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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 2021





**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



## An overview of Global Pharma Industry & India's Role

Global market has recorded a turnover of \$ 1265.2 billion during the calendar year of 2020 and has grown by just 1%. However, India's Pharmaceutical exports during Fy-21, has recorded a growth of over 18%, which happens to be the highest during the last seven years.

India is the largest exclusive generic exporter in the world.

Currently India is ranked as the 11th largest market and is expected to be ranked as 9th largest by 2025

Eight of India based companies feature among top 20 Generic companies in the world based Calendar year of 2019 turnover.

## India's Role in Covid-19 Control

India stands out as an essential component to a concrete global action plan being readied to fight COVID-19, including for large-scale vaccine manufacturing. India's Pharma industry responded resiliently to the global needs of some of the medicines employed in the treatment of Covid-19 pandemic. Industry could respond to various country's urgent appeals for supplies of products like Remdesivir, Favipiravir, Azithromycin, Doxycycline, Paracetamol, and Hydroxychloroquine alongside PPE & diagnostics kits and many others.

India, being the "powerhouse of vaccine manufacturing" playing a lead role in overcoming the ongoing pandemic. Several Indian pharmaceutical firms are working on a coronavirus vaccine as part of global efforts to find a preventive to stem the spread of the deadly virus. India's Vaccine manufacturers besides commercial exports of estimated \$140 million could also meet our government's commitment of millions of free doses supplied abroad.

It is with great pride, Pharmexcil notes that M/s. Bharat Biotech performed on par with many western innovative vaccine companies by introducing its own version of covid vaccine (Covaxin) which is developed totally in house with support of Indian Council of Medical Research (ICMR) & National Institute of Virology (NIV). Another company M/s. Serum Institute of India could manufacture Oxford-AstraZeneca Covid vaccine 'Covidshield'. These products could meet all the requirements of a safe vaccine and were made market ready in almost less than a year, which normally takes more than three full years. This speaks volumes of our biologists' & manufacturers' capabilities to meet even exigencies with high accuracy and speed.



## India's Exports of Pharmaceuticals

India's Exports of Pharmaceuticals from April 2020- March 2021 has been to a tune of USD24.47 billion with a growth of 18.2%.

India's Pharma exports contributed 8.38% of Merchandise exports.

Drug formulations & Biologicals is the second largest Principal commodity being exported by India.

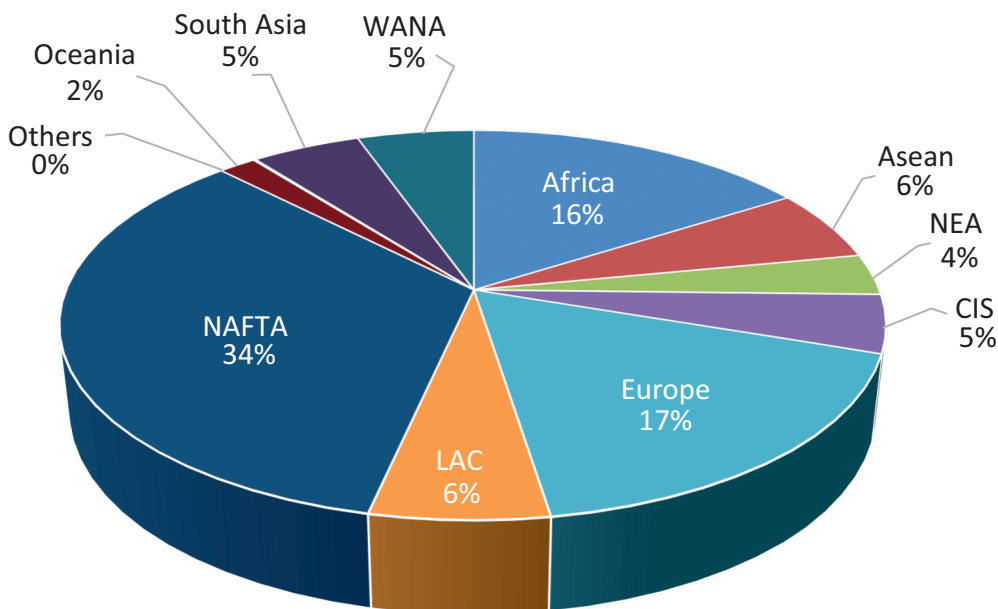
India's exports during April - March \$ million				
Category	Fy-20	Fy-21	Change%	Contbn%
Ayush	147.19	165.60	12.50	0.68
Bulk Drugs & Intermediates	3867.77	4405.36	13.90	18.00
Drug formulations & Biologicals	14959.09	17959.27	20.06	73.40
Herbal Products	280.88	374.27	33.25	1.53
Surgicals	630.57	677.09	7.38	2.77
Vaccines	817.96	887.65	8.52	3.63
<b>Grand Total</b>	<b>20703.5</b>	<b>24469.2</b>	<b>18.19</b>	<b>100.00</b>

