Review Article

Generic giants to biotech frontiers: mapping India's pharma trajectory—part I

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Abstract

The Indian pharmaceutical industry is a large, mature, stable, and expansive global leader, recognized as the "pharmacy of the world." The industry turns out high-quality, low-cost generic medicines, catering to domestic and international markets. The government of India promotes the development of the industry with a sharp focus on the availability of quality medicines at affordable prices to its people. To maintain and excel from the present performance state, the industry needs to improve its manufacturing base and use and add more generic active pharmaceutical ingredients (APIs) and biotech drugs, including vaccines and biosimilar molecules, in its formulation kitty. In this review, efforts have been made to identify the more vibrant individual manufacturing companies in the country that contribute to more than 90% of the turnover of the production of the Indian pharmaceutical industry. Identifying the key pharma companies can facilitate providing targeted support by the government through policies, thereby strengthening the industry to increase their turnover, supplying quality drugs at affordable prices, and conducting more research and development. Another aspect of the review was to identify the APIs that are being produced in the country, as well as those that are imported, and the need to list the quantum of imports of the APIs so that steps can be explored to get some of them to be manufactured locally by imbibing suitable policy supports.

Keywords: Active pharmaceutical ingredients, biosimilars, biotech drugs, generic APIs, Indian pharmaceutical industry, vaccines

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INTRODUCTION

The products of the Indian pharmaceutical industry include generic bulk drugs, also termed generic active pharmaceutical ingredients (APIs); sera and vaccines; finished pharmaceutical formulations, including prescription medicines and over-the-counter medicines; biosimilar products, also known as similar biologics; diagnostics; and contract manufacturing activities. The government of India, from its various arms, oversees the development of the industry with a sharp focus on the availability of essential medicines for its people at affordable prices. Therefore, a rational pricing system is in place. However, because of inadequate availability of funds, R&D spending has remained low at both the government and industry levels. Therefore, there is a lack of innovative new drugs from in-country research.

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Consequently, the most recent drugs approved in the developed markets are available in India as branded products at extremely expensive prices. However, the Indian industry is poised to grow robustly, using generic APIs and biosimilars because of the rise in demand for such products (both locally and from foreign countries), which are of high quality and are sold by Indian companies at affordable prices.

India is currently manufacturing about 60,000 brands of generic formulations. Over 1000 generic APIs are produced locally, whereas over 1200 are imported and used.[1] The manufactured APIs cover multiple categories of drugs, such as analgesics, antipyretics, antirheumatics, and neuropathic pain management products; anti-allergic drugs; antibiotic and antibacterial drugs; antidiarrheals; antifungal and antiprotozoal drugs, including antimalarials; anthelmintic drugs; gastrointestinal drugs; antacids; cardiovascular drugs; antithrombotic drugs; diuretics; anti-asthmatic drugs; central nervous system stimulants; steroidal anti-inflammatory drugs; decongestants; antidiabetics; muscle relaxants; anesthetic drugs; fertility drugs and erectile dysfunction medications; vitamins; amino acids; large volume parenteral drugs; iodides; citrates; iron salts; other minerals; sera and vaccines; biosimilar products; antivirals; cancer treatment drugs; and others.

India started its fermentation-based biopharmaceutical industry by setting up its penicillin factory in Pimpri, Pune, in the public sector, and the unit went into production in 1954. Thereafter, the fermentation-based antibiotics production industry flourished heavily in the country and remained the most dominant part of the country up to the early 1980s in terms of production value. Microbe-based production of vaccines in India was started much earlier by the British Empire; the first production unit was at the Haffkine Institute, Mumbai. Dr. Waldemar Mordecai Haffkine developed vaccines for cholera and plague. The plague vaccine[2] was developed and produced at the Haffkine Institute in 1897.

Biopharmaceutical products include a wide range of biological substances used in therapy. These are derived from living organisms, natural or genetically modified organisms. The product range includes rDNA-based therapeutic proteins, biosimilars, sera and vaccines, hormones, mono- and polyclonal antibodies, fermentation-based antibiotics, blood products, gene therapies, cell therapies, and bio-diagnostics.

