced, fair and objective information on drugs. It provides guidelines regarding supply of drug samples and redressal mechanisms for resolving ethical conduct-related complaints. It specifies guidelines to medical representatives to avoid ambiguous and misleading information in their literature and advertising campaigns. The 2016 notification includes medical device manufacturers among the companies that need to comply (See UCPMP PDF, <a href="Recent UCPMP Notification dated 30.08.2016).

A revised final draft of the UCPMP has been sent by the Department of Pharmaceuticals to the Law Ministry in December 2017 and is expected to get enforced soon. As per this draft, UCPMP would be brought under the ambit of Essential Commodities (EC) Act (1955) and any company violating the Code will be penalized as per the EC Act. ¹¹

https://www.researchgate.net/publication/12106594_Pharmaceutical_Drug_Promotion_How_it_is_being_Practiced in India

 $^{{\}color{blue} {}^{11}} \underline{\text{https://www.livemint.com/Industry/QPdAkmblaEHTqGcX1xTggK/Code-for-pharma-marketing-practices-may-be-enforced-soon.html} \\$

4. Pharma-Related Consumer Guidance

In the year 2011, Dr. Suchitra Ramkumar, Trustee at CAG, had prepared a guidance set (i.e., "CAVEATS") for educating consumers in evaluation and purchase of medical drugs. See Cost of Medical Drugs, Medical Drug Price Regulation, Consumer Guidelines for Purchase of Medical Drugs, Irrational Combinations, Pharmaceutical Marketing and Promotions.

(<u>Authors' Note</u>: A few time-dependent information may have changed since the time of writing. However, core advise and guidelines are valid now also.)

5. 4 Pharma-Related Surveys

- 1. <u>Ernst & Young Survey</u>: A two-part survey of 100 respondents was conducted by audit firm Ernst and Young in September 2011 on pharma ethics (<u>Download Report</u>). The first part of the survey questioned marketing professionals in the pharma sector on their knowledge of UCPMP code. The second part of the survey questioned medical practitioners on their knowledge of the Medical Council of India's code of conduct of interactions between doctors and the pharmaceutical and allied healthcare companies. The survey (conducted telephonically with the help of a market survey agency) revealed the following¹²:
 - **About 72%** felt that the Medical Council of India (MCI) was not stringently enforcing its medical ethics guidelines.
 - Only 36% felt that the MCI's guidelines would have any impact on the overall sales of pharma companies.
 - About 67% believed that implementation of UCPMP would influence the pharma marketing in India.
 - *More than 50%* felt that the UCPMP's guidelines may lead to manipulation in recording of actual sampling activity.
 - More than 50% indicated that the effectiveness of the UCPMP code will be very low in the absence of legislative support provided to the UCPMP committee.
 - A high majority (90%) felt that pharma companies need to focus on building strong internal controls system for ensuring compliance with the UCPMP.
- 2. <u>Mumbai Study</u>: A close tie-up between drug manufacturers, chemists and doctors in India at the cost of consumers was revealed by a study conducted in

http://www.ey.com/in/en/services/assurance/fraud-investigation---dispute-services/pharmaceutical-marketing---ethical-and-responsible-conduct

¹²"Pharmaceutical marketing: ethical and responsible conduct - A survey on effectiveness of the guidelines"

Mumbai.¹³ In this survey, open-ended interviews with 15 senior executives in drug companies, 25 chemists and 25 doctors as well as group discussions with 36 medical representatives were conducted. It was seen from this study that the nexus between drug companies, pharmacists and doctors, and medical representatives that led to many unethical drug promotion practices was well-organized and highly methodical. Medical representatives were seen playing major roles here. The study asserted that the people ultimately bear health and price-related consequences due to such 'unholy alliances'. Researchers conclude that better industry regulation involving doctors, pharmaceutical companies, chemists and the common people can help prevent such tie-ups.

- 3. Pharma Research by CAG, Chennai: A research study to quantify the effects of drug promotions by pharma companies on Indian consumers was conducted by CAG, with valuable assistance by the Federation of Medical Representatives Association of India (FMRAI), Chennai. This survey included doctors, pharmacies, medical representatives, the common public and hospitals. Key observations from this survey are listed below.
 - 1. There are numerous brands in the market for the same drug doctors struggle to isolate the most suitable brand to prescribe to patients. Additionally, it is perhaps because of many irrational drug combinations that drug prices are increased excessively.
 - 2. There is extremely high variation in drug prices across different drug brands.
 - 3. Survey respondents asserted strongly that drug prices must be regulated.