## Exports by Region

Region wise India's pharma exports during April-March \$ million				
Region	Fy-20	Fy-21	Change%	Contbn%
NAFTA	7244	8378	15.65	34.24
Europe	3574	4238	18.56	17.32
Africa	3212	3912	21.81	15.99
Asean	1293	1462	13.14	5.98
LAC	1225	1446	18.07	5.91
WANA	1036	1325	27.92	5.41
South Asia	1168	1240	6.17	5.07
CIS	905	1178	30.17	4.82
Asia (Excluding Middle East)	684	836	22.21	3.42
Oceania	345	428	24.26	1.75
Others	18	26	39.37	0.10
<b>Grand Total</b>	<b>20703</b>	<b>24469</b>	<b>18.19</b>	<b>100.00</b>



## Region Wise India's Pharma Exports Fy 2020-21



### Salient Features

- During Fy-21 India has exported to 202 destinations.
- 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.
- India companies have bagged 37% of market authorizations granted by USFDA in the calendar year 2020.
- India shares 40% of Africa's Generic market value of \$ 8000 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 Pharma Exports to Top 30 countries during 2020-21 \$ million						
Rank	Country	FY-19	FY-20	FY-21	Change%	Contbn%
1	U S A	5820.41	6749.60	7723.55	14.43	31.57
2	SOUTH AFRICA	619.08	612.01	833.60	36.21	3.41
3	U K	630.17	557.89	716.97	28.52	2.93
4	RUSSIA	485.55	552.41	590.80	6.95	2.41
5	GERMANY	445.78	504.17	576.39	14.33	2.36
6	NIGERIA	447.95	443.09	573.22	29.37	2.34
7	BRAZIL	452.05	473.10	525.57	11.09	2.15
8	CANADA	325.26	334.54	441.77	32.05	1.81
9	FRANCE	276.66	319.50	413.10	29.29	1.69
10	CHINA P RP	230.19	287.97	382.73	32.91	1.56
11	NETHERLAND	205.92	321.05	375.64	17.00	1.54
12	BELGIUM	277.49	297.18	370.19	24.57	1.51
13	AUSTRALIA	276.19	274.10	346.97	26.59	1.42
14	U ARAB EMTS	260.24	203.13	321.78	58.41	1.32
15	TURKEY	164.66	216.57	295.65	36.51	1.21
16	PHILIPPINES	240.02	263.99	284.39	7.73	1.16
17	KENYA	261.01	275.55	283.06	2.73	1.16
18	SRI LANKA DSR	219.19	220.47	274.40	24.46	1.12
19	TANZANIA REP	162.08	218.35	262.63	20.28	1.07
20	BANGLADESH PR	191.60	250.95	261.73	4.30	1.07
21	VIETNAM SOC REP	245.09	223.76	243.91	9.00	1.00
22	JAPAN	175.81	196.31	236.10	20.27	0.97
23	MYANMAR	201.95	224.75	234.58	4.37	0.96
24	NEPAL	232.76	247.26	232.03	-6.16	0.95
25	THAILAND	190.06	182.67	229.50	25.63	0.94
26	UGANDA	177.13	172.09	226.20	31.44	0.92
27	MEXICO	159.35	159.96	212.44	32.81	0.87
28	UZBEKISTAN	66.04	81.02	186.16	129.77	0.76
29	IRAN	181.14	205.10	183.41	-10.57	0.75
30	UKRAINE	108.20	126.20	181.56	43.87	0.74
	<b>Total of above</b>	<b>13729.03</b>	<b>15194.74</b>	<b>18020.03</b>	<b>18.59</b>	<b>73.65</b>
	<b>Grand Total</b>	<b>19137.38</b>	<b>20700.39</b>	<b>24465.98</b>	<b>18.19</b>	<b>100</b>



## Regulatory Approvals for Indian Pharmaceuticals

India has the maximum no. of US FDA-approved manufacturing sites outside the US and India holds 12% of global manufacturing sites catering to US markets. India supplies 32% of total exports to USA.

India's ANDAS totaling 4346 by Dec 2020 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 June 2021)	725
	Total No of DMF's (Type II Active) filed by India companies (as on 30 Sep 2019)	4500
	ANDAs Market Authorizations Granted to manufacturing units based in India of India companies(As on Dec 2020)	4346
	Formulation companies with USFDA approvals.	68
EUROPE	Number of CEPs received (as on May 2021)	1821
	Number of companies with CEPs (as on May 2021)	179
	No. of Sites with Registered with EU GMP (May 2021)	542
	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)	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

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