Modern biotech products started evolving globally after Herbert Boyer and Stanley Cohen invented the recombinant-DNA (rDNA) technique in 1973, and the techniques for the production of monoclonal antibodies by hybridoma technology by Köhler and Milstein in 1975. The first rDNA-based product, the hepatitis B vaccine, was introduced in India by Shantha Biotechnics, Hyderabad, in 1997. Thereafter, the modern biotech product-based Indian biopharmaceutical industry flourished very fast. There was strong government support, and the necessary laws for introducing such products were in place,[3] resulting in the country's fast industry growth.

India has acquired skills in developing genetically modified *Escherichia coli, Saccharomyces cerevisiae, Pichia pastoris, Hansenula polymorpha,* and Chinese hamster ovary cell lines so that the modified microbes and cell lines express rDNA-based proteins and peptides. India has also developed expertise in the multiplication of viruses in different animal and human cell lines. Currently, the country produces a wide range of therapeutic and diagnostic recombinant proteins, including several therapeutic monoclonal antibodies. India also has a vast vaccine manufacturing establishment. The turnover of Indian biopharmaceutical products was approximately Rs 32,261 crores (US$ 4.032 billion) during 2021–2022 and approximately 1.14% of the global biopharmaceutical turnover.[4] The turnover of the Indian biopharmaceutical industry is a part of the total turnover of the Indian pharmaceutical industry.

The development of the Indian pharmaceutical industry has continuously and strongly been supported by the government[5] since independence in 1947. Presently, the industry benefits from low production costs, mainly due to lower labor costs and lower expenses in clinical trials; it benefits from using a reverse logistics approach. Large local populations, a rise in income for the middle class, an increase in lifestyle-related illness, and global trade potential enable the subsistence of many companies. However, introducing newer products requires longer waiting for the expiry of the IPR. There is also a shortage of high-class skills, especially those required to introduce complex biotech drugs. Furthermore, the requirement of adherence to varying regulatory requirements across domestic and export markets, especially for modern biotech drugs, is one of the issues hindering faster progress in the industry.[6] Furthermore, foreign formulation brands hindered the sale of IPR-expired Indian brands.[7] Therefore, efforts were made to encourage the sale of a part of the formulations in generic names.[8] However, the policy could not be forced upon the industry, nor could it be implemented effectively.

Indian government policies[9] on the development and growth of the Indian pharmaceutical industry have registered a sea change over 77 years, from 1947 to 2024.

The policies are truly responsible for the development and progress of the country's pharmaceutical sector. Public sector undertakings first aimed to reduce foreign dependence on APIs. The policies framed in the late 1960s and early 1970s were built on a perturbed economic situation, on the experience of wars, and on the observations that local multinational companies (MNCs) were not ready to invest in infrastructure for APIs unless compelled to. Indian industrial laws were modified over the years to benefit the country. The Indian companies manufacturing APIs were earlier "protected" for many years by administering "cost-plus" prices on selected APIs and formulations made therefrom. This policy, found useful during earlier years, promoted inefficiency in the global context of manufacturing APIs and was required to be amended in 1991 when India joined the World Trade Organization (WTO) in 1991. The drug policies and pricing measures were then altered, intending to move toward a price monitoring regime gradually. Such measures led to a price rise of several medicines in trade, raising people's out-of-pocket medical expenses. However, the policy change brought many other economic advantages, which are not discussed here. It is stated in this context that the government fixes the ceiling prices of a variety of medications across different therapeutic categories, including those for diabetes, high cholesterol-reducing drugs, drugs for treating asthma and respiratory issues, microbial infections, anti-cancer drugs, and certain antiviral formulations, considered by the government as more essential. Until December 31, 2021, the ceiling prices of a list of 886 formulations[10] in various therapeutic categories were fixed, and the list kept varying occasionally, with time. No manufacturer of such formulations can sell such formulations above the ceiling price.

As a result of changes in the drug policies and pricing measures, fondly referred to as the liberalization of the economy, Indian policies were required to provide an equal trade playing ground to the suppliers of local or foreign APIs for the sale of their products. Consequently, a large part of the local API industry was affected and had to be closed down, as such units could not compete with the prices at which the APIs were available through imports. Interestingly, the shock was well played upon by the industry by concentrating on manufacturing APIs, where their production from India was globally competitive. Manufacturers also improved upon many earlier processes by inventing more competitive skills, identifying advantageous manufacturing starting points and measures, eventually absorbing the shock of policy change, and coming out as winners. Simultaneously, during this long period after 1991, there was immense progress in the manufacture of biopharmaceuticals, as India already had skills in handling sterile manufacturing unit operations and unit processes emanating from Indian hands-on experience in manufacturing vaccines, sera, blood products, and antibiotics by fermentation.

