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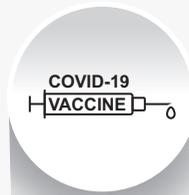
Ministry of Commerce & Industry
Government of India



Pharmaceuticals Export Promotion Council of India

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

Hand Book 2022





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 had recorded a turnover of USD 1265.2 billion during the calendar year of 2020 and had grown by just 1%. However, India's Pharmaceutical exports during FY 2020-21, recorded a growth of over 18%, which happened to be the highest during the last seven years. During the last decade, between FY 13 and FY 22, India's pharma exports have grown by over 95%.

During FY 22, the Indian Pharmaceutical Industry apart from facing delay in site inspections and new site approvals by the USFDA, also faced pricing pressures, frequent lockdowns, global supply chain interruptions, and a sluggish manufacturing sector. Further a large number of countries were increasingly moving towards localization. During this period, the Indian pharma sector showed immense resilience and commitment amid the disruption caused by the pandemic. The pharmaceutical sector not only showed its capacity to produce adequate medicines, but also made substantial contributions to other areas like sanitation, preventative healthcare, and quarantine facilities. Despite the above-mentioned challenges exports in pharmaceuticals registered a growth of almost 1% in FY22 in a year rife with the after-effects of the pandemic.

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

Seven of India based companies feature among top 20 global Generic companies as per Calendar year 2020 turnover.

India's Role in Covid-19 control

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, Hydroxychloroquine and many others.

India, being the "powerhouse of vaccine manufacturing" played a lead role in overcoming the ongoing pandemic. 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 that Pharmexcil notes that two of its members M/s. Bharat Biotech & M/s. Zydus Cadila performed on par with many western innovative vaccine companies by introducing its own version of covid vaccines (COVAXIN & ZyCov-D) which is developed totally in house. The products could meet all the requirements of a safe vaccine and was made market ready in shortest possible times. This speaks volumes of our biologists' capabilities to meet even exigencies with high accuracy and speed. Another company M/s. Serum Institute of India in agreement with AstraZeneca-Oxford manufactures "Covishield" and supplying to the world.



India's Exports of Pharmaceuticals

There are 500 API manufacturers contributing about 8% in the global API Industry. Access to affordable HIV treatment from India is one of the greatest success stories in medicine. India is one of the biggest suppliers of low-cost vaccines in the world. Because of the low price and high quality, Indian medicines are preferred worldwide, thereby rightly making the country the "pharmacy of the world".

India is the largest exclusive generic exporter in the world.

India's Exports of Pharmaceuticals during April 2021 till March 2022 has been to the tune of USD 24.62 billion with a growth of almost 1%.

India's Pharma exports contributed 5.92% of Merchandise exports.

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

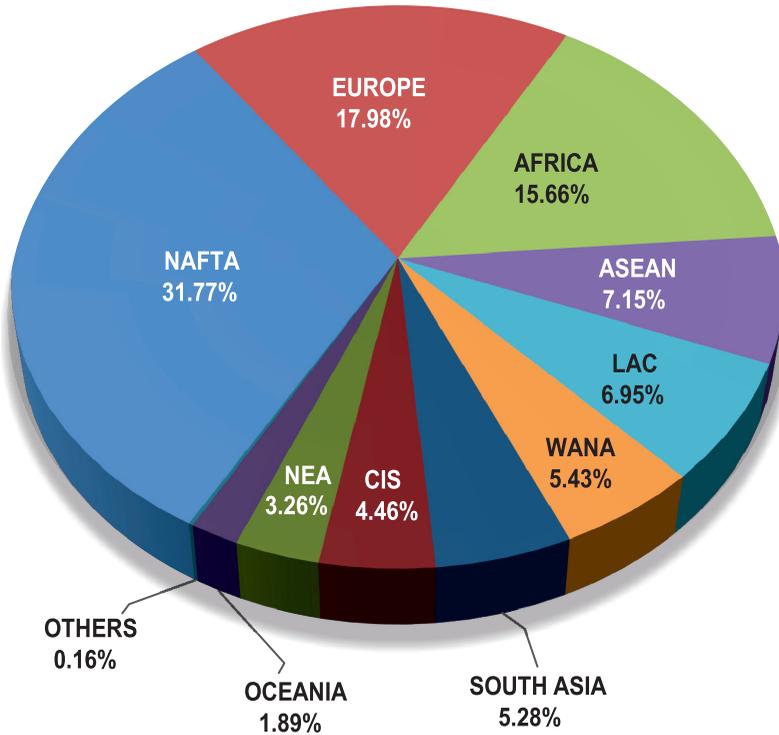
India's Exports during April - March \$ million						
Product Category	FY20	FY21	% Change	FY22	% Change	% Share
Drugs Formulations & Biologicals	15123.20	18143.36	19.97%	18047.70	-0.53%	73.31%
Bulk Drugs & Drug Intermediates	3867.77	4405.39	13.90%	4437.64	0.73%	18.03%
Vaccines	820.59	909.25	10.80%	988.14	8.68%	4.01%
Ayush & Herbals	428.07	539.88	26.12%	612.83	13.51%	2.49%
Surgicals	463.83	446.15	-3.81%	532.47	19.35%	2.16%
Total Exports	20703.46	24444.03	18.07%	24618.78	0.71%	100.00%

