

Pharmaceutical Sector in Bangladesh: Investing for Growth, Global Integration and Post-LDC Market Opportunities

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Presented by

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Country Statistics



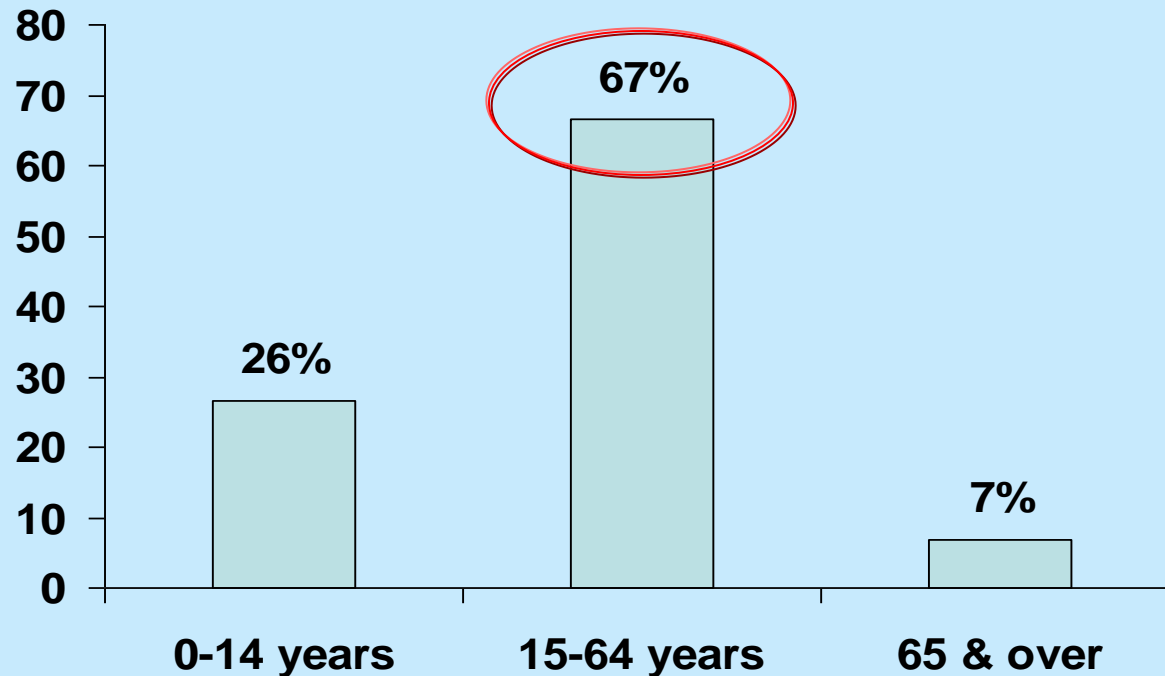
- Population: ~ 169 Million (2021)
- GDP (current price) : 416.26 B USD (2021)
- GDP per capita : 2457 USD (2021)
- GDP growth (annual %): 6.9% (2021)
- Income level: Lower middle income.

Source: The World Bank (<https://data.worldbank.org>)



Human Capital

- Population: ~ 169 million (2021)
- Country position for population in the world : 8
- Population dividend: 1980 to 2040
- The median age in Bangladesh is 27.6 years.



Age Structure (2021 est.)

Source: CIA world fact book

Dr. Khan A. Matin, 2012 (ISRT, DU)

History of Pharmaceutical Industry

1950s:

Several small scale companies were established by local entrepreneurs



1960s:

A number of companies including some multinational started production units



History of Pharmaceutical Industry

1970 - 1989:

A large number of local entrepreneurs came into pharmaceutical business

1990s - Onwards:

- Many companies went for massive expansion of formulation products.
- Country achieved almost self-sufficiency in formulation products.



Pharma Companies in Bangladesh

- Total Number of Registered Companies : 265
- Number of Companies in operation : 213
(including importers)