On the existing system of WTO rules respected by the WTO member countries, which are dedicated to fair and undistorted trade competition, the developing world, including India, may find more difficulties to operate gainfully in the context of exporting goods to the United States of America (USA), impacting adversely from the consequences of tariff policies of the present USA government. The export sales and margins of Indian pharmaceutical firms are anticipated to shrink if the USA's import duties on imported pharma products are increased. It is, however, unlikely to impose a high import duty on imported pharma products by the United States of America, as this would impact the availability of generic medicines in that country. The cost of production of generic medicines in the United States of America shall be high when compared to their costs in India. However, on this issue, a close watch must be kept, and where necessary, the industry and the government may have to explore how to minimize the adverse consequences together.

The promulgation of future Indian policies in drugs and pharmaceuticals beyond 2024 would have to be a judicial balancing act between the consumer's expectations of "fair prices" of essential medicines globally, but particularly in India, and the industry's concerns of remaining financially healthy while ensuring a strong API production base in India.

WHY THIS PAPER?

The Indian pharmaceutical industry faces several challenges, such as dependence on imports for the manufacture of a large number of generic APIs; inadequacy of R&D funds for conducting research for discovering novel APIs; quality control issues in the products turned out and marketed; concerns about the existing laws on intellectual properties in some situations; regulatory hurdles and delays for the fast introduction of generic APIs and novel formulations; and, on the top, facing fierce global competition. This paper is a review of identifying the more vibrant individual manufacturing companies in the country that contribute to more than 90% of the turnover of the production of Indian pharmaceutical industry; the identification of the generic APIs manufactured in the country; the quality control issues requiring improvement for enhancement of the performance of the industry; the limitations of the existing laws on intellectual properties; and the current

regulatory hurdles and delays for the fast introduction of generic APIs so that the industry becomes stronger and achieves a more dominant position in the international generic pharmaceutical market.

As the canvas and the contents in the canvas are anticipated to be large, the review is divided into two parts. In the first part, full attention has been paid to identifying and exploring the companies contributing to 90% or more of the industry's total turnover. By focusing on the major players, policymakers and industry stakeholders can develop strategies that promote a more robust and globally impactful Indian pharmaceutical industry. Economically, it would allow for targeted investment strategies, focusing on the key players driving growth and export success, which are crucial issues, given India's strong global position in low-cost generics and medicine supplies. This knowledge would also facilitate more efficient resource allocation within the industry and government support programs. It would enhance transparency and accountability within the sector and enable better drug pricing and availability monitoring, impacting public health outcomes.

In the second part of the review, the quality control issues requiring improvement to enhance the industry's performance, the limitations of the existing laws on intellectual property, and the current regulatory hurdles and delays to fast-track the introduction of generic APIs so that the industry becomes stronger and achieves a more dominant position in the international generic pharmaceutical market have been discussed. Strengthening R&D in specific areas in India has been suggested besides other areas nationally identified.

METHODOLOGY OF THE STUDY

The relevant information on all the above issues has been collected from the Google Search engine by consulting the web pages of relevant information. The information on the web pages of the relevant government departments, the international agencies like WHO, USFDA, and the European Medical Agency, and information provided by the companies operating in India on their web pages were exhaustively consulted. The author has hands-on experience in dealing with the Indian drugs and pharmaceuticals industry and the Indian biotech industry in his government service for over 30 years. He has also worked in senior positions in the public sector and private pharmaceutical units for many years.

INDIAN PHARMACEUTICAL COMPANIES AND MANUFACTURING PREMISES

It is estimated that about 3000 registered individual pharmaceutical companies manufacturing allopathic medicines, in their manufacturing facilities, are spread all over the country in its 28 states and eight union territories. As per the information provided by the Central Drugs Standard Control Organization, the numbers[11] of pharmaceutical drug manufacturing premises/facilities, state/UT-wise, in India on May 29, 2020, were 8532. The manufacturing facilities have increased thereafter and are estimated to be about 10,500.

