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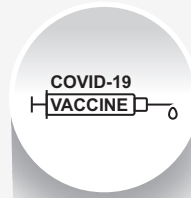


Ministry of Commerce & Industry
Government of India



Pharmaceuticals Export Promotion Council of India
(Set up by Ministry of Commerce & Industry, Govt. of India)

Hand Book 2023



www.pharmexcil.com





Pharmaceutical Industry being knowledge based and keeping in view of the available opportunities and Indian Pharma industry's keen enthusiasm to serve the global healthcare industry, Government of India felt the need of an exclusive export promotion council.

Accordingly, Ministry of Commerce and Industry, Government of India, set up Pharmaceuticals Export Promotion Council of India (Pharmexcil) under Foreign Trade policy by issuing DGFT notification in the year 2004, with its headquarters at Hyderabad, India.

India in the field of pharmaceuticals has made its presence significantly by the turn of the century in the global market after becoming self-sufficient in the previous century. India's noble act of delivering ARV's at almost 3-4 of the cost of the then ruling price has alleviated the misery of millions of people across the globe especially in Africa and some parts of LAC. India with its exports, on account of excellent pharmaceutical chemistry skills of its workforce, has begun to become an important global player by the beginning of this century.

India's Pharma industry has presence in all therapeutic segments with almost all types of dosage forms and is a rich source of Generic medicines. India is popularly known as "Pharmacy of the world".

Role of the Council

- Make representations to Govt. of India and other agencies in India and abroad to get amicable Solutions for the common problems of the Industry.
- Make suggestions to Govt. of India on policy issues relating to Pharma exports.
- Online Issue of Certificate of Origin & RCMC (Registration cum Membership Certificate).
- Organizing periodical Seminars/ Interactive meetings on export related issues.
- Assisting members to get their MAI (Market Access Incentives) claims refunded from Govt. of India.
- Organizing Business Meetings in India and abroad.
- Organizing Trade delegations abroad.

Products and Services falling under purview of Pharmexcil

- Active Pharmaceutical Ingredients
- Finished Dosage Forms (FDF)
- Herbal / Ayurveda
- Unani
- Siddha
- Homeopathy
- Biologics
- Diagnostics
- Surgicals
- Nutraceuticals
- Collaborative Research
- Contract Manufacturing
- Clinical Trials & Consultancy
- Regulatory Services



An overview of Global Pharma Industry & India's Role

Global market had recorded a turnover of USD 1,407 billion during the calendar year of 2022 and had grown by just 1%. India's Pharmaceutical exports during FY 2022-23, recorded a growth of over 3.25%, and has touched \$ 25.394 billion.

Global generic market as per Fitch solutions has touched \$422.81 billion in 2022 and has grown by just 1%. Out of this India's domestic generic market was of the value \$ 24.2 Billion. Currently India is ranked as the 11th largest market and is expected to be ranked as 9th largest by 2025.

- India is the largest exclusive generic exporter in the world.
- Access to affordable HIV treatment from India is one of the greatest success stories in medicine.
- Because of the low price and high quality, Indian medicines are preferred worldwide, thereby rightly making the country called as "pharmacy of the world".
- India is one of the biggest suppliers of low-cost vaccines in the world.

Regulatory Developments

- During the calendar year of 2022 USFDA has granted 1181 Market authorizations of ANDAs. Out of these India companies garnered 493 working out to. 41.74% (Source: Orange Book USFDA site).
- There were One hundred and seven Market authorizations granted by USFDA of First Time generics in 2022, out of which India origin companies bagged 41 of them.

Trade Agreements

During FY-23, India has entered into Trade agreements with

- UAE (Comprehensive Economic Partnership Agreement (CEPA)
- Australia (Economic Cooperation & Trade Agreement (ECTA)

Trade Negotiations are underway with UK, Canada, Israel & EU.



India's Exports of Pharmaceuticals

- India's Exports of Pharmaceuticals during April 2022 till March 2023 has been to the tune of USD 25.4 billion with a growth of almost 3.25%.
- India's Pharma exports contributed 5.6% of Merchandise exports during 2022-23.
- Drug formulations & Biologicals is the third largest Principal commodity being exported by India.

