Government of India
Ministry of Commerce & Industry
Department of Commerce

pharmexcil

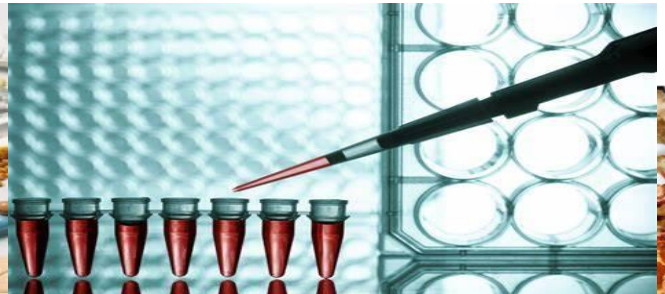
Pharmaceuticals Export Promotion Council of India
(Set up by Ministry of Commerce and Industry, Govt. of India)

Indian Pharmaceuticals

Meeting Global Needs

18th Aug 2020

Dr.Dinesh Dua
Chairman



Pharmaceuticals Export Promotion Council of India

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

FACILITATOR

- Organises Export Promotional events and Trade delegations
- Industry's Voice - Represents issues with concerned Agencies

ADVISOR

- Make suggestions to Govt. of India & Regulators on policy issues relating to Pharma exports

EDUCATE

- Market / Regulatory reports of countries
- Importers / Distributors in overseas countries

Indian Pharmaceutical Industry

Market Size	• Current Size US$ 40.6 Bn. • Divided equally in Domestic & Exports. • Went Up from US$6 Bio in 2005 with CAGR 17%
Leading Pharma Producer	• 3rd Largest exporter of formulations by volume & • 10th by value
Export Behemoth	• Exports to 206 scountries • 22% of Global Exports • US$ 20.58 Bn in FY-20
Fast Growth	• CAGR 13%
Attracts FDI	• 5% of Total FDIs in India • Total FDI US$ 14 Bn

Indian pharmaceutical companies have contributed towards better health outcomes Globally

Shaping global vaccination

60%
Global vaccine production

90%
WHO demand for measles vaccine

40-70%
WHO demand for DPT (Diphtheria, Tetanus and Pertussis) and BCG (Bacillus Calmette-Giuerin) vaccines

Driving access of medicines globally

25%
Medicines used in UK are made in India

33%
Pills consumed in US is produced by Indian generic manufacturer

37%
AIDS patients receiving treatment in 2009, vs 2% in 2003 in Africa

Indian Industry – Strong Regulatory Presence

Highest no.of USFDA approved sites outside USA

- No: of Sites(Bulk drugs + Formulations) Registered with US FDA (as on June 2020): 664

> 30% of ANDAs

- ANDAs Market Authorizations (As on April 2020) : 5029

33% of CEPS granted by EDQM

- Number of CEPs received (as on April 2020): 1744
- No of Sites with Registered with EU GMP: 697

Strong presence in Semi Regulated Markets

Robust presence in almost all Semi-Regulated Markets like South East Asia, CIS and LATAM.

India's Contribution to the Suffering Mankind

Medicine Sans Frontiers

- Purchases 80% of its ARVs from India

Partnership with Global NGOs

- The United Nations Children's Fund (UNICEF)
- Bill & Melinda Gates Foundation
- The Global Fund and
- The Clinton Foundation

PEPFAR

- Indian Generic ARVs approved by the USFDA also resulted in cost-savings over 90% of the ARVs for PEPFAR

WHO

- 90% of WHO prequalified APIs are sourced from India

India's Role in Global Fight against Pandemic

INDIA
Pharmacy of the World

→ **HCQ Tablets** → **112 Nations**

Remdesivir

- Hetero Labs Ltd
- Cipla Ltd
- Dr. Reddy's Laboratories
- Jubilant Lifesciences
- Zydus Cadila Healthcare Ltd
- Syngene