Among the pharmaceutical companies, there are about 100 companies that also produce biopharmaceuticals, some exclusively, while others have an independent manufacturing wing. The manufacturers of biopharmaceuticals include vaccines and biosimilar products; these companies convert their bulk biopharmaceutical products into finished formulations and offer the finished formulations for sale. It is estimated that there are also nearly 9000 biotech startups,[12] promoted by the government and other agencies. About 100 registered individual pharmaceutical companies manufacture APIs. Most API manufacturers also have pharmaceutical formulation manufacturing outfits.

The annual turnover of the Indian pharmaceutical companies during 2023–2024 was reported by the government at Rs 417,345 crores (USD 50.28 billion) with an annual growth rate of 10% over the previous year.[13] This figure is assumed as the 2023 turnover in this study, and for 2024, it is projected at Rs 459,080 crore (USD 55.31 billion) from government-reported figures, as above.

A few public and private sector companies manufacture and supply finished pharmaceutical formulations for the Pradhan Mantri Bhartiya Janaushadhi Pariyojana,[13,14] where the product basket comprises over 2000 formulations. It is anticipated that the turnover of such companies are already included in the total government turnover, as reported in annual turnover figures.

While the above government-reported total figures indicate the aggregated annual turnover of the Indian pharmaceutical industry, the unit components of the Indian pharmaceutical industry turnover contributed by each of the about 3000 registered individual pharmaceutical companies are not known. The reported turnover is anticipated to cover the turnover of allopathic drugs and pharmaceuticals only, including sales turnover of APIs and pharmaceutical formulations, including biopharmaceutical products.

To assess the individual turnover of Indian drug and pharmaceutical manufacturers in India producing allopathic

drugs, the data on sales turnover and profit after tax (PAT) information were collected for each of the major producers of pharmaceuticals in the country from the secondary information of turnover and profitability figures reported in the websites of listed companies at Money Control.[15] The Money Control website is owned by M/s Money Control Dot Com India Limited, Mumbai, a private company owned by the Reliance Group.[16] The information for the non-listed companies was collected from various other published sources, some of which are available on the Google Search engine. However, the information provided for the non-listed companies may have more errors. There's a significant difference in the financial information between listed and unlisted companies. Listed companies are required by regulatory bodies like securities and exchange board of India to disclose detailed financial and operational data regularly, promoting transparency and investor confidence. On the contrary, the unlisted companies have more privacy as they are not obligated to share such comprehensive financial reports. In this report, in a few cases, intelligent projections were made on information about the unlisted companies from available old information on the internet.

Individual turnover and PAT could be collected and collated from 152 major companies only, which are listed in Table 1. There are a set of multiple other sectors, such as herbal medicines, *in vitro* diagnostic reagents, blood testing laboratories,

Table 1: Pharmaceutical companies with turnover and PAT 2024 and 2023 (Rs crores)