 It is ironic that the brands with the largest market share are also the maximum-priced a clear consequence of aggressive marketing practices by pharma companies.
 - (<u>Author's Addenda</u>: Drug pricing by pharma companies should consider the reality in India where 22% of the population are below the official poverty limit categorized as 'BPL' ('Below Poverty Line').¹⁴
 - 4. Drug prices have not stabilized to affordable levels despite the claims by the pharma industry that free-market based open competition without price controls would facilitate the evolution of low drug prices. The Government of India must take concrete steps to regulate drug prices.
 - 5. The cost of these drug promotions by companies are ultimately borne by the consumer.
 - 6. Promotions by drug companies need to be regulated as done in some of the other countries.

(Author's Addenda:

¹³ Roy N1, Madhiwalla N, Pai SA., "Drug promotional practices in Mumbai: a qualitative study", https://www.ncbi.nlm.nih.gov/pubmed/18630221

¹⁴ "Poverty in India", Wikipedia, https://en.wikipedia.org/wiki/Poverty in India (accessed on 05/12/2017)

- The World Health Organization (WHO) has issued ethical guidelines for promotion of medicinal drugs titled "Ethical Criteria for Medicinal Drug Promotion" (Geneva, 1988) (<u>Download PDF</u>-<u>WHO's guidelines</u>).
- The Code of Practice from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) (established in 1981, latest revision in 2012) has become a well-accepted international model code adapted by all countries.
- USA's Foreign Corrupt Practices Act (FCPA) and Bribery Act (U.K.) too have global reach to some extent.
- The European Federation of Pharmaceutical Industries and Associations (EFPIA)'s <u>Code of Practice</u> represents the voice of the pharma industry in Europe.¹⁵
- In addition to regional and international regulations, countries implement their National Codes of Practice of IFPMA-Affiliated Associations and National Company Codes of conduct.)
- Citizen consumer and civic Action Group (CAG) drafted rules to prevent the unethical practices in the promotion of drugs by pharmaceutical companies, to be incorporated under the Drugs and Cosmetics Act, 1940, and presented it in a National Seminar. The rules were then forwarded to the Department of Pharmaceuticals for necessary action. Later, it was shared with All India Drug Action Network (AIDAN) for further action.
- 7. Significant cash payments and gifts were being given by companies to convince doctors to prescribe their company's drugs to consumers. The Top 50 drug companies in India spend about 18.56% of their income on selling expenses which is the highest among all manufacturing activities! The survey thus raises ethical questions on whether the pharma industry is overly-commercialized and if medicinal drugs are marketed the same way as ordinary consumer goods.
- 4. <u>Literature Review and Financial Analysis (by CAG)</u>: A literature study and analysis of top Indian pharma companies was carried out by CAG Intern, Sudha Periasamy. (Read report summary here: <u>Ethics in Drug Promotion</u>, <u>Drug Promotion in Mumbai</u>, <u>Financial tables</u>).

¹⁵ "Ethical pharmaceutical promotion and communications worldwide: codes and regulations", Jeffrey Francer, Jose Zamarriego Izquierdo, Tamara Music, Kirti Narsai, Chrisoula Nikidis, Heather Simmonds and Paul Woods; *Philosophy, Ethics, and Humanities in Medicine*; 2014, 9:7, https://peh-med.biomedcentral.com/articles/10.1186/1747-5341-9-7.

6. Pharma Sector Market Snapshots (Global, USA, and India)

6.1 Global Pharma Sector

6.1.1 Total Global Pharma Revenue

Global Pharma Revenue (USD)	Year
390.20 billion	2001
963 billion	2011
Over 1 trillion	2014
1.4 trillion	2021 (Forecast)

(Sources:

- 1. https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/)
- 2. https://www.statista.com/statistics/280572/medicine-spending-worldwide/

6.1.2 Total Global Spending on Medicines

= US\$ 887 billion (2010)

(Source:

https://www.statista.com/statistics/280572/medicine-spending-worldwide/)

6.1.3 Per Capita Pharmaceutical Spending - Country-Wise Ranking

Year 2016

United States	US\$1112
Canada	US\$ 787
Japan	US\$783
Germany	US\$ 741
Switzerland	US\$730
Ireland	US\$703

