

Supported by



Ministry of Commerce & Industry
Government of India



Pharmaceuticals Export Promotion Council of India

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

Handbook 2020





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

India's Exports of Pharmaceuticals

India's Exports of Pharmaceuticals from April 2019- March 2020 has been to a tune of 20.58 billion USD with a growth of 7.57.

Drug formulations & Biologicals is the third largest among the principal commodities exported by India during 2019-20.

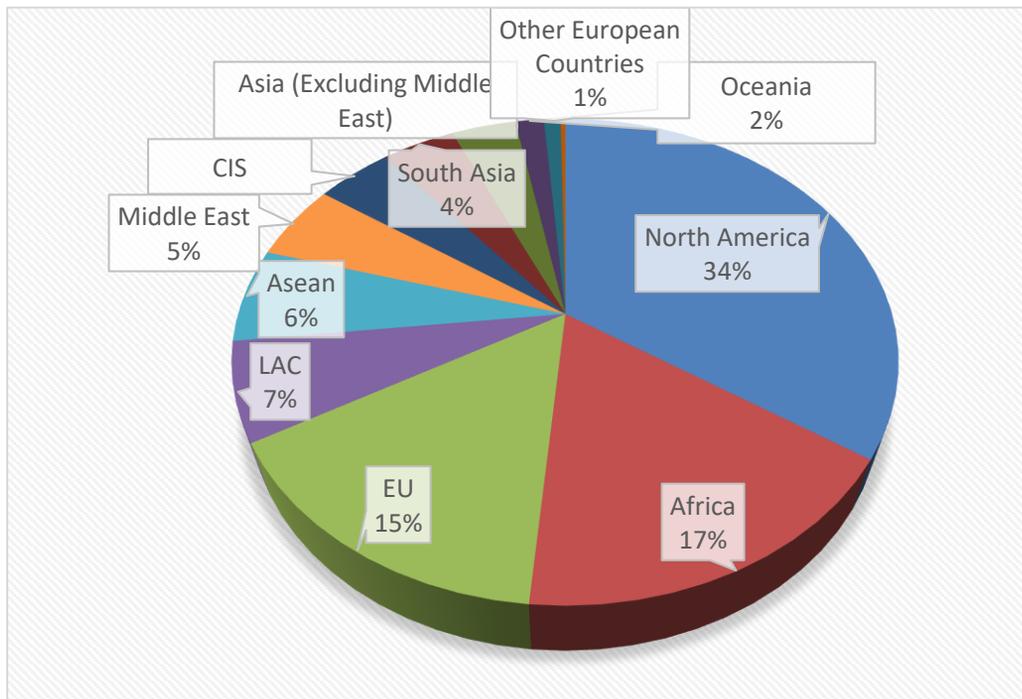
India's exports During April - March \$ million					
Category	FY-18	Fy-19	Fy-20	%Change	Contbn%
Ayush	144.38	147.23	147.17	-0.04	0.71
Bulk Drugs & Drug intermediates	3525.65	3895.38	3867.11	-0.73	18.79
Drug formulations & Biologicals	12094.48	13503.84	14782.14	9.47	71.81
Herbal Products	311.74	300.85	280.92	-6.62	1.36
Surgicals	552.16	570.18	629.90	10.47	3.06
Vaccines	653.40	719.89	878.64	22.05	4.27
Grand Total	17281.81	19137.36	20585.89	7.57	100.00

Exports by Region

Region wise India's pharma exports during April-March \$ million					
Region	FY-18	FY19	FY 20	% change	%Contbn
North America	5348.00	6145.69	7074.03	15.11	34.36
Africa	3346.97	3436.55	3513.64	2.24	17.07
EU	2752.64	3004.14	3140.43	4.54	15.26
LAC	1181.45	1308.3	1341.37	2.53	6.52
Asean	1135.15	1310.21	1292.16	-1.38	6.28
Middle East	869.05	1074.01	1068.5	-0.51	5.19
CIS	764.33	788.29	905.18	14.83	4.40
South Asia	733.17	815.36	873.15	7.09	4.24
Asia (Excluding Middle East)	627.30	693.65	773.5	11.51	3.76
Oceania	320.25	340.84	343.41	0.75	1.67
Other European Countries	150.99	162.95	202.98	24.57	0.99
Other America	52.48	57.37	57.83	0.80	0.28
Grand Total	17281.81	19137.36	20586.19	7.57	100



Region wise India's Pharma exports FY 2019-20



Salient Features

- Around 55% India's exports are to highly regulated markets like North America and Europe. USA is the largest exporting partner of India by country.
- 8 out of top 20 global Generic companies are from India.
- Year after Year India companies have been bagging more than 30% of market authorizations granted by USFDA from 2016
- India shares 50% of Africa's Generic market value of \$ 6000 million.
- During FY-20 India has exported to 202 destinations.
- 70% of WHO's vaccines (essential Immunization schedule) requirement are sourced from India.