Ref: Directorate General of Drugs Administration (DGDA) , Bangladesh



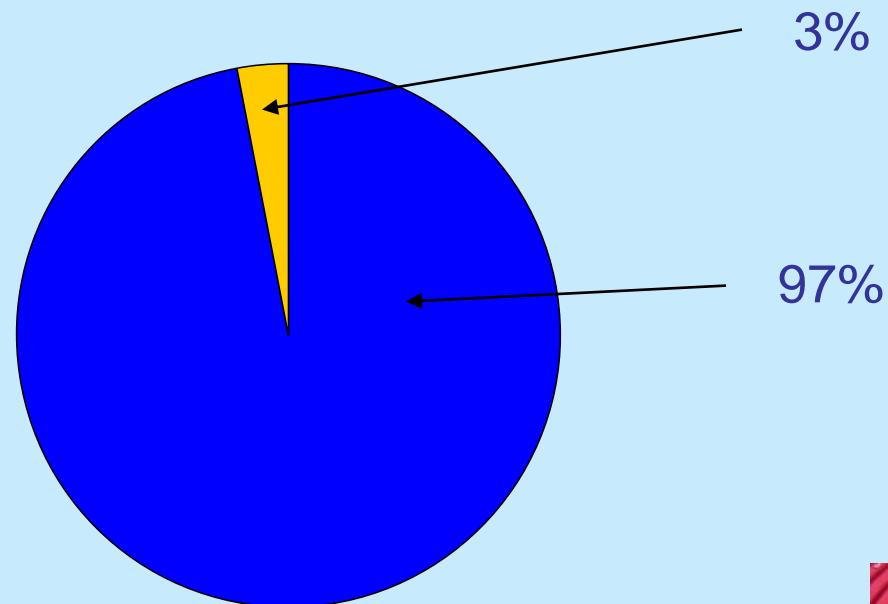
Market Share Distribution

Companies	Market Share	Cumulative Market Share
Top 1 - 5	52.35%	52.35%
Top 6 - 10	20.01%	72.36%
Top 11 - 15	13.24%	85.60%
Top 16 - 20	5.88%	91.48%
Top 21 - 25	4.23%	95.71%
Top 26 - 30	2.60%	98.31%
Next 31 – 150 (120 companies)	1.69%	100%



Local Production vs. Import

- Local Production : 97%
- Import : 3%



Ref: Directorate General of Drugs Administration , Bangladesh



Bangladesh is almost self-sufficient, many of our neighbours import significant part of their requirement.

- Singapore 80%
- Malaysia 70%
- Philippines 65%
- Vietnam 60%



Pharmaceuticals Sector of Bangladesh

- In 3Q 2022, market size was 3.32 B US\$
- Growth rate was 4.03%
- Per Capita consumption ~ 19.65 US\$