France	US\$ 656
--------	----------

Source:

https://www.statista.com/statistics/266141/pharmaceutical-spending-per-capita-in-selected-countries/

Year 2014

United States	US\$1112
Canada	US\$772
Germany	US\$ 741
France	US\$ 659
Japan	US\$782 (2013 data)
Norway	US\$ 457
Portugal	US\$399
Denmark	US\$325

Source:

https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/ (Data from OECD)

6.1.4 Total Global Pharmaceutical R&D Spending¹⁶

- = US\$ 157 billion (2016)
- = US\$ 180 billion (Forecast for 2022)

6.1.5 Top 10 Global Pharma Companies by R&D Expenses and Prescription 'Rx' Sales (2016)

TABLE (A)

Company R&D Spend (2016) Rx Sales (2016)
--

¹⁶ "Total global pharmaceutical research and development (R&D) spending from 2008 to 2022 (in billion U.S. dollars)", https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/

	(US \$ millions)	(US \$ millions)
Pfizer (New York, USA)	7841	45,906
Novartis (Basel, Switzerland)	7916	41,554
Roche (Basel, Switzerland)	8717	39,552
Merck & Co. (Kenilworth, USA)	9760	35,563
Sanofi (Paris, France)	5722	34,174
Johnson & Johnson (New Brunswick, USA)	6967	31,671
Gilead Sciences (Foster City, USA)	3925	29,992
GlaxoSmithKline (Brentford, England)	4697	27,775
AbbVie (North Chicago, USA)	4152	25,299
Amgen (Thousand Oaks, USA)	3755	21,892

(Source: Pharmaceutical Executive)

http://nordic.businessinsider.com/largest-pharmaceutical-companies-by-prescription-sales-and-rd-2017-7/

TABLE (B) (Another Data Source)

COMPANY	PRESCRIPTION SALES (US\$ BN)	R&D SPEND (US\$ BN)
Pfizer (US)	45.91	7.84
Novartis (Swiss)	41.55	7.92
Hoffmann-La Roche (Swiss)	39.55	8.72
Merck (US)	35.56	9.76
Sanofi (France)	34.17	5.72

Johnson & Johnson (US)	31.67	6.97
Gilead Sciences (US)	29.99	3.93
GSK (UK)	27.78	4.70
AbbVie (US)	25.30	4.15
Amgen (US)	21.89	3.76
AstraZeneca (UK)	20.97	5.63
Allergan (US)	18.60	2.85

Source: "Top 50 global pharmaceutical companies by prescription sales and R&D spending in 2016 (in billion U.S. dollars)",

https://www.statista.com/statistics/273029/top-10-pharmaceutical-companies-sales-and-rundd-spending-in-2010/

6.1.6 Total Global Pharmaceutical Marketing Spending

- = US\$ 70.7 billion (2014)
- = US\$ 85 billion (2013)

6.1.7 R&D Expenses Vs. Marketing Expenses of World's Largest Pharma Firms (2014)

Company	Total Revenue (Us\$ Bn)	R&D Spend (Us\$ Bn)	Sales And Marketing Spend (Us\$ Bn)	Profit (Us\$ Bn)	Profit Margin (%)
Johnson & Johnson (US)	71.3	8.2	17.5	13.8	19
Novartis (Swiss)	58.8	9.9	14.6	9.2	16
Pfizer (US)	51.6	6.6	11.4	22.0	43
Hoffmann-La Roche (Swiss)	50.3	9.3	9.0	12.0	24
Sanofi (France)	44.4	6.3	9.1	8.5	11

Merck (US)	44.0	7.5	9.5	4.4	10
GSK (UK)	41.4	5.3	9.9	8.5	21
AstraZeneca (UK)	25.7	4.3	7.3	2.6	10
Eli Lilly (US)	23.1	5.5	5.7	4.7	20
AbbVie (US)	18.8	2.9	4.3	4.1	22

(Source: GlobalData)

"Pharmaceutical industry gets high on fat profits", Richard Anderson, Business reporter, BBC News, 6 November 2014, http://www.bbc.com/news/business-28212223

6.2 USA's Pharma Sector

6.2.1 Market Size: US\$ 446 billion (2016)

6.2.2 Market Share: 45% of the global pharmaceuticals market

(Source: "U.S. Pharmaceutical Industry - Statistics & Facts" https://www.statista.com/topics/1719/pharmaceutical-industry/)