← Voluntary license with Gileads Inc To supply to 127 Nations

Indian Vaccine Industry : Powerhouse of Vaccine Manufacturing

Serum Institute of India	➿Licensing deal for Oxford vaccine & Novavax Covid vaccine ➿Partnership with Gavi, The vaccine Alliance and Bill & Melinda Gates Foundation for 100 million doses
Bharath Biotech	➿Covaxin is under Phase 1 & 2 Trial
Zydus Cadila	➿ZyCoV-D is under Phase 1 & 2 Trial
Biological E	Agreement with Janssen Pharmaceutica NV, a subsidiary of Johnson & Johnson

"Indian Pharma Industry can Produce COVID-19 Vaccines for Entire World"

Bill Gates

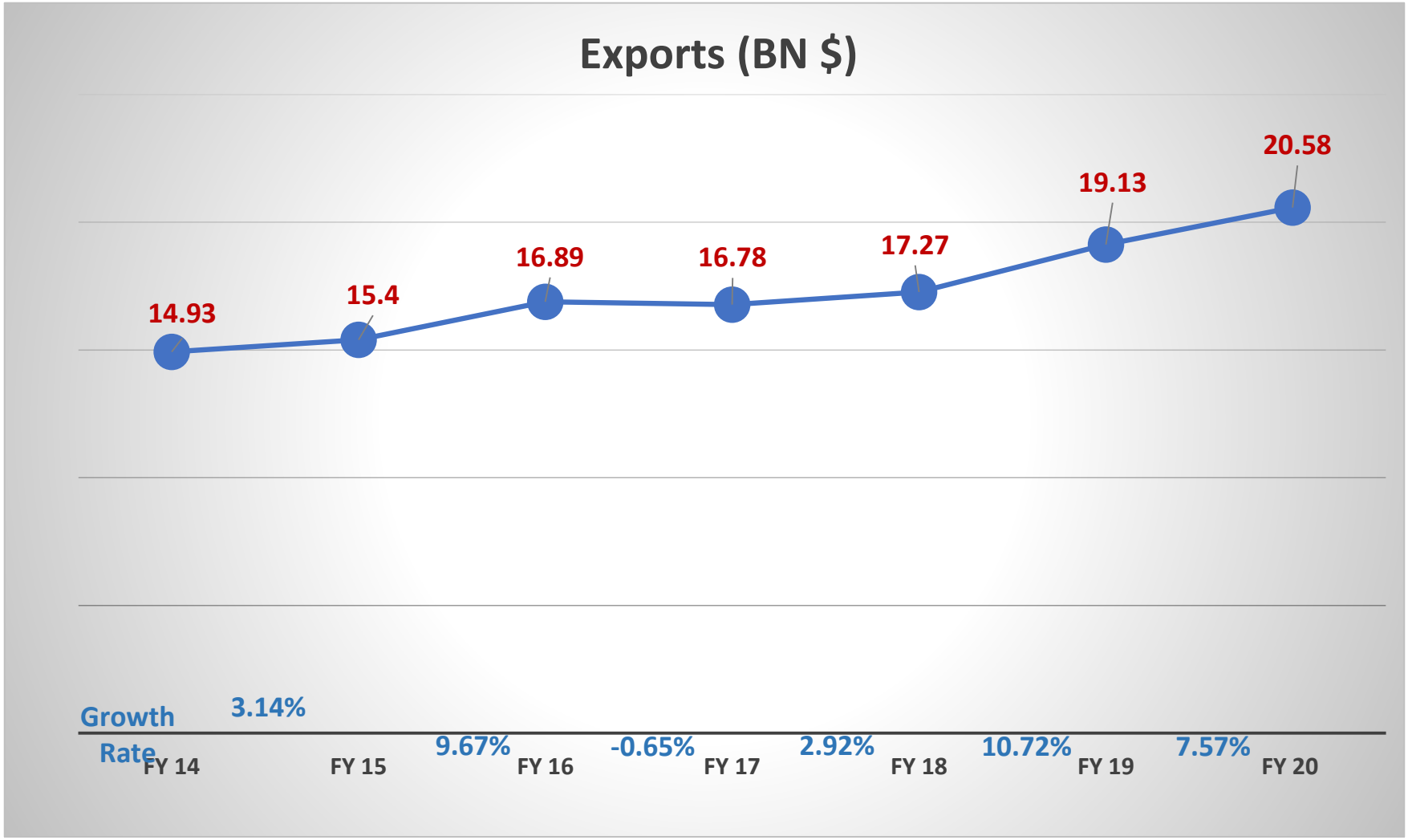
"Indian Pharma Industry

Is an Asset not just for India

But for the Entire World"