Sr. No.	Name of company	Turnover 2024	Net profit (PAT) 2024	Turnover 2023	Net profit (PAT) 2023
1	Sun Pharma	48,496.00	9648.00	43,885.00	8560.00
2	Aurobindo Pharma	29,001.00	3186.00	24,855.00	1939.00
3	Dr. Reddy's Lab	28,011.00	5563.00	24,669.00	4470.00
4	Cipla Ltd	25,774.00	4155.00	22,753.00	2835.00
5	Lupin Lab	20,010.00	1935.00	16,641.00	447.00
6	Zydus Life	19,547.00	3831.00	17,237.00	2001.00
7	Biocon Ltd	14,755.00	1382.00	11,174.00	810.00
8	Glenmark	11,813.00	−1830.00	12,990.00	377.00
9	Serum Institute	9142.00	3756.38	10,190.00	4187.00
10	Torrent Pharma	10,727.00	1656.00	9620.00	1245.00
11	Mankind Pharma	9264.00	1823.00	8127.00	1248.00
12	Piramal Pharma	8171.00	−41.00	7081.00	−240.00
13	Divis Labs	7845.00	1600.00	7767.00	1823.00
14	Ipca Lab	7705.00	529.00	6244.00	491.00
15	Jubilant Pharmova	6702.00	48.00	6281.00	−77.00
16	AlembicPharma	6228.00	616.00	5652.00	372.00
17	Abbott India	5848.00	1201.00	5348.00	949.00
18	MSN Lab	5810.00	1100.00	5310.00	1999.00
19	Aristo Pharma	5184.00	1466.00	4640.00	1355.00
20	Laurus Labs	5040.00	168.00	6040.00	796.00
21	Granules India	4506.00	405.00	4511.00	516.00
22	Ajanta Pharma	4208.00	816.00	3742.00	587.00
23	Gland Pharma	4334.09	1043.33	3856.99	775.83
24	Strides Pharma	4051.00	27.00	3688.00	54.00
25	Natco Pharma	3998.00	1388.00	2707.00	715.00
26	Ajanta Pharma	3971.12	807.24	3411.27	558.72
27	Entero Health	3922.00	39.00	3300.00	−11.00
28	J B Chemicals	3484.00	552.00	3149.00	410.00
29	Glaxo Smith Kline	3453.00	589.00	3251.00	607.00
30	Alchem Lab	3414.00	701.00	3031.00	550.00
31	Emcure Pharma	3497.00	160.00	3107.00	160.00
32	Sanofi India	2851.00	603.00	2770.00	620.00
33	Wockhardt	2798.00	−472.00	2651.00	−621.00
34	Dishman Carbogen Amcis	2615.00	−153.00	2412.00	−29.00
35	Cadila Pharma	2500.00	12.00	2523.00	12.00
36	Aarti Drugs	2528.00	171.00	2716.00	166.00
37	Glenmark Life/Alivas	2283.00	470.00	2161.00	466.00
38	Biological E	2235.00	558.00	3820.30	953.00
39	Pfizer	2193.00	551.00	2424.00	623.00
40	Marksans Pharma	2177.00	314.00	1852.00	265.00
41	IOLChem & Phar	2132.00	134.00	2217.00	139.00
42	Eris Lab	2009.00	397.00	1685.00	374.00
43	Nectar Lifesciences	1925.83	5.00	1746.56	−22.46
44	Vaniti Organics	1899.00	322.00	2084.00	457.00
45	Aarti Pharma Lab	1852.00	216.00	1945.00	193.00