6.2.3 Growth Rate: 5% per annum (Forecast for 2015-2020)

6.2.4 Total Nominal Spending on Medicines (2002-2016)

Total Spending on Medicines in USA (US\$, Billions)	Year
195	2002
316	2010
425	2015
450	2016

(Source:

https://www.statista.com/statistics/238689/us-total-expenditure-on-medicine/)

6.2.5 R&D Expenditure of U.S. Pharma (1995-2015)

Total R&D Spending by the Pharma Sector in USA (US\$, Billions)	Year
60 (approx.)	2017*
53.25	2014**
67.4	2010
47.6	2004

^{*} https://www.statista.com/topics/1719/pharmaceutical-industry/ (Source:

https://www.statista.com/statistics/265085/research-and-development-expenditure-us-pharmaceutical-industry/)

6.2.6 Average R&D Expenses as % of Total Revenue

Average R&D Expenses as % of Total Revenue = 14.4% (1990) (Includes PhRMA* Members Only)

* Pharmaceutical Research and Manufacturers of America ('PhRMA') represents the leading bio-pharmaceutical researchers and biotechnology companies in U.S.A (See http://www.phrma.org).

(Source:

https://www.statista.com/statistics/265100/us-pharmaceutical-industry-spending-on-research-and-development-since-1990/)

6.2.7 Total Spending on Medicines by Americans

Americans spend much more than people in most other countries on prescribed drugs. A report, titled *'Health at a Glance 2015'* from the Organisation for Economic Cooperation and Development (OECD) showed that the total pharmaceutical spending by OECD countries in 2013 was \$800 billion while the US' medical spending was the highest and double the OECD average.¹⁷

^{**} International Federation of Pharmaceutical Manufacturers & Associations, https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf

¹⁷ "Americans are by far spending the most on pharmaceuticals", AKIN OYEDELE, Nov. 4, 2015, https://www.businessinsider.in/Americans-are-by-far-spending-the-most-on-pharmaceuticals/articleshow/49661815.cms

Total Money Spent by Americans on Medicines (US\$, billions)	Year
325	2015
374	2014 (4.3 billion prescriptions were filled)
329.20	2013* (about \$1000 per person)

Sources:

- 1. "Americans Spent a Record Amount on Medicine in 2014" http://time.com/3819889/medicine-spending/
- 2. https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmac-eutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.97d0a8bcf20e
- 3. https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/)

6.2.8 Marketing Expenses of the U.S. Pharma Sector

<u>Study 1</u>: As per researchers - Donald Light and Joel Lexchin; <u>for every \$1 that pharmaceutical companies spend on "basic research," \$19 goes toward marketing and promotion! (See 'Pharmaceutical research and development: what do we get for all that money?' BMJ 2012, http://www.bmj.com/content/345/bmj.e4348).</u>

Total R&D Expenses, Marketing Expenses, and Marketing Expenses to R&D Expenses for Top US Pharma (Year 2013)

U.S. Pharma Company	R&D Spend, US\$ billions, (Year 2013)	Sales and Marketing Spend, US\$ billions (Year 2013)	Sales & Marketing Spend / R&D Spend
Johnson & Johnson	8.2	17.50	2.13
Novartis	9.9	14.60	1.47
Pfizer	6.6	11.40	1.73
GlaxoSmithKline (GSK)	5.3	9.90	1.87

Merck	7.5	9.50	1.27
Sanofi	6.3	9.10	1.44
Roche	9.3	9.00	0.97
AstraZeneca	4.3	7.30	1.70
Lilly	5.5	5.70	1.04
Abbvie	2.9	4.30	1.48

Sources:

- "Pharma Companies Spend 19x more on Marketing than Research, and Returns are Dropping - Drug prices are going up while R&D spending is going down" http://naturalsociety.com/research-development-new-drugs-not-paying-off-6321/)
- 2. http://naturalsociety.com/90-big-pharma-spent-marketing-research-2013-alone/

<u>Study 2:</u> As per the study done by Julie M. Donohue, Marisa Cevasco et al. ("A Decade of Direct-to-Consumer Advertising of Prescription Drugs", The New England Journal of Medicine, Volume 357, #7 (August 16, 2007): 673-681),