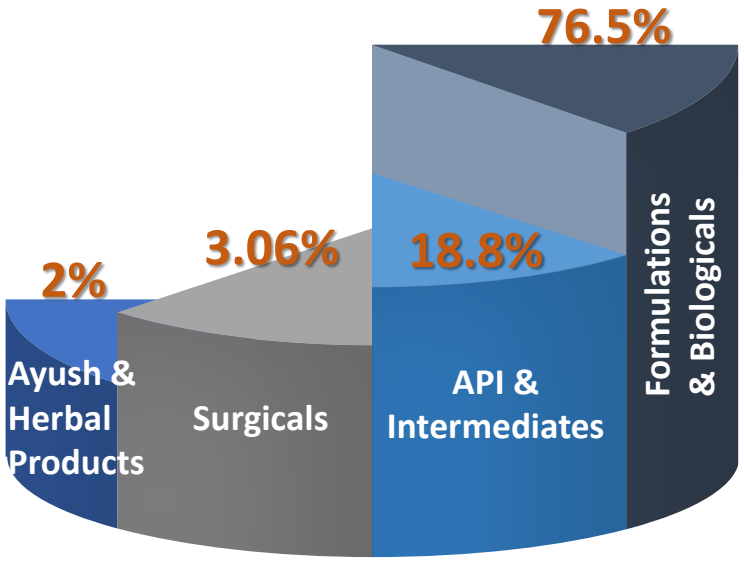
PM Narendra Modi

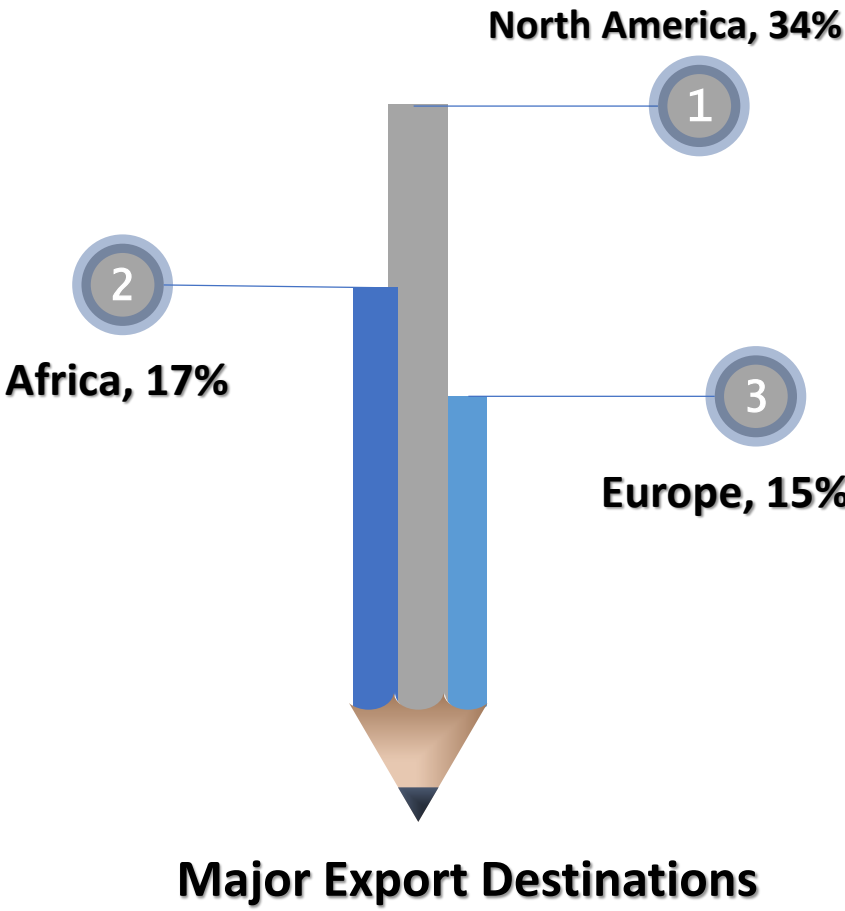
Indian Pharma Export Performance



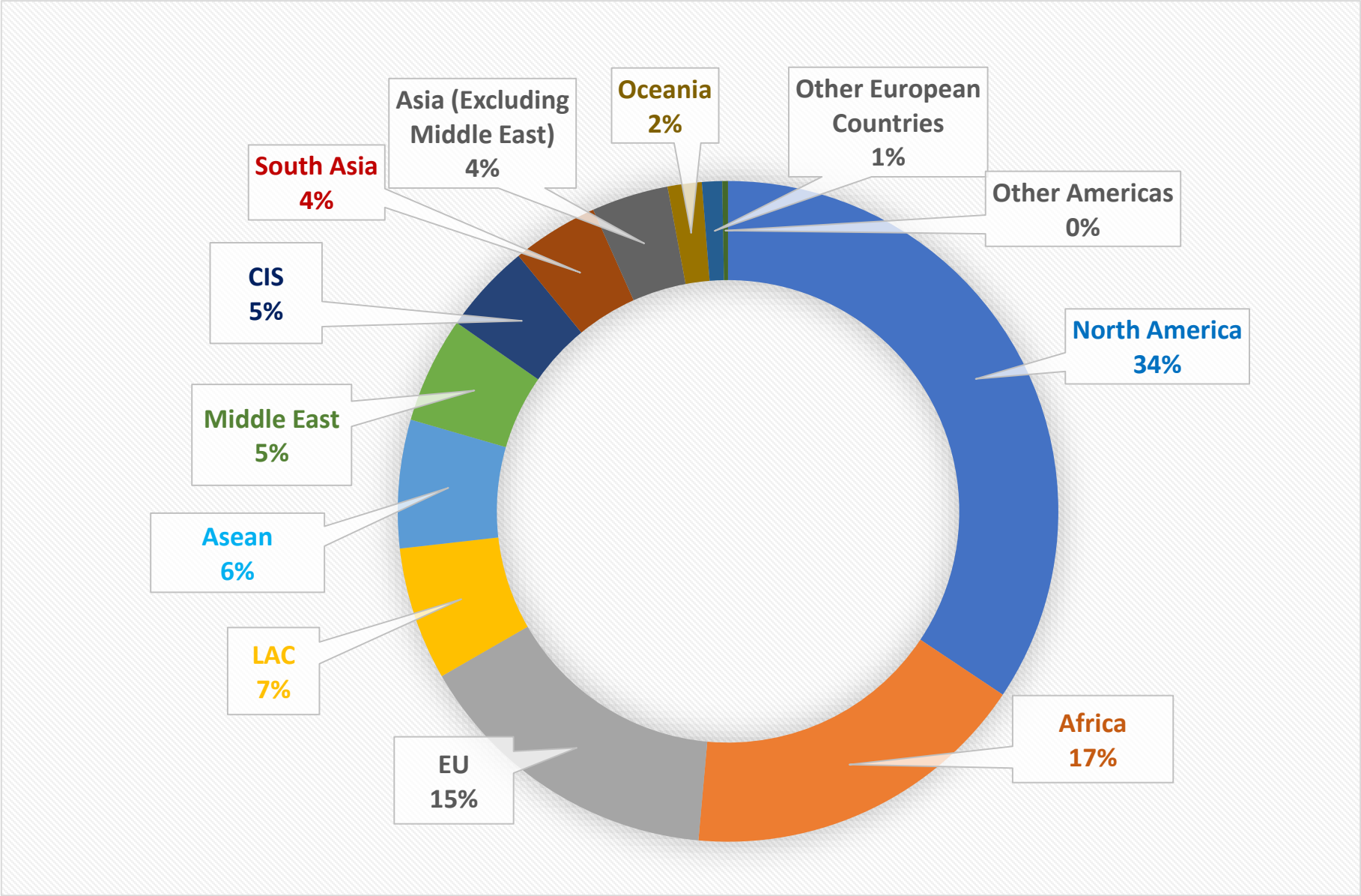
Export Outlook

Over 55% Exports to Highly Regulated Markets





Indian Pharma Exports- Region wise



Top Ten Exporting Destinations

	Exports in FY-20 ($ Mn)	Growth (%)
01 USA	6739.43	(15.79%)
02 SOUTH AFRICA	610.79	(-1.34)
03 UK	557.86	(-11.48)
04 RUSSIA	552.41	(13.77%)
05 GERMANY	504.05	(13.07%)
06 BRAZIL	473.10	(4.65%)
07 NIGERIA	419.43	(-6.37%)
08 CANADA	334.54	(2.85%)
09 NETHERLAND	319.29	(55.05%)
10 FRANCE	309.23	(11.77%)