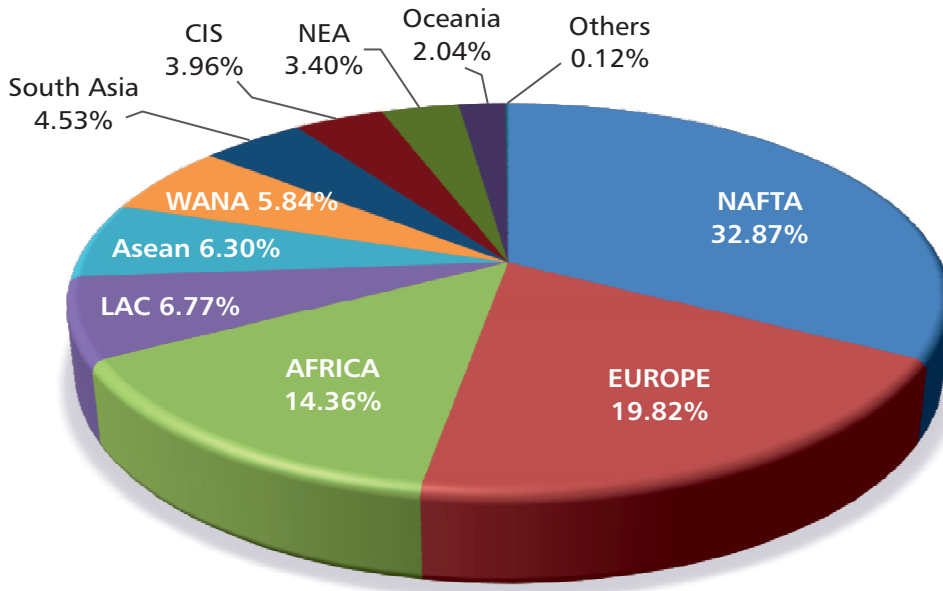
India's Exports during April - March \$ Million						
Product Category	FY-21	FY-22	Change %	FY-23	Change %	Share %
Drugs Formulations & Biologicals	18145.17	18027.8	-0.65%	18420.76	2.18%	72.54%
Bulk Drugs & Drug Intermediates	4405.39	4434.16	0.65%	4681.29	5.57%	18.43%
Vaccines	888.12	967.52	8.94%	1017.63	5.18%	4.01%
Ayush & Herbals	539.88	612.12	13.38%	628.47	2.67%	2.47%
Surgicals	465.47	553	18.8%	645.9	16.87%	2.54%
Total Exports	24444.03	24594.27	0.61%	25394.05	3.25%	100.00%

Exports by Region

India's Pharma Exports Region wise \$ Million						
Region	FY-21	FY-22	Change %	FY-23	Change %	Share %
NAFTA	8392.84	7814.61	-6.89	8347.24	6.82	32.87
EUROPE	4234.59	4432.06	4.66	5032.40	13.55	19.82
Africa	3917.9	3851.35	-1.70	3646.27	-5.32	14.36
LAC	1447.66	1708.88	18.04	1717.94	0.53	6.77
Asean	1462	1758.19	20.26	1598.76	-9.07	6.30
WANA	1320.44	1340.56	1.52	1481.76	10.53	5.84
South Asia	1238.02	1303.70	5.31	1151.49	-11.67	4.53
CIS	1177.96	1096.88	-6.88	1004.55	-8.42	3.96
NEA	823.98	803.71	-2.46	864.03	7.51	3.40
Oceania	428.23	465.61	8.73	518.79	11.42	2.04
Others	0.41	18.72	4466.00	30.82	64.64	0.12
Grand Total	24444.03	24594.27	0.61	25394.05	3.25	100



Region wise India's Pharma Exports FY 2022-23



Salient Features

- During FY-23 India has exported to over 210 destinations across the world.
- Around 60% India's exports are to highly regulated markets like North America and Europe
- India has the maximum no. of US FDA-approved manufacturing sites outside the USA.
- USA is the largest exporting partner of India by country.
- Nine India companies feature among the top 25 Global generic companies.
- India companies have bagged 41.74% of market authorizations granted by USFDA in the calendar year 2022.
- India shares 38.25% of Africa's Generic market value of \$ 8500 million.
- 65-70% of WHO's vaccines (essential Immunization schedule) requirement are sourced from India.