Total Advertising and Marketing Spend of U.S. Pharma

- = US\$29.9 billion (2005)
- **= US\$11.4 billion (1996)**

Study 3: IMS (a firm specializing in pharma market intelligence and considered as an authority for assessing pharmaceutical promotion expenditures) estimates expenditures as below:

Total R&D Spend of US Pharma = **US\$29.6 billion (2004)**Total Marketing Spend of US Pharma = **US\$27.7 billion (2004)**

<u>Study 4</u>: In a study by Marc-André Gagnon & Joel Lexchin ("The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States", PLoS Med, Volume 5, Issue 1 (January 2008): 29-33)

Total Advertising and Marketing Spend of U.S. Pharma (<u>including meetings and e-promotions</u>) = **US\$57.5 billion (2005)**

The researchers conclude the study with a new estimate of Marketing spend at **US\$57.5 billion** and assert that pharmaceutical companies spend almost twice as much on promotion as they do on R&D. **These numbers clearly show how promotion**

predominates over R&D in the pharmaceutical industry, contrary to the industry's claim.

(Source: "Pharma 2020: Marketing the future - Which path will you take?", PricewaterhouseCoopers, (2009),

https://www.pwc.com/gx/en/pharma-life-sciences/pdf/ph2020-marketing.pdf).

Total R&D Expenses and Marketing Expenses of US Pharma Sector (Year-wise)

Year	Total R&D Spend of U.S. Pharma	Total Advertising and Marketing Spend of U.S. Pharma
2017	US\$60 billion (nearly)	
2014	US\$ 53.25 billion	
2012		US\$27.35 billion*
2010	US\$ 67.4 billion	
2005		US\$29.9 billion
2004	US\$29.6 billion	US\$27.7 billion
1996		US\$11.4 billion

*(Source: Cegedim Strategic Data Estimates, https://www.emarketer.com/Article/US-Pharma-Marketing-Spend-Falls-Most-Cha nnels/1009721)

6.2.9 Average Profit Margins of U.S. Pharma Companies in 2013

- Among the five main industrial sectors namely (Banks, Car-makers, Oil and Gas, Media and Pharmaceuticals), the highest was the pharma giant 'Pfizer' with 42% profit margin!
- In 2013, the five pharmaceutical companies (Pfizer, Hoffmann-La Roche, AbbVie, GlaxoSmithKline (GSK) and Eli Lilly) made a profit margin of 20% or more.
 Source: "Pharmaceutical industry gets high on fat profits", Richard Anderson, Business reporter, BBC News, 6 November 2014 http://www.bbc.com/news/business-28212223

6.3 Indian Pharma Sector

6.3.1 Indian Pharma Industry Facts¹⁸

- Robust growth over the last 25 years, from a turnover of approx. US \$1 billion in 1990 to above US \$30 billion in 2015 of which the export turnover is approximately US \$15 billion
- Ranks 3rd worldwide by volume of production and 14th by value
- Accounts for around 10% of world's production by volume and 1.5% by value
- Globally ranks 4th in terms of generic production
- 17th in terms of export value of bulk actives and dosage forms

6.3.2 Indian Pharma Sector Landscape

- The organized sector of India's pharma industry is made of 250 to 300 companies
- These account for **70**% of products on the market with the top 10 firms representing 30 percent
- Total pharma sector has about **20,000 businesses**, including micro-level enterprises
- Approximately 75% of India's demand for medicines is met by local manufacturing.

Source: "The Indian Pharmaceutical Industry: Collaboration for Growth', (2006), KPMG, https://www.in.kpmg.com/pdf/Indian%20 Pharma%20Outlook.pdf

6.3.3 Overall Indian Pharma Sector's Market Size

US\$ in Millions	Year
100	2025 Forecast
55	2020 Forecast*
27.57	2016
20	2015
23	2012
20.95	2011
23	2002

¹⁸ Pharma Industry Promotion", Department of Pharmaceuticals, Government of India, http://www.pharmaceuticals.gov.in/pharma-industry-promotion

Sources:

- 1. https://www.ibef.org/industry/pharmaceutical-india.aspx
- http://info.shine.com/industry/pharma/2.html
 (* Estimate by consulting firm McKinsey & Company)

