

Supported by



Ministry of Commerce & Industry
Govt. of India



Pharmaceuticals Export Promotion Council of India

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

HAND BOOK 2018



Website: www.pharmexcil.com

Rx INDIA
Pharmacy of the World
Responsible Healthcare



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
- ◆ 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:

- | | | |
|--|------------------|---------------------------------|
| ◆ Bulk Drugs (API) & its Intermediates | ◆ Homeopathy | ◆ Collaborative Research |
| ◆ Formulations | ◆ Biologics | ◆ Contract Manufacturing |
| ◆ Herbal / Ayurveda | ◆ Diagnostics | ◆ Clinical Trials & Consultancy |
| ◆ Unani | ◆ Surgicals | ◆ IPR & Regulatory |
| ◆ Siddha | ◆ Nutraceuticals | |

India's Exports of Pharmaceuticals:

India's Exports of Pharmaceuticals in 2017-18 has been to a tune of \$ 17.27 billion and has the following composition.

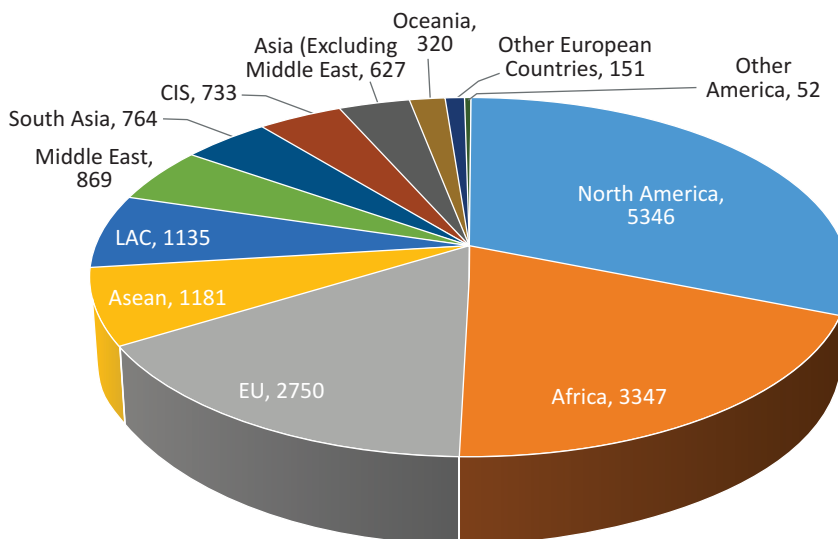
Drug formulations & Biologicals is the third largest among the principal commodities exported by India during 2017-18.

India's Exports During April - March \$ million				
Category	Fy-17 \$ mn	Fy-18 \$ mn	Growth%	Contbn%
Ayush	124	144	16.73	0.84
Bulk Drugs And Drug Intermediates	3,384	3,540	4.61	20.49
Drug Formulations and Biologicals	12,666	12,909	1.91	74.72
Herbal Products	278	312	12.04	1.80
Surgicals	333	372	11.53	2.15
Grand Total	16,785	17,276	2.92	100.00

Exports by Region

Region wise India's pharma exports during April-March \$ million				
Region	Fy-17	Fy-18	Gr%	Contbn%
North America	5770	5346	-7.35	30.95
Africa	3214	3347	4.14	19.37
EU	2523	2750	9.02	15.92
Asean	1083	1181	9.07	6.84
LAC	993	1135	14.33	6.57
Middle East	808	869	7.60	5.03
South Asia	722	764	5.81	4.42
CIS	632	733	16.02	4.24
Asia (Excluding Middle East)	565	627	10.83	3.63
Oceania	297	320	7.71	1.85
Other European Countries	130	151	16.34	0.87
Other America	48	52	10.13	0.30
Others	1	0	-97.77	0.00
Grand Total	16785	17276	2.92	100.00

Pictorial representation of India's exports in 2017-18.



Salient Features

- 1) Contribution of Indian pharma industry in Global pharma production :
10% in terms of volume &
2.49% in terms of value.
- 2) India produces 65% of WHO demand for DPT & BCG and 90% of Measles vaccine.
- 3) 8 out of top 20 global Generic companies are from India.
- 4) India's Pharma exports FY-18 has recorded an average of \$ 80.35 million during the period per destination. Total number of Destinations during the period is 215.
- 5) Exports to 129 destination countries are growing.
- 6) 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.
- 7) India shares 50% of Africa's Generic market value of \$ 6000 million.

India's Pharmaceutical exports to top 30 countries.