Table 1. Continued

Sr. No.	Name of company	Turnover 2024	Net profit (PAT) 2024	Turnover 2023	Net profit (PAT) 2023
46	Indoco Remedies	1817.00	97.00	1668.00	142.00
47	Hikal	1784.00	69.00	2023.00	78.00
48	Caplin Pharma	1694.00	461.00	1466.00	376.00
49	Morphen Lab	1690.00	96.00	1417.00	38.00
50	Nectar Life	1684.00	5.00	1523.00	−24.00
51	Neuland Lab	1558.00	300.00	1191.00	163.00
52	Akums Drugs	1444.00	−165.00	1286.00	125.00
53	Anthen Biosciences	1419.00	517.00	1056.00	385.00
54	Polymedi Cure	1375.00	255.00	1115.00	177.00
55	Indian Immuno	1359.00	194.34	1234.00	176.46
56	Sequent Scientific	1369.00	−29.00	1420.00	−121.00
57	Astra Zeneca	1295.00	161.00	1002.00	99.00
58	Solara Active Phar	1288.00	−566.00	1443.00	−22.00
59	Ind-Swift Lab	1280.00	421.00	1207.00	47.00
60	Procter & Gamble Health	1151.00	200.00	1229.00	229.00
61	Shilpa Madicare	1151.00	36.00	1050.00	−27.00
62	Innova Captab	1081.00	94.00	926.00	67.00
63	Suven Pharma	1051.00	300.00	1340.00	411.00
64	Tirupati Medicare	1050.00	77.34	964.52	39.06
65	Middley Pharma	1040.00	73.00	896.00	142.00
66	Concord Biotech	1016.00	304.00	888.20	62.63
67	Zeta Formulation	893.12	119.82	816.20	21.94
68	Innovio Captab	863.06	68.16	857.86	57.55
69	Orchid Pharma	819.00	95.00	665.00	55.00
70	Gufic Bio	806.00	86.00	690.00	79.00
71	Bliss GVS	770.00	81.00	751.00	76.00
72	TTK Health	752.00	62.00	725.00	44.00
73	Fourrts	730.00	40.00	698.65	38.08
74	Valiant Organic	723.00	−6.00	1051.00	102.00
75	Bluejet Health Care	711.00	163.00	720.00	160.00
76	SMS Pharma	709.00	49.00	522.00	3.00
77	Ami Organics	687.00	43.00	616.00	83.00
78	Malladi Drugs	652.45	75.43	600.25	61.41
79	Sentis Pharma	650.00	180.00	612.80	173.30
80	Anuh Pharma	647.00	60.00	527.00	36.00
81	Alivas Life	641.00	136.00	506.00	95.00
82	Windlas Biotech	630.00	58.00	513.00	42.00
83	Advanced Enzyme	623.00	136.00	540.00	103.00
84	Kopran	614.00	50.00	550.00	27.00
85	Gufic Bio	806.00	86.00	699.00	79.00
86	Venus Remedies	601.00	28.00	555.00	26.00
87	RPG Life	582.00	87.00	512.00	67.00
88	Lincon Pharma	580.00	93.00	510.00	72.00
89	Wanbury	575.00	55.00	499.00	−10.00
90	Supriya Life Sci	570.00	119.11	460.00	89.86
91	Panacea Biotech	559.00	−1.00	459.00	−33.00
92	Penam Lab	531.83	53.70	508.05	44.12
93	FDC	513.00	72.00	638.00	119.00
94	Dishman Carbogen	510.00	87.00	478.00	58.00
95	Bajaj Health	473.00	−14.00	673.00	43.00
96	Unichem Lab	462.00	30.00	446.00	9.00
97	Astec Life Sciences	458.00	−46.00	628.00	25.00
98	Torque Pharma	450.00	55.00	401.20	49.18
99	Amrutanjan Heal	421.00	44.00	379.00	39.00
100	Aarey Drugs	395.00	4.00	418.00	3.00
101	Themis Medicare	381.00	24.00	354.00	43.00
102	Mangalam Drugs	368.00	−9.00	372.00	1.00
103	ZIM Lab	367.00	17.00	398.00	24.00
104	Albert David	362.00	75.00	341.00	36.00
105	Meficef Pharma	350.00	6.25	327.00	4.70
106	FredumPharmace	348.00	15.00	275.00	10.00
107	NGL Fine Chemic	338.00	41.00	278.00	20.00
108	Bal Pharma	339.00	7.00	304.00	2.00
109	Novartis India	335.00	85.00	378.00	103.00
110	Fermenta Biotech	315.24	−18.74	336.48	−57.53
111	Sigachichi Industries	317.00	41.00	290.00	41.00
112	Kwality Pharma	307.00	23.00	251.00	19.00

Table 1. Continued

Sr. No.	Name of company	Turnover 2024	Net profit (PAT) 2024	Turnover 2023	Net profit (PAT) 2023
113	Hester Bioscience Ltd	304.00	16.00	266.00	23.00
114	Samrat Pharma	281.00	2.00	310.00	16.00
115	Sanzyme Biologics	281.00	107.00	238.00	39.41
116	Acne Generics	265.00	14.00	259.00	13.66
117	Syncom Formula	263.00	25.00	224.00	20.00
118	Bharat Parenter	257.00	10.00	217.00	15.00
119	East India Pharma	249.54	3.86	233.34	1.69
120	Cydmax (India)	230.00	−40.00	234.44	−46.50
121	Chandra Bhagat	221.00	1.00	119.00	0.00
122	Jagsonpal Pharma	208.00	22.00	236.00	26.00
123	Everest Organic	197.00	0.00	183.00	0.00
124	Beta Drugs	197.00	21.00	157.00	18.00
125	Valiant lab	182.00	0.00	333.00	29.00
126	Medicamen Bio	179.00	9.00	140.00	14.00
127	Gujarat Themis	169.00	59.00	148.00	57.00
128	Denis Chem Lab	167.00	11.00	160.00	7.00
129	Zota Healthcare	166.59	3.38	138.37	6.59
130	Dipna Pharma	164.00	1.00	99.00	0.00
131	Alembic Ltd	157.00	92.00	127.00	80.00
132	Godavari Drugs	156.00	5.00	159.00	3.00
133	Natural Capsule	155.00	5.00	172.00	18.00
134	Kilitch Drugs	154.00	13.00	139.00	8.00
135	Bafna Pharma	152.00	7.00	115.00	11.00
136	ANG Lifesciences	146.00	10.00	219.00	0.00
137	Medico Remedies	144.00	8.00	140.00	7.00
138	Jenburkt Pharma	141.00	25.00	136.00	24.00
139	Dey's Medical	120.00	2.00	115.00	1.50
140	Alpa lab	108.00	16.00	92.00	12.00
141	Kimia Biosciences	104.00	−5.00	128.00	−9.00
142	Coral Lab	83.00	15.00	78.00	6.00
143	Brooks Laboratories	80.44	1.55	55.65	−8.19
144	Sun Pharma Advres	75.00	−388	238.00	−222.00
145	Krebs Biochem	50.00	−19.00	52.00	−24.00
146	Vivo Biotech	45.00	2.00	52.00	2.00
147	Concord Drugs	43.00	0.00	51.00	0.00
148	Biofil Chem & Pharma	40.00	0.00	30.00	0.00
149	Arvee Lab	30.00	1.00	61.00	6.00
150	Godavari Drugs	29.00	0.00	26.00	1.00
151	Ishita Drugs	15.00	0.00	12.00	0.00
152	Suven lifesciences	11.00	−105.00	13.00	−118.00
	Total	420,059.31	60,283.89	38,3517.13	49,924.69

