

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)

Hand Book 2019





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 India) 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 2018- March 2019 has been to a tune of 19.13 billion USD with a recorded growth of 10.72%.

Drug formulations & Biologicals is the third largest among the principal commodities exported by India during 2018-19.

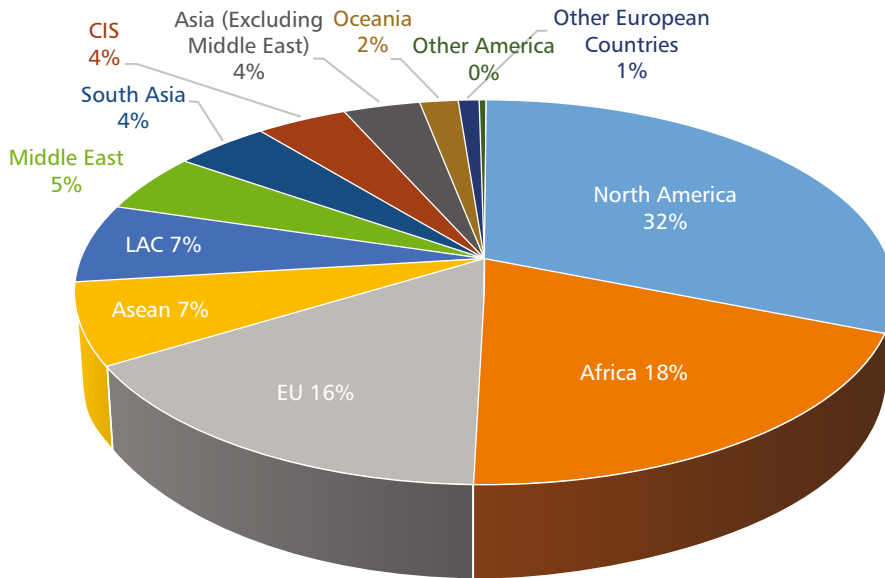
India's exports During April - March \$ million				
Category	Fy-18	Fy-19	Change%	Contbn%
Ayush	144.38	147.22	1.96	0.77
Bulk Drugs & Drug intermediates	3525.65	3895.14	10.48	20.36
Drug formulations & Biologicals	12094.48	13561.53	12.13	70.87
Herbal Products	311.74	298.90	-4.12	1.56
Surgicals	552.16	569.77	3.19	2.98
Vaccines	653.40	661.93	1.31	3.46
Grand Total	17281.81	19134.49	10.72	100.00

Exports by Region

Region wise India's pharma exports during April-March \$ million				
Region	Fy-18	Fy-19	Change%	Contbn%
North America	5348.00	6145.67	14.92	32.12
Africa	3346.97	3436.44	2.67	17.96
EU	2752.64	3003.91	9.13	15.70
Asean	1181.45	1310.14	10.89	6.85
LAC	1135.15	1308.30	15.25	6.84
Middle East	869.05	1074.11	23.60	5.61
South Asia	764.33	812.84	6.35	4.25
CIS	733.17	788.27	7.52	4.12
Asia (Excluding Middle East)	627.30	693.62	10.57	3.63
Oceania	320.25	340.84	6.43	1.78
Other European Countries	150.99	162.86	7.86	0.85
Other America	52.48	57.38	9.33	0.30
Grand Total	17281.81	19134.39	10.72	100.00



Region wise India's Pharma exports Fy 2018-19



Salient Features

- India produces 65% of WHO demand for DPT & BCG and 90% of Measles vaccine.
- 8 out of top 20 global Generic companies are from India.
- 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.
- India shares 50% of Africa's Generic market value of \$ 6000 million.
- During Fy-19 India has exported to 201 Countries averaging \$95.2 million. Exports to top 25 destinations contribute 68.3 % to the total exports.