India's Pharma Exports to Top 30 countries during 2015-18 \$ million						
Rank	Country	2015-16	2016-17	2017-18	Growth %	% Contribtn by Value
1	U S A	5514	5564	5116	-8.04	-447
2	SOUTH AFRICA	605	485	583	20.23	98
3	U K	564	550	557	1.25	7
4	RUSSIA	374	383	469	22.24	85
5	NIGERIA	437	398	467	17.26	69
6	GERMANY	348	333	388	16.54	55
7	BRAZIL	326	337	384	13.74	46
8	KENYA	332	325	255	-21.76	-71
9	AUSTRALIA	233	237	254	7.15	17
10	FRANCE	232	209	251	20.38	43
11	BELGIUM	192	231	243	5.07	12
12	NETHERLAND	244	203	234	15.33	31
13	NEPAL	177	207	233	12.47	26
14	CANADA	201	207	230	11.23	23
15	VIETNAM SOC REP	221	227	226	-0.36	-1
16	PHILIPPINES	193	208	217	4.00	8
17	SRI LANKA DSR	205	217	207	-4.82	-10
18	CHINA P RP	146	145	200	37.52	55
19	TANZANIA REP	179	196	186	-5.26	-10
20	MYANMAR	154	186	182	-2.35	-4
21	TURKEY	160	166	173	4.62	8
22	THAILAND	148	141	173	22.37	32
23	MEXICO	160	157	165	4.61	7
24	BANGLADESH PR	136	154	162	5.78	9
25	UGANDA	169	154	156	1.47	2
26	ITALY	123	124	153	23.52	29
27	JAPAN	144	168	147	-12.33	-21
28	PAKISTAN IR	102	129	142	9.59	12
29	SPAIN	134	124	141	13.97	17
30	INDONESIA	69	97	141	44.82	44
	Total of top 30	12221	12263	12433	1.38	170
	Grand Total	16912	16785	17276	2.92	491

Regulatory Approvals for Indian Pharmaceuticals:

India's Pharmaceutical industry has filed the highest number of DMFS with USFDA and by the end of July 2017, the number of filings stands at 3980. India's ANDAS totaling 4325 by March 2018 covers all ATCs.

Following Table gives an overview of India's Accreditations.

Authority	Name of Regulatory Agency	Nos.
USA	DMFs filed with U.S. FDA (companies) (As on 31st July 2017)	195
	No: of Sites(Bulk drugs + Formulations) Registered with US FDA (as on April 2018)	700
	Total No Of DMF's (Type II Active) Filed by India companies (as on 31 July 2017)	3980
	ANDAs market Authorizations (As on March 2018)	4325
	Formulation companies with USFDA approvals.	53
EUROPE	Number of CEPs received (as of Feb 2018)	1597
	Number of companies with CEPs	194
	Number of Molecules for which CEPs have been filed with EDQM	426
	No of Sites with EU GMP Compliance as on April 2018	769
	UK MHRA (Medicines Healthcare Regulatory Agency), Market authorizations as on March 2018	1950
	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 2018-19 (TENTATIVE)

S.No.	Name of the Event	Proposed Dates	Nature of the Event
1	Workshop on "GST/IGST/ITC pending refunds & corrective steps" in New Delhi	04 April 2018	Seminars & Interactive Meetings in India
2	India Pavilion at CPhI Japan, Tokyo	18-20 April 2018	Exhibition Abroad
3	iPHEX 2018, New Delhi	08-10 May 2018	International Exhibitions in India
4	Seminar on Barcode/Dava at Hyderabad	11 May 2018	Seminars & Interactive Meetings in India
5	Seminar on Barcode/Dava at Ahmedabad	12 June 2018	Seminars & Interactive Meetings in India
6	BSM to EEC Countries Czech Republic, Slovenia, Croatia & Bulgaria	16-30 June 2018	BSMs Abroad
7	India Pavilion at CPhI China, Shanghai	20-22 June 2018	Exhibition Abroad
8	Buyer Seller Meet at Shanghai, China	20-22 Aug 2018	BSMs Abroad
9	Business delegation/ III All-Russian GMP conference at Kazan, Tatarstan	26-29 Aug 2018	International Conference
10	Business Delegation to Brazil, Honduras & Guatemala	03-12 Sep 2018	BSMs Abroad
11	India Pavilion at Maghreb Pharma Expo, Algeria	17-19 Sep 2018	Exhibition Abroad
12	India Pavilion at Iran Pharma, Tehran, Iran	24-26 Sep 2018	Exhibition Abroad
13	India Pavilion at CPhI World Wide, Madrid, Spain	09-11 Oct 2018	Exhibition Abroad
14	BSM to CIS Region (Russia, Turkmenistan, Ukraine, Georgia)	24-28 Nov 2018	BSMs Abroad
15	CPhI India at Noida, Uttar Pradesh	12-14 Dec 2018	International Exhibitions in India
16	Expo Cum BSM in Myanmar/Indonesia/ Philippines and Vietnam	January, 2019	BSMs Abroad
17	India Pavilion at Arab Health, Dubai, UAE	28-31 Jan 2019	Exhibition Abroad
18	India Pavilion at Iphex Africa in Nigeria, Uganda and Sudan	February, 2019	Exhibition Abroad



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