and multiple types of medical devices. The turnover of these sectors is sometimes aggregated in the total turnover of pharmaceuticals. In this assessment, such companies' sales turnover and PAT are not included. Many companies in India manufacture herbal, Ayurvedic, Unani, Siddha, homeopathic, and natural health care medicines. The turnovers of none of these companies are included in this study.

It can be seen from the data presented in Table 1 that the turnover and net profits (PAT) from all the above 152 companies worked out to about Rs 383,517.13 crores (US$ 46.21 billion) and Rs 49,924.69 (US$ 6.015 billion), respectively, in 2023 and Rs 420,059.31 crores (US$ 50.61 billion) and Rs 60,283.89 (US$ 7.263 billion), respectively, in 2024 [Table 1] (taken 1 USD = 83 INR).

The annual growth rate in value terms during the period was 9.52% over the previous year, which closely matched the government-reported growth figure of 10%.

The turnover of the above 152 companies in 2024 (US$ 50.61 billion) worked out to around 91.5% of the total turnover of Indian pharmaceutical companies as reported by the government (US$ 55.31 billion). It is imperative that the government report figures are the aggregate turnover of all the registered individual pharmaceutical companies in India, and their numbers are presently estimated to be around 3000. It is surmised that the leftover companies whose data are not reported in the above 152 companies comprise companies with lower annual turnover. It is anticipated that some such companies may have annual turnover between Rs 500 and 800 crores, a few between 100 and 500 crores, some between Rs 10 and 100 crores, but with most between Rs 1 and 10 crores.

The total annual turnover of the Indian pharmaceutical industry producing allopathic medicines by the end of 2023, as worked out from the data of 152 companies and escalating them by 8.5%, would be Rs 416,116.1 crores (US$ 50.13 billion), and by the end of 2024 would be Rs 455,764.4 crores (US$ 54.91 billion), respectively, which figures closely resemble the figures reported in the government document. The industry is anticipated to reach a turnover of around Rs 786,500 crores by the end of 2030 at this growth rate. Since the exchange rate between INR and USD varies considerably, the industry's equivalent USD value in 2030 cannot be precisely projected.

In this context, no well-researched paper depicting the individual turnover of Indian pharmaceutical companies is in the public domain. This effort to determine the aggregate turnover of the Indian pharmaceutical industry from the individual turnover and PAT figures, as compiled from secondary information sources, is anticipated to benefit researchers and policymakers in various ways.

MANUFACTURE AND USE OF GENERIC APIS AND BIOTECH DRUGS

The author estimated in 2016 that about 2200 APIs of various kinds were being utilized in the country to manufacture a range of finished pharmaceutical formulations, of which about 1000 were locally produced, while the remaining 1200 were imported and used. The author compiled a list of 669 APIs manufactured in India and exported[17] in 2016. The country is presently, in 2024, estimated to utilize 2400 APIs and manufacture over 150 biotech drugs, including biosimilar products, vaccines, and sera. The current local production of APIs has increased in numbers and quantities.