Exports by Region

Region wise India's Pharma Exports during April-March \$ million						
Region	FY20	FY21	% Change	FY22	% Change	% Share
NAFTA	7258.60	8392.84	15.63%	7820.77	-6.82%	31.77%
EUROPE	3574.36	4234.59	18.47%	4426.61	4.53%	17.98%
AFRICA	3213.86	3917.90	21.91%	3856.27	-1.57%	15.66%
ASEAN	1292.65	1462.00	13.10%	1761.01	20.45%	7.15%
LAC	1227.99	1447.66	17.89%	1710.25	18.14%	6.95%
WANA	1034.02	1320.44	27.70%	1335.73	1.16%	5.43%
SOUTH ASIA	1167.69	1238.02	6.02%	1300.48	5.04%	5.28%
CIS	905.27	1177.96	30.12%	1097.89	-6.80%	4.46%
NEA	684.07	823.98	20.45%	803.03	-2.54%	3.26%
OCEANIA	344.94	428.23	24.15%	466.21	8.87%	1.89%
OTHERS	0.02	0.41	1951.82%	40.52	9774.91%	0.16%
Total Exports	20703.47	24444.03	18.07%	24618.78	0.71%	100.00%



Region wise India's Pharma Exports FY 2021-22



Salient Features

- During FY-22 India has exported to over 200 destinations across the world.
- 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 out of top 20 global Generic companies are from India by 2020 values.
- India companies have bagged 33.48% of market authorizations granted by USFDA in the calendar year 2021.
- India shares 45.5% 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 2020-22 \$ million							
Rank	Country	2019-20	2020-21	% Change	2021-22	% Change	% Share
1	U S A	6749.60	7718.80	14.36%	7101.60	-8.00%	28.85%
2	U K	557.89	716.52	28.43%	704.51	-1.68%	2.86%
3	South Africa	612.01	833.53	36.19%	612.30	-26.54%	2.49%
4	Russia	552.41	590.69	6.93%	597.81	1.21%	2.43%
5	Nigeria	443.09	573.17	29.36%	588.59	2.69%	2.39%
6	Brazil	473.10	525.28	11.03%	580.78	10.57%	2.36%
7	Germany	504.17	575.47	14.14%	528.30	-8.20%	2.15%
8	France	319.50	412.81	29.20%	512.20	24.08%	2.08%
9	Netherland	321.05	375.18	16.86%	460.08	22.63%	1.87%
10	Belgium	297.18	370.19	24.57%	449.77	21.50%	1.83%
11	Canada	334.54	441.77	32.05%	418.57	-5.25%	1.70%
12	Australia	274.10	346.73	26.50%	386.90	11.58%	1.57%
13	China P Rep	287.97	371.31	28.94%	343.76	-7.42%	1.40%
14	Philippines	263.99	284.40	7.73%	342.25	20.34%	1.39%
15	Kenya	275.55	282.79	2.63%	341.37	20.72%	1.39%
16	U A E	203.13	321.64	58.34%	333.77	3.77%	1.36%
17	Myanmar	224.75	234.57	4.37%	329.95	40.66%	1.34%
18	Nepal	247.26	231.32	-6.44%	320.12	38.39%	1.30%
19	Bangladesh	250.95	261.43	4.18%	309.12	18.24%	1.26%
20	Mexico	159.96	212.43	32.80%	287.61	35.39%	1.17%
21	Turkey	216.57	295.24	36.32%	282.48	-4.32%	1.15%
22	Vietnam Soc Rep	223.76	243.90	9.00%	269.05	10.31%	1.09%
23	TANZANIA Rep	218.35	262.62	20.27%	260.00	-1.00%	1.06%
24	Indonesia	107.16	158.51	47.93%	253.32	59.82%	1.03%
25	Pakistan	124.71	152.32	22.13%	243.36	59.77%	0.99%
26	Japan	196.31	236.10	20.27%	237.90	0.92%	0.97%
27	Sri Lanka	220.47	274.40	24.46%	235.43	-14.06%	0.96%
28	Thailand	182.67	229.50	25.63%	234.98	2.45%	0.95%
29	Uganda	172.09	226.20	31.44%	207.43	-8.28%	0.84%
30	Spain	171.44	173.46	1.18%	197.24	13.84%	0.80%
	Total Exports for above 30	15185.71	17932.25	18.09%	17970.54	0.22%	73.00%
	Rest of the countries	5517.66	6516.09	18.10%	6648.24	2.08%	27.00%
	Total Exports	20703.37	24448.34	18.09%	24618.78	0.71%	100.00%