India's Pharmaceutical exports to top 30 countries

India's Pharma Exports to Top 30 countries during 2016-20 \$ million							
Rank	Country	2016-17	2017-18	2018-19	2019-20	% Growth	% Contbn
1	U S A	5564	5118.20	5820.41	6,739.43	15.79	32.74
2	SOUTH AFRICA	485	582.99	619.08	610.79	-1.34	2.97
3	U K	550	556.65	630.17	557.86	-11.48	2.71
4	RUSSIA	383	468.77	485.55	552.41	13.77	2.68
5	GERMANY	333	389.24	445.78	504.05	13.07	2.45
6	BRAZIL	337	383.72	452.05	473.10	4.65	2.30
7	NIGERIA	398	466.67	447.95	419.43	-6.37	2.04
8	CANADA	207	229.80	325.26	334.54	2.85	1.63
9	NETHERLAND	203	233.71	205.92	319.29	55.05	1.55
10	FRANCE	209	252.12	276.66	309.23	11.77	1.50
11	BELGIUM	231	242.95	277.49	296.74	6.94	1.44
12	CHINA P RP	145	200.46	230.19	287.92	25.07	1.40
13	AUSTRALIA	237	253.86	276.19	274.16	-0.74	1.33
14	KENYA	325	254.63	261.01	269.42	3.22	1.31
15	PHILIPPINES	208	216.72	240.02	263.92	9.96	1.28
16	BANGLADESH PR	154	162.67	191.60	250.87	29.37	1.22
17	NEPAL	207	232.82	232.76	247.21	6.12	1.20
18	MYANMAR	186	181.98	201.95	224.74	11.29	1.09
19	VIETNAM SOC REP	227	226.30	245.09	223.76	-8.72	1.09
20	SRI LANKA DSR	217	206.79	219.19	220.30	0.50	1.07
21	TURKEY	166	173.46	164.66	216.57	31.62	1.05
22	TANZANIA REP	196	185.91	162.08	210.99	30.18	1.02
23	IRAN	160	124.05	181.14	204.95	13.15	1.00
24	U ARAB EMTS	113	128.29	260.24	202.99	-22.00	0.99
25	JAPAN	168	147.66	175.81	196.31	11.66	0.95
26	THAILAND	141	172.58	190.06	182.69	-3.88	0.89
27	SPAIN	124	141.45	171.30	171.44	-0.04	0.83
28	UGANDA	154	155.82	177.13	161.31	-8.93	0.78
29	MEXICO	157	164.73	159.35	159.96	0.38	0.78
30	EGYPT A RP	128	131.43	145.25	152.84	5.22	0.74
	Total Exports	16785	17281.81	19134.49	20585.89	7.57	100



Regulatory Approvals for Indian Pharmaceuticals

India has the maximum no. of US FDA-approved manufacturing sites outside the US and over 17.5% of the units USFDA inspects outside of USA are in India. India supplies 33% of total exports to USA.

India's ANDAS totaling 5029 by Apr 2020 covers all ATCs.

Accreditations to Indian Pharmaceutical Companies

Authority	Name of Regulatory Agency	Nos.
USA	No: of Sites(Bulk drugs + Formulations) Registered with USFDA (as on June 2020)	664
	Total No of DMF's (Type II Active) filed by India companies (as on 30 Sept 2019)	4500
	ANDAs Market Authorizations (As on April 2020)	5029
	Formulation companies with USFDA approvals.	58
EUROPE	Number of CEPs received (as of April 2020)	1744
	Number of companies with CEPs	220
	No of Sites with Regd with EU GMP	697
	UK MHRA (Medicines Healthcare Regulatory Agency), Market authorizations	1943
	Number of CEPs with Irish Medicines Board	300
	Number of companies registered in Irish Medicines Board	19
	Number of Authorizations with Sweden MPA (Läkemedelsverket)	209
WHO GMP	WHO GMP Certified Plants (as per Drug Controller General of India)	2050 (approx.)
	DACA (Drug Administration and Control Authority), Ethiopia (companies)	50
Tanzania	(TFDA) Tanzania Food and Drugs Authority (companies)	1373



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