Indian Pharma Market Reaches Record High in 2015¹⁹

- The Indian pharmaceutical market, for the first time crossed the Rs 1,00,000 crore mark in November 2015 calculated on the basis of Moving Annual Total (MAT)
- In November 2015, the Indian pharma market was at Rs 1,00,115 crore, of which the retail sector was valued at Rs 84,279 crore.
- On an average over the last three years, Indian pharmaceutical market has grown by 12%
- Almost 38% of the market is made of drugs that treat infections, heart ailments and patients with gastrointestinal issues

6.3.4 Growth Rates 'CAGR'²⁰

CAGR ('Compound Annual Growth Rate') %	Years
13-14	(2001-2005)
5.64	(2011 - 2016)
15.00	2016 to 2020 (forecast)

<u>Note:</u> Growth Rate of Aggregate Total Income (of 59 pharma companies for which financial data for FY16 was available) **was 11.5**%*

Source:

6.3.5 Total Indian Pharma Exports

Exports (US\$, billions)	Year
--------------------------	------

¹⁹"Indian pharma market crosses Rs 1,00,000 crore mark: IMS Health", ET Bureau, Dec 16, 2015 https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indian-pharma-market-crosses-rs-100000-crore-mark-ims-health/articleshow/50196243.cms

²⁰ http://info.shine.com/industry/pharma/2.html

^{*} India's Leading Pharmaceutical Companies 2016, Dun and Bradstreet, 2016; http://www.dnb.co.in/Publications/LeadingPharmaceutical2016/IndiasLeadingPharmaceuticalCompanies2016.pdf

40.00	FY 2019-2020 (Forecast)*
18.02	FY 2016-2017*
16.89	FY 2015-2016**
15.43	FY 2014-2015**
14.94	FY 2013-2014**
14.67	FY2012-2013**
13.27	FY 2011-2012**

Sources:

6.3.6 Total R&D Expenses of Indian Pharma Sector

Total R&D Spend (US\$ billions)	Year	Comments
1.25	2017	Rs. 8,025 crore by the top 5 drug makers (Source: Bloomberg) ²¹
1.05	2016	6 top drug makers (Source: IBEF)
0.48	2008	10 top drug makers (Source: PwC)

Pharma R&D Tally in FY2016-2017²⁰

1. Top 5 Indian drugmakers together spent a record Rs 8,025 crore in R&D in FY 2016-2017.

https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/top-five-indian-pharma-companies-together-spent-over-rs-8000-crore-on-rd-spend-in-fy17/articleshow/59049624.cms

^{*} https://www.brandindiapharma.in/uploads/documents/Pharmaceutical-June-2017.pdf)

^{**} India's Leading Pharmaceutical Companies 2016, Dun and Bradstreet, 2016; http://www.dnb.co.in/Publications/LeadingPharmaceutical2016/IndiasLeadingPharmaceuticalCompanies2016.pdf

²¹"Top five Indian pharma companies together spent over Rs 8000 crore on R&D spend in FY17", Kiran Kabtta Somvanshi, Economic Times Bureau, Jun 08, 2017

- 2. R&D Expense was 9% of the Cumulative Revenues of the top 5 pharma companies
- 3. Cumulative R&D Expenses of more than Rs 8,000 crore is more than the profit earned by the largest pharma company in FY 2016-17
- 4. Total R&D expenditure for the top five Indian companies has increased six-fold since FY10
- 5. In FY 15-16, Dr. Reddy's Labs spent around 13.8 percent of sales on R&D.

6.3.7 Average R&D Expenses as % of Total Turnover

= 8-11%

6.3.8 Total Marketing Expenses

Marketing Expenses to R&D Expenses Ratios Trends²²

Marketing to R&D Expenses Ratio for FY 2003-2004	Indian Pharma Company Ranking
289 %	Top 10
719 %	Top 11-20
1025 %	Top 21-50

Source: Economic Times,

https://economictimes.indiatimes.com/pharma-firms-rd-spend-less-than-western-majors/articleshow/957804.cms

6.3.9 Overall Profit Margins

• Profit Margins of the Top 5 Indian Pharma Companies in FY 2011-2012

Company Name	Profit Margin (as % of Sales)
Sun Pharma	32.26
Cipla	16.30
Dr. Reddy's Labs	13.33
Cadila Healthcare	12.40

²²"Pharma firms' R&D spend less than western majors", Haresh Soneji & Aayam Banerjee, https://economictimes.indiatimes.com/pharma-firms-rd-spend-less-than-western-majors/articleshow/9578 04.cms