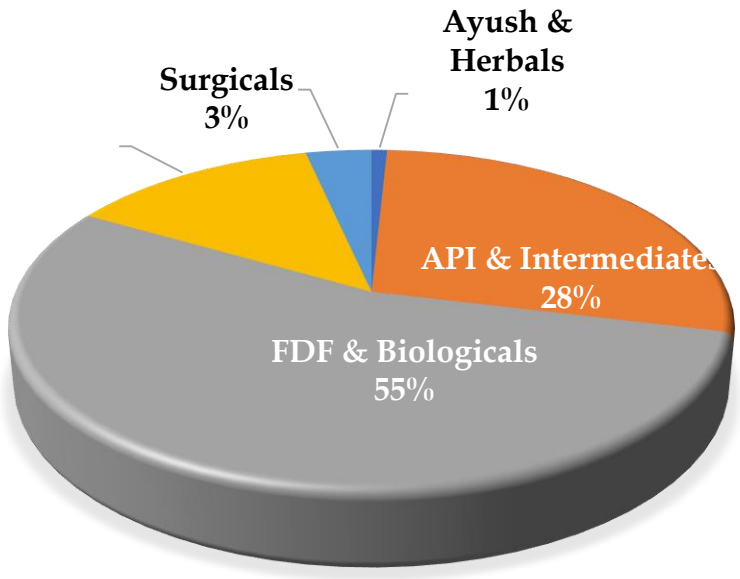
Source: DGCIS

LAC Pharma Market & India's Exports

Market Size • 67 billion USD

Generic Market • 17 billion USD

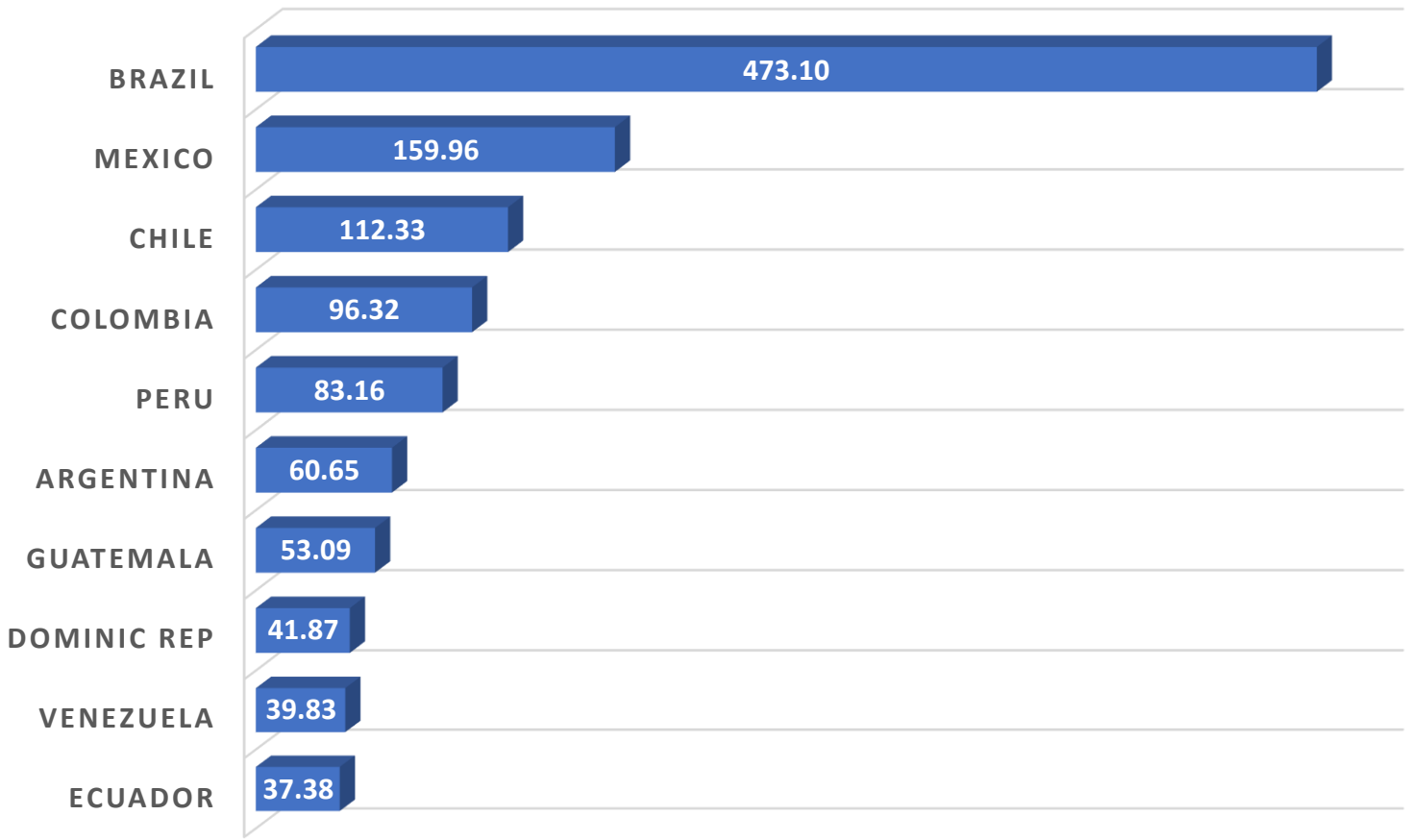
India's Exports to LAC (mn USD)



Category	FY-19	FY-20	% Gr
Bulk Drugs & Drug Intermediates	388.39	372.75	-4.03
Formulations & Biologicals	730.10	726.81	-0.45
Vaccines	137.30	176.20	28.34
Ayush & Herbals	9.74	10.86	11.51
Surgical	36.07	46.13	27.91
Total	**1308.30**	**1341.37**	**2.53**