India's Pharmaceutical exports to top 30 countries

India's Pharma Exports to Top 30 countries during 2015-19 \$ million							
Rank	Country	2015-16	2016-17	2017-18	2018-19	% Growth	% Contbn by value
1	U S A	5514	5564	5118.20	5820.41	13.72	30.42
2	U K	564	550	556.65	630.17	13.21	3.29
3	SOUTH AFRICA	605	485	582.99	619.08	6.19	3.24
4	RUSSIA	374	383	468.77	485.55	3.58	2.54
5	BRAZIL	326	337	383.72	452.05	17.81	2.36
6	NIGERIA	437	398	466.67	447.95	-4.01	2.34
7	GERMANY	348	333	389.24	445.78	14.53	2.33
8	CANADA	201	207	229.80	325.26	41.54	1.70
9	BELGIUM	192	231	242.95	277.49	14.22	1.45
10	FRANCE	232	209	252.12	276.66	9.73	1.45
11	AUSTRALIA	233	237	253.86	276.19	8.80	1.44
12	KENYA	332	325	254.63	261.01	2.51	1.36
13	U ARAB EMTS	110	113	128.29	260.24	102.85	1.36
14	VIETNAM SOC REP	221	227	226.30	245.09	8.30	1.28
15	PHILIPPINES	193	208	216.72	240.02	10.75	1.25
16	NEPAL	177	207	232.82	232.76	-0.03	1.22
17	CHINA P RP	146	145	200.46	230.19	14.83	1.20
18	SRI LANKA DSR	205	217	206.79	219.19	6.00	1.15
19	NETHERLAND	244	203	233.71	205.92	-11.89	1.08
20	MYANMAR	154	186	181.98	201.95	10.98	1.06
21	BANGLADESH PR	136	154	162.67	191.60	17.79	1.00
22	THAILAND	148	141	172.58	190.06	10.12	0.99
23	IRAN	181	160	124.05	181.14	46.02	0.95
24	UGANDA	169	154	155.82	177.13	13.68	0.93
25	JAPAN	144	168	147.66	175.81	19.06	0.92
26	SPAIN	134	124	141.45	171.30	21.10	0.90
27	ITALY	123	124	153.64	166.70	8.50	0.87
28	TURKEY	160	166	173.46	164.66	-5.07	0.86
29	TANZANIA REP	179	196	185.91	162.08	-12.82	0.85
30	MEXICO	160	157	164.73	159.35	-3.27	0.83
	Others	4570	4476	5692.37	6065.82	6.56	31.7
	Total Exports	16912	16785	17281.81	19134.49	10.72	100



Regulatory Approvals for Indian Pharmaceuticals

India has the maximum no. of US FDA-approved manufacturing sites outside the US and supplies 40 per cent of the generic formulations marketed in the US.

India's ANDAS totaling 4769 by Feb 2019 covers all ATCs.

Accreditations to Indian Pharmaceutical Companies

Authority	Name of Regulatory Agency	Nos.
USA	No: of Sites(Bulk drugs + Formulations) Registered with US FDA (as on Feb 2019)	722
	Total No of DMF's (Type II Active) filed by India companies (as on 31 July 2017)	3980
	ANDAs Market Authorizations (As on Feb 2019)	4769
	Formulation companies with USFDA approvals.	53
EUROPE	Number of CEPs received (as of Feb 2019)	1670
	Number of companies with CEPs	194
	No of Sites with EU GMP Compliance as on Feb 2019	826
	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 Authorisations with Sweden MPA (Läkemedelsverket)	209
	Number of companies having MA`s with Sweden MPA (Läkemedelsverket)	14
WHO GMP	WHO GMP Certified Plants (as per Drug Controller General of India)	1400 (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 ACTIVITIES UNDER MAI SCHEMES FOR THE YEAR 2019-20 (TENTATIVE)

No.	Name of the Event	Proposed Dates	Nature of the Event
1	India Pavilion at PHARMACONEX, Cairo, Egypt	6-8 April 2019	Exhibition Abroad
2	India Pavilion at Korea Pharm & Bio, South Korea	16-18 April 2019	Exhibition Abroad
3	iPHEX 2019, Gandhinagar	10-12 June 2019	International Exhibitions in India
4	CPhI China, Shanghai	18-20 June 2019	Exhibition Abroad
5	BSM / Pharma Business Delegation to South Africa (BSM) & Tanzania (BSM)	15-19 July 2019	BSMs Abroad
6	Pharmexcil's Business Delegation to Australia & New Zealand	22-26 July 2019	BSMs Abroad
7	Pharma Business Meet at China & Mongolia	04-10 Aug 2019	BSMs Abroad
8	BSM/Business delegation to Peru, Mexico, Columbia & Chile	17 Aug - 02 Sep 2019	BSMs Abroad
9	AGM / International Regulators Meet	19-20 Sep 2019	Seminars & Interactive Meetings in India
10	India Pavilion at Iran Pharma, Tehran, Iran	24-26 Sep 2019	Exhibition Abroad
11	India Pavilion at Maghreb Pharma Expo, Algeria	01-03 Oct 2019	Exhibition Abroad
12	CPhI World Wide, Germany	5-7 Nov 2019	Exhibition Abroad
13	CPhI India, Noida, Uttar Pradesh	10-12 Nov 2 019	International Exhibitions in India
14	BSM to CIS Region Russia, Uzbekistan, Armenia	16-30 Nov 2019	BSMs Abroad
15	Arab Health , Dubai	27-30 Jan 2020	Exhibition Abroad



Pharmaceuticals Export Promotion Council of India

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