Lupin	12.25
-------	-------

Source: "STATSGURU: Indian pharma is high on profit, low on R&D", http://www.business-standard.com/content/general_pdf/040813_04.pdf

(Data Source: Capitaline)

6.3.10 Total Health-Related Out-of-Pocket Expenditure ('OOPE')

= Rs. 3,02,425 Crores (US\$ 51.75 Billion)

(62.6% of THE, 2.4% of GDP, $\mbox{\bf Rs.}$ 2,394 per capita) for 2014-15 23

(Note: 1 US\$ = 58.441 INR on May 2014)

7. Comparison of Marketing Expenses Vs. R&D Expenses of the Top 7 Indian Pharma Companies (FY10 - FY17)

Sales Revenues, R&D Spends and Advertising/Marketing Spends for 8 years between FY 2009-2010 and FY 2016-2017 for the top 7 pharma companies were calculated from Annual Reports from their official websites. These data (**from 56 reports in all**) were consolidated for analysis. Summary tables of results found are given below. Detailed tables are in the **Datasheet**.

7.1 Summary of Expenses of Top 7 Pharma Companies (FY10-FY17)

TOTAL R&D EXPENSES	= Rs. 41,590.51 Crores
TOTAL MARKETING EXPENSES	= Rs. 34,186.95 Crores

7.2 Average R&D Expenses (FY10 - FY17)

COMPANY	Rs. in Crores
SUN PHARMA	1,164.71
DR. REDDY'S LABS	1,120.93
LUPIN	1,053.21

²³ https://mohfw.gov.in/newshighlights/national-health-accounts-estimates-india-2014-15

CIPLA	587.38
GLENMARK	524.95
CADILA HEALTHCARE LTD.	449.65
AUROBINDO PHARMA	298.00

7.3 Average Marketing Expenses (FY10 - FY17)

COMPANY	Rs. in Crores
SUN PHARMA	1,300.33
DR. REDDY'S LABS	815.75
CADILA HEALTHCARE LTD.	555.94
LUPIN	499.99
CIPLA	480.45
GLENMARK	378.12
AUROBINDO PHARMA	242.79

7.4 Averages of Marketing Expenses to R&D Expenses Ratio (FY10 - FY17)

COMPANY	Average M.Exp / R&D		OBSERVATIONS		
	<= 0.50 (GOOD)	> 0.50 , <= 0.75 (ACCEPTABLE)	> 0.75, <= 1.00 (NOT GOOD)	> 1.00 (ALARMING)	
LUPIN		0.56		-	On a continuous positive trend. Consistently < 1.00 all 8 years till now. Reduced from 0.74 to 0.32 these 8 years. At 0.32 Now.

AUROBINDO PHARMA	0.67		(On a Negative Trend <u>Now at</u> <u>1.12.</u> Gotten > 1.00 since FY 2014-2015)	Was < 0.50 between FY 2009-2010 and FY 2013-2014
DR. REDDY'S LABS		0.88	(Was above 1.00 between FY 2009-2010 and FY 2011-2012)	But on a continuous Positive Trend. Reduced from 1.37 to 0.55 now in these 8 years. At 0.55 now.
GLENMARK		0.88	-	Consistently < 1.00 since FY 2011-2012. At 0.67 now.
CIPLA		0.94	(Was above 1.00 between FY 2009-2010 and FY 2011-2012.)	At 0.77 now.
CADILA HEALTHCARE LTD.			1.11	Has been on a negative trend throughout. Was consistently > 1.00 since FY 2013-2014. At 1.38 Now.
SUN PHARMA			1.14 (Was above 1.00 between FY 2010-2011 to FY 2015-16.)	<u>At 0.98 Now.</u>

7.5 Summary of R&D Expenses Vs. Marketing Expenses

- 1. As seen from table above,
 - None of the Top 7 companies' Marketing to R&D Spend ratios perform in the 'Good' category
 - o 2 companies (Lupin and Aurobindo Pharma) are in the 'Acceptable' category
 - 3 companies (Dr. Reddy's Labs, Glenmark, Cipla) are in the 'Not Good' category
 - o 2 companies (Cadila Healthcare, Sun Pharma) are in the 'Alarming' category.