Top 10 Export Destinations in LAC

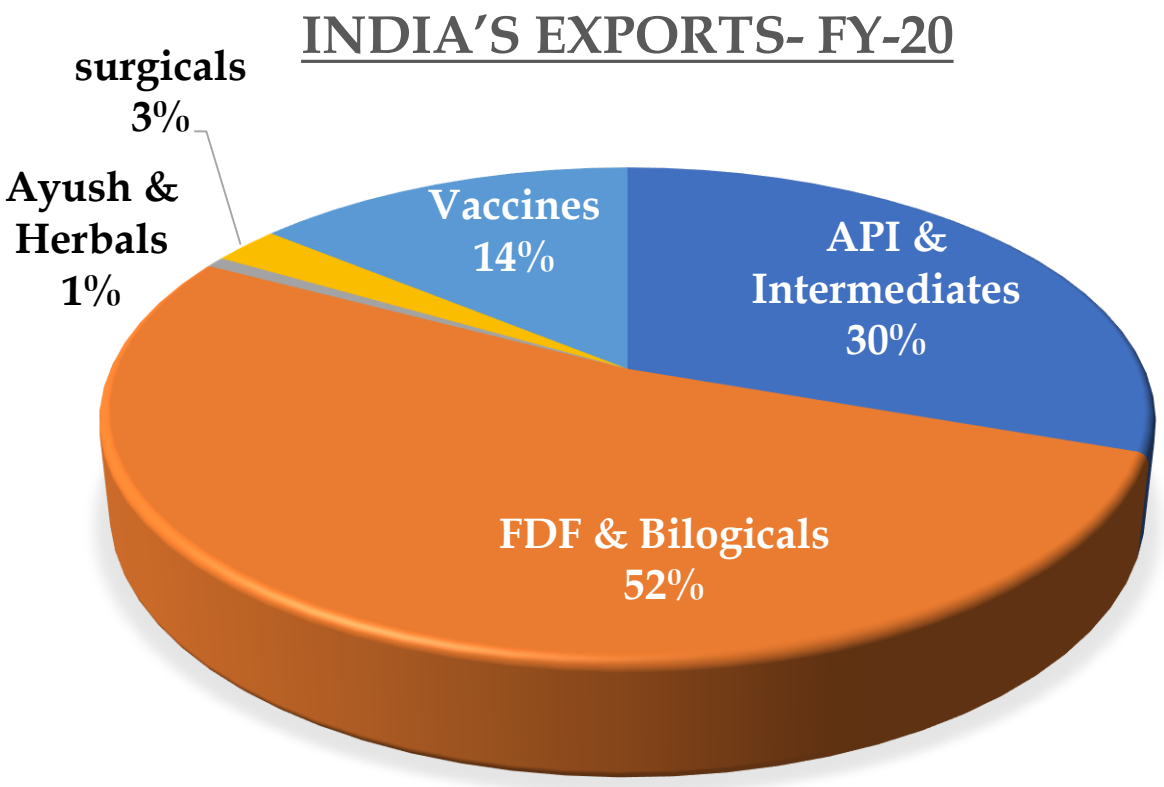
Exports in 2019-20: US$ 1341.37 million with 2.53% growth



Top 10 exporting destination of Indian pharma
(Exports in million USD in 2019-20)

Colombia Pharma Market & India's Exports

- **Fifth largest Market in LAC region.**
- **Market size in 2019 - $ 4.8 bn**
- **Generic market in 2019 - $ 2.04 bn (42.6% of total market)**



- **FDF & Biologicals -- $ 50.47 mn**
- Vaccines – $ 13.52 mn
- Surgicals -- $ 2.39 mn
- **API & Intermediates- $ 29.27 mn**
- Ayush & Herbals – $ 0.67 mn