As of November 2019, India had over 95 approved biosimilars (similar biologics) in the domestic market.[18] The names of the "similar biologics" approved and marketed in India as of February 2018 and their usage indications were also compiled.[19] In August 2017, the first rDNA-based hepatitis B virus vaccine was approved[20] for production and use in India.

Vaccines are available in India[21] against 21 major diseases, including diphtheria, pertussis (whooping cough), tetanus, polio, measles, mumps, rubella, varicella (chickenpox), hepatitis A, hepatitis B, Hemophilus influenza type b (Hib), influenza, pneumococcal disease, meningococcal disease, rotavirus, rabies, yellow fever, cholera, typhoid fever, malaria, and dengue fever. Vaccines for 20 diseases are manufactured in the country, except those against dengue fever. These vaccines are available in various forms in the market, including inactivated vaccines, toxoid vaccines, subunit, recombinant, conjugate, and polysaccharide vaccines; live-attenuated vaccines; viral vector vaccines; mRNA vaccines; and DNA vaccines.

India produces several therapeutic sera, including various antitoxins and antisera for various conditions. These consist of snake venom antiserum, scorpion venom antiserum, tetanus antiserum, diphtheria antiserum, rabies antiserum, and mixed gas gangrene antiserum. These products serve both therapeutic and prophylactic purposes.

As new drug discovery and use are continuous, the number of APIs and biotech drugs used and/or manufactured will keep varying over time. The expiration of intellectual property rights (IPR) allows generic versions of the drugs to be produced and used, lowering prices. Synthetic and biotech drugs, including some blockbuster ones, have their IP rights expire over time. Efficient pharmaceutical companies need to have a strong patent watch cell, which should surf the world literature on IPR on APIs and biotech drugs to pick and choose the suitable ones for manufacture and use soon after the expiry of IPR. The other ways of accessing such drugs after the expiry of IPR are to collaborate with companies that can facilitate access to such drugs for use and sale in the market. Companies that can produce such drugs at more cost-effective prices would be the winners.

DISCUSSION AND CONCLUDING REMARKS

In this part of the review, efforts have been made to identify the key Indian companies primarily responsible for contributions to the Indian pharmaceutical industry. Identifying key contributors allows targeted support and policies to strengthen the industry's economic foundations further. The pharmaceutical sector is a significant contributor to India's gross domestic product and employment. Focusing on the companies driving this growth can enhance job creation and economic activity. Indian pharma companies play a crucial role in the global drug supply, contributing to a substantial trade surplus and increasing foreign exchange reserves. These companies often lead the development and supply of affordable generic drugs, making health care more accessible to a wider population. Identifying the key drivers of innovation within the industry can facilitate targeted support for research and development, leading to new treatments and vaccines. Indian pharma companies are major suppliers of vaccines and medicines to various countries, thereby contributing to global health initiatives. Understanding which companies are essential to the industry helps build a more resilient and adaptable system that can withstand market fluctuations and crisis, as seen during the recent COVID-19 pandemic.

Efforts have also been made to identify the APIs being produced in the country. However, a sizable portion of the country's requirement is imported and used. There is an urgent need to identify and sort them out in terms of value. Such an exercise would allow the Indian pharma industry to explore how some can be manufactured locally and what alternative sourcing can be, mitigating supply chain risks associated with over-reliance on a single source, like China.

Complementing policy supports can help plan the domestic production of many APIs. For example, India imports large quantities of potassium penicillin G first crystals, which can be locally produced if sugar is subsidized to local manufacturers and electricity is available at subsidized prices. If this is done, a couple of thousand jobs will be generated, and India may also emerge as a global leader in manufacturing and supplying of beta-lactam APIs.

Understanding import patterns also aids in strategic planning, ensures a stable supply of critical APIs for domestic drug manufacturing, and potentially enhances India's global pharmaceutical supply chain position. To reduce India's reliance on imported APIs, the government and industry must take proactive measures to bolster and increase domestic production. Such measures could include investing in establishing bulk drug parks, offering financial incentives through schemes like the production-linked incentive, and promoting increased research and development initiatives through various encouragement-linked programs. Some such measures have already been initiated in the country.

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Conflicts of interest

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