Regulatory Approvals for Indian Pharmaceuticals

India has the maximum no. of US FDA-approved manufacturing sites outside the US and India holds 18% of global manufacturing sites catering to US markets. India supplies almost 29% of its total pharma exports to USA.

As of March 2022 India has 4573 Market authorizations granted by USFDA manufactured in India based units and another 1678 authorizations granted to India subsidiaries with overseas units.

Accreditations to Indian Pharmaceutical Companies

Authority	Name of Regulatory Agency	Nos.
USA	No: of Sites (Bulk drugs + Formulations) Registered with US FDA (as on Aug 2021).	741
	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 March 2022).	4573
	Formulation companies with USFDA approvals.	58
	First time Generics Granted to India companies in 2021 by Percentage.	25
EUROPE	Number of CEPs received (as on Dec 2021).	1953
	Number of companies with CEPs (as on Dec 2021).	219
	No. of Sites Registered with EU GMP (as on Dec 2021).	284
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

India's Trade Agreements: Advantage Pharma

Pharmexcil played an active role in the recently concluded Trade Agreements with the UAE and Australia in respect to the Pharma sector. India-UAE Comprehensive Economic Partnership Agreement (CEPA), allows automatic registration of Indian pharmaceuticals and grant of market authorization within ninety (90) days without any inspections for Pharmaceutical Products approved by stringent regulatory authorities.

Likewise, India-Australia Economic Cooperation and Trade Agreement (ECTA) will be opening up the provision for fast track approvals for Indian medicines already approved by stringent regulatory authorities and also eliminate tariffs on certain pharmaceutical products over five to seven years.



Pharmaceuticals Export Promotion Council of India

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

Head Quarters / Regd. Office :

201, Aditya Trade Center, Ameerpet, Hyderabad-500 038

Ph: +91-40-23735462 / 5464 / 5466

E-mail: info@pharmexcil.com

Regional Office - Mumbai :

New India Chamber, Office No:306, 3rd Floor, B wing, Mulgaon (V),

MIDC, Andheri East, Mumbai-400093

Ph: +91-22-28200593 / 594 Fax: +91-22-28200595

E-mail: romumbai@pharmexcil.com

Regional Office - New Delhi :

H.28, 2nd Floor, 23 Himalaya House, K.G. Marg,

Connaught Place, New Delhi-110 001

Ph: +91-11-41536658 / 45062550 / +91-11-43091971 / 72 / 73 / 74

E-mail: rodelhi@pharmexcil.com

Branch Office - Ahmedabad :

7-C, Trade Centre, Near Stadium Cross Road,

Navarangpura, Ahmedabad-380 009

Ph: +91-79-40050497

E-mail: boahmedabad@pharmexcil.com