2. Lupin

 had the least Average M.Exp/R&D ratio of 0.56 i.e., 'Acceptable' category showing a stronger commitment to R&D than Marketing for these 8 years.

3. Aurobindo Pharma

- o Aurobindo's Average M.Exp/R&D ratio is **0.67 i.e., 'Acceptable'** category
- Aurobindo Pharma spent the least in Marketing among these 7 pharma majors (Rs. 1,942.33 Crores totally).

- **4. Dr. Reddy's Labs** and **Glenmark** have Average M.Exp./R&D at **0.88 (i.e., 'Not Good'** category)
 - Both are in the 'Acceptable' category (i.e., FY 2016-2017) at 0.55 and 0.67 respectively.
 - Dr. Reddy's Labs had the second highest Marketing Spend at Rs. 6,526
 Crores totally.

5. Cipla

Cipla's Average M.Exp./R&D is at 0.94; i.e., 'Not Good' category.

6. Cadila Healthcare

- o Cadila's Average M.Exp/R&D ratio is **1.11**, i.e., 'Alarming' category.
- Cadila Healthcare has been spending more on Marketing than on R&D all 4 years since the merger in FY2012-2013.

7. Sun Pharma

- Sun Pharma's Average M.Exp./R&D ratio is 1.14 i.e., 'Alarming' category and is the Highest among the 7 firms.
- Sun Pharma spent the maximum in R&D (Rs. 9317.70 Crores totally) among these 7 companies and had the Highest Marketing Spends among the 7 drug companies (Rs. 10,402.66 Crores Totally for these 8 years).

7.6 Recommendations

- It is encouraging that the Total R&D Spend by the pharma sector leaders was Rs. 41,590.51 Crores in the last 8 years (i.e., Average of 7.11% of Sales Income or 6.91% of Total Consolidated Income for past 8 years), however, it can be seen that the Top 7 pharma companies together spent Rs. 34,186.95 Crores in Sales and Marketing Spending in the last 8 years. Thus, Marketing Spending could exceed sector's R&D Spends in just a few years from now unless corrective actions are urgently taken.
- Specifically, **SUN PHARMA** and **CADILA HEALTHCARE LTD.** (both in the 'Alarming' category) need to focus on minimizing their Marketing Expenses to the 'Acceptable' category by making the interests of the "Common Good" as top priority.
- At 'Not Good' category levels, Cipla, Dr. Reddy's Labs and Glenmark should make proactive reductions in marketing spends now itself as their Marketing spending are liable to exceed R&D expenses in the coming few years.

7.7 Estimate of Health-Related OOPE ('Out-Of-Pocket Expenditure') Savings on Reducing Marketing Expenses

(ESTIMATE FOR FY16)

Total Pharma Market Size US\$ 27.57 billion	Total Pharma Market Size	US\$ 27.57 billion
---	--------------------------	--------------------

Total Pharma R&D Spend	US\$ 1.33 billion*
Total Pharma Marketing Spend	US\$ 1.01 billion**
Total Pharma Sector Profit	US\$ 7.22 billion*** At 26.2% Operating Profit Margin For FY 2015-2016 ***
Total Health OOPE	US\$ 51.75 billion****

From this estimate, we can see that if the pharma sector Marketing Expenses were reduced to \$0, the OOPE can reduce correspondingly by US\$ 1.01 billion to U\$ 50.74 billion, (i.e., by 1.95% of the present OOPE) - from the top 7 pharma companies alone - assuming that the reduction in marketing expenses to zero triggers a corresponding reduction in the pharma drug prices that cumulatively sums up to \$1.01 billion i.e. the total marketing expenses before reductions. This will help bring about direct reductions in the Indians' OOPE if pharma companies achieve these estimates.

Key:

- * R&D Spends for the top 7 pharma firms is **Rs. 8821.57 Crores (US\$ 1.33 billion)**; CAG Study (http://www.cag.org.in). See datasheet.
- ** Marketing Spends for the top 7 pharma firms is **Rs. 6679.65 Crores (US\$ 1.01 billion**). CAG Study. See <u>datasheet</u>.

http://www.careratings.com/upload/NewsFiles/SplAnalysis/Report%20on%20Pharma%20sector%20July%202017.pdf

**** "National Health Accounts Estimates for India 2014-15",

https://mohfw.gov.in/sites/default/files/National%20Health%20Accounts%20Estimates% 20Report%202014-15.pdf