India's Pharmaceutical Exports to Top 30 Countries

India's Exports of Pharma During April - March Country wise (\$ Million)							
Rank	Country	FY-21	FY-22	Change %	FY-23	Change %	Contbn %
1	U S A	7718.80	7108.22	-7.91	7547.54	6.18	29.72
2	BELGIUM	370.19	449.06	21.31	714.92	59.20	2.82
3	SOUTH AFRICA	833.53	612.68	-26.50	657.00	7.23	2.59
4	UNITED KINGDOM	716.52	706.00	-1.47	647.68	-8.26	2.55
5	BRAZIL	525.28	583.75	11.13	642.67	10.09	2.53
6	NETHERLANDS	375.18	460.58	22.76	594.31	29.04	2.34
7	RUSSIA	590.69	598.24	1.28	573.20	-4.19	2.26
8	FRANCE	412.81	513.69	24.44	569.80	10.92	2.24
9	GERMANY	575.47	529.28	-8.03	523.03	-1.18	2.06
10	NIGERIA	573.17	588.34	2.65	515.96	-12.30	2.03
11	CANADA	441.77	419.01	-5.15	506.61	20.91	2.00
12	AUSTRALIA	346.73	386.79	11.55	422.33	9.19	1.66
13	KENYA	282.79	342.58	21.14	362.50	5.81	1.43
14	CHINA	371.31	343.64	-7.45	348.13	1.31	1.37
15	U A E	321.64	331.91	3.19	342.47	3.18	1.35
16	TURKEY	295.24	281.79	-4.55	318.63	13.07	1.25
17	PHILIPPINES	284.40	341.77	20.17	314.44	-8.00	1.24
18	MEXICO	212.43	287.39	35.29	293.09	1.98	1.15
19	THAILAND	229.36	233.04	1.61	273.18	17.23	1.08
20	TANZANIA	262.62	259.98	-1.00	264.66	1.80	1.04
21	BANGLADESH	261.43	308.69	18.08	261.86	-15.17	1.03
22	VIETNAM SOC REP	243.90	269.34	10.43	260.70	-3.21	1.03
23	NEPAL	231.32	323.98	40.05	257.15	-20.63	1.01
24	SRI LANKA	273.94	234.94	-14.24	248.03	5.57	0.98
25	JAPAN	235.73	238.46	1.16	247.50	3.79	0.97
26	SPAIN	173.26	197.14	13.78	235.66	19.54	0.93
27	MYANMAR	234.57	329.06	40.28	209.21	-36.42	0.82
28	INDONESIA	158.51	253.45	59.89	207.20	-18.25	0.82
29	ITALY	168.87	167.88	-0.59	193.25	15.11	0.76
30	PAKISTAN	152.32	243.84	60.09	191.36	-21.52	0.75
	Total of Top 30	17873.75	17944.49	0.40	18744.10	4.46	73.81
	Rest of the Total	6570.28	6649.78	1.21	6649.95	0.00	26.19
	Grand Total	24444.03	24594.27	0.61	25394.05	3.25	100.00



Regulatory Approvals for Indian Pharmaceuticals

- As of April 2023 India has 703 manufacturing sites (API & FDF) registered with USFDA. This constitutes almost 20% of the total manufacturing sites registered with USFDA and situated outside of USA. India supplies almost 29% of its total pharma exports to USA.
- As of April 2023 India has 6316 Market authorizations Granted to India companies (This includes Authorizations Granted to India subsidiaries situated overseas).

Accreditations to Indian Pharmaceutical Companies

Authority	Name of Regulatory Agency	Nos.
USA	No. of Sites (Bulk Drugs + Formulations) Registered with US FDA (as on April 2023).	703
	Total No of DMF's (Type II Active) filed by India companies (as on 31 st Jan 2023).	4505
	Market Authorizations Granted to India Companies As on April 2023 Formulation Companies with USFDA approvals.	6316
	Formulation Companies with ANDAs approvals.	58
	First time Generics Granted to India Companies in 2022 by Percentage.	41
EUROPE	No. of CEPs received (as on April 2023).	2200
	No. of Companies with CEPs (as on April 2023).	243
	No. of Sites Registered with EU GMP (as on November 2022).	386
	No. of CEPs with Irish Medicines Board	300
	No. of Companies Registered in Irish Medicines Board	19
	No. of Authorizations with Sweden MPA (Läkemedelsverket)	209
	No. of Companies having MA`s with Sweden MPA (Läkemedelsverket)	14
WHO GMP	WHO GMP Certified Plants (as per Drug Controller General of India).	2050 (approx.)
ETHIOPIA	DACA (Drug Administration and Control Authority), Ethiopia (Companies).	50
TANZANIA	(TFDA) Tanzania Food and Drugs Authority (companies).	1373



Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Govt. of India)

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