Colombia's top Ten formulations Importing partners $ Mn

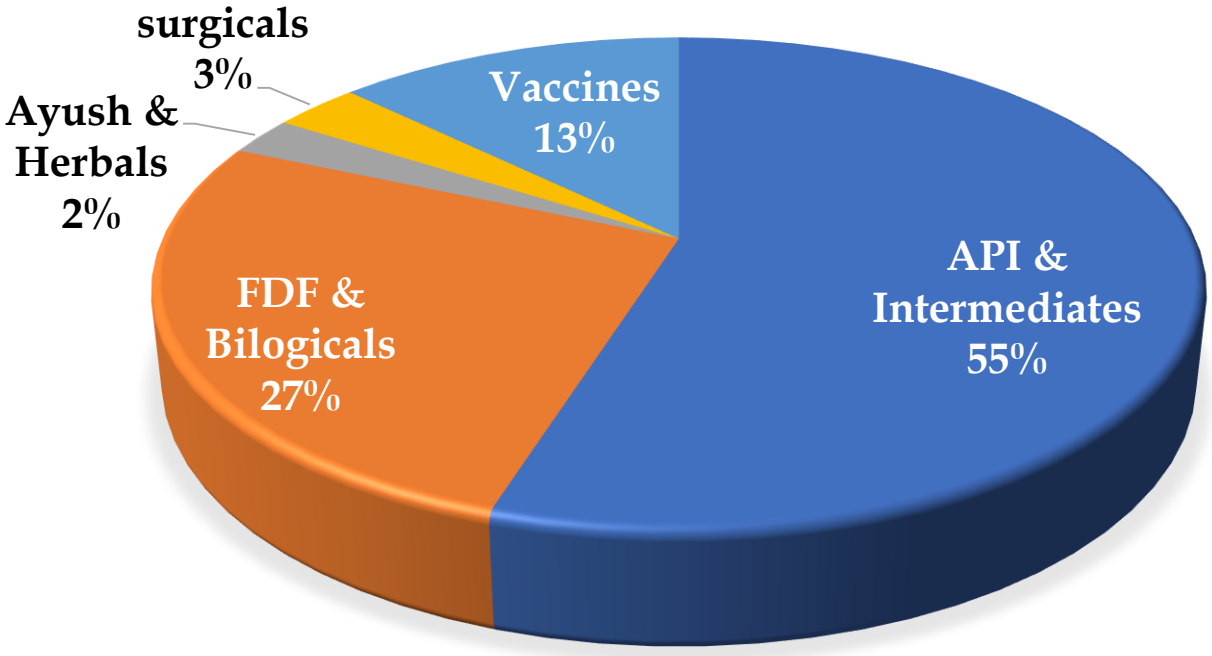
Rank	Country	2017	2018	GR%	Share %
1	USA, Puerto Rico and US Virgin Islands	488.42	523.75	7.23	21.63
2	Germany	358.17	430.43	20.18	17.78
3	Switzerland, Liechtenstein	183.85	200.20	8.89	8.27
4	France, Monaco	128.78	131.90	2.42	5.45
5	Mexico	102.08	98.83	-3.19	4.08
6	Belgium	81.74	84.97	3.95	3.51
7	Italy	97.63	83.97	-13.99	3.47
8	Ireland	87.46	82.52	-5.64	3.41
9	**India**	**77.88**	**81.05**	**4.08**	**3.35**
10	Brazil	74.05	72.75	-1.76	3.00
	Total of the above	1680.05	1790.37	6.57	73.95
	World	2220.23	2421.05	9.05	100.00

Source: Un comtrade

Mexico Pharma Market & India's Exports

- **Second largest Market in LAC region.**
- **Market size in 2019 - $10.6 billion**
- **Generic market in 2019 - $ 3.2 bn bn (% of total market)**

INDIA'S EXPORTS-FY-20



- **FDF & Biologicals -- $ 42.54 mn**
- Vaccines – $ 20.46 mn
- Surgicals -- $ 5.10 mn
- **API & Intermediates- $ 87.85 mn**
- Ayush & Herbals – $ 4.01 mn

Mexico's top Ten formulations Importing partners $ Mn

Rank	Country	2017	2018	GR%	Share %
1	USA, Puerto Rico & US Virgin Islands	1233.08	1325.51	7.50	31.81
2	Germany	711.84	768.72	7.99	18.45
3	France, Monaco	247.42	367.75	48.63	8.82
4	Switzerland, Liechtenstein	238.50	236.19	-0.97	5.67
5	Canada	158.26	205.76	30.02	4.94
6	Italy	178.73	202.40	13.24	4.86
7	Spain	167.66	166.49	-0.70	4.00
8	Brazil	105.65	128.45	21.58	3.08
9	China	106.62	112.27	5.29	2.69
10	Ireland	71.14	89.15	25.32	2.14
13	**India**	**63.62**	**68.93**	**8.34**	**1.65**
	World	3686.09	4167.38	13.06	100.00

Source: Uncomtrade

Issues faced by Indian Exporters

Anti-Dumping Duty imposed on India's imports into Mexico

- Metoprolol Tartarate in 2015
- Dicloxacilline sodium & Amoxicillin(2012)

Accelerating India's Exports

- **Affordable of Indian generics are best alternative to reduce the healthcare expenditure during this economic crises of Pandemic**

- **Policy measures of Indian Government to reduce Import dependence on APIs, KSMs & Drug Intermediates (Dis)**

  - **Schemes for Promotion of Bulk Drug Parks**
  - **Production Linked Incentive Scheme (PLI) for promotion of domestic manufacturing of APIs, KSMs & Dis**

- **Regulatory Convergence for optimum utilization of Resources & to FastTrack the Approvals**

Thank You !