Source: IQVIA formerly known as IMS Health

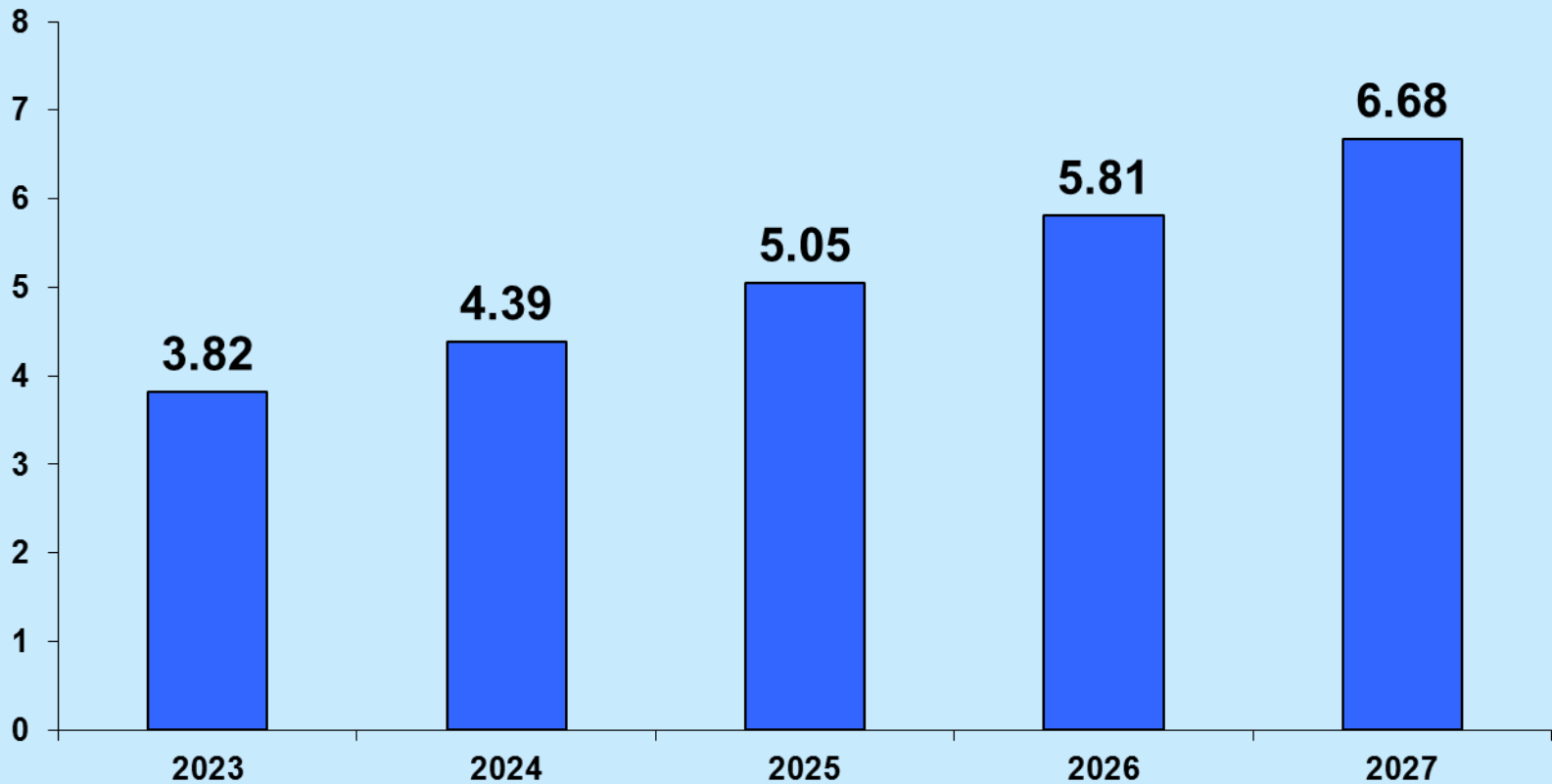


Pharmaceutical Sector



Market grew three (03) folds in last ten years

Future prospect of Pharma Industry considering 15% annual growth (Value in \$ Billion)



Production Facility

Bangladesh Pharmaceutical Industries are capable of producing all types of dosage forms -

- Tablet,
- Capsule,
- Liquid preparations,
- Dry suspension,
- Injections,
- Ointment/cream,
- Nasal spray,
- Granules in sachets,
- Lyophilized vials,
- Eye drops,
- Meter Dose Inhalers,
- Large volume parenterals,
- Pre-filled syringes etc.



Bangladesh is capable to produce many specialized delivery products

- Inhalers
- Pre-filled syringe injections
- Lyophilized Injections
- DPI
- Sustain Release formulations, etc



Formulation:

- Total number of Brand : 25,656
- Total number of generic : 1,326
- Dosage forms : 40
- Number of Pharmacy : 116,826



Active Pharmaceuticals Ingredients (API):

- 15 Companies are currently producing API
- APIs like, Azithromycin, Diclofenac Na, Flucloxacillin, Amoxicillin, Paracetamol etc. are produced locally



Bangladesh is capable of producing high quality Products

The industry employs -

- State-of-the-art manufacturing facilities
- Sophisticated production & analytical equipment and apparatus
- Highly skilled human resources

Finest quality medicine



A number of pharmaceutical companies have already obtained GMP certifications from -

- UKMHRA,
- EU,
- US FDA,
- TGA Australia,
- ANVISA
- MOH Turkey,
- Other recognized regulatory authorities etc.



By 2024, another 10 companies may receive certification from these regulatory authorities

Future Opportunities

- Biosimilar
- Vaccine
- Active Pharmaceutical Ingredient (API)
- Global Generic Export



A number of Biosimilar products are now produced by Bangladeshi Companies

- Human Insulin
- Erythropoeitin
- Filgrastim
- Insulin Glargine
- Monoclonal Antibodies (Mabs)



Biosimilar from Bulk stage are now produced locally

- Peg-Filgrastim,
- Adalimumab,
- Peg- Erythropoietin,
- Trastuzumab, etc.

Vaccines



Bangladesh is producing the following vaccines and many are in development:

Sl.	Vaccine
1	HPV vaccine
2	Pneumococcal vaccine (polysaccharide)
3	Oral Cholera Vaccine
4	Hepatitis B vaccine (rDNA)
5	Influenza Vaccine
6	Meningococcal Polysaccharide vaccine
7	Hepatitis A vaccine
8	Rabies vaccine
9	Tetanus vaccine
10	Typhoid Polysaccharide vaccine
11	Varicella vaccine

Sl.	Immunoglobulins
1	Anti snake venom
2	Human Normal Immunoglobulin
3	Tetanus Immunoglobulin / Tetanus antitoxin
4	Rabies Immunoglobulin



API Park

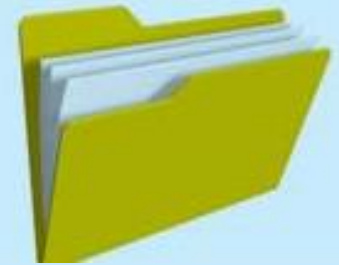


- Government is establishing API Park at Bausia in Munshiganj, about 40 km away from Dhaka
- About 27 API industry will be established
- Central ETP, Incinerator & other facilities
- BAPI will aim for all 27 companies to be approved by regulated markets



API Park

- BAPI will aim to produce about 800-1000 generic bulk drugs
- Most of the bulk materials will have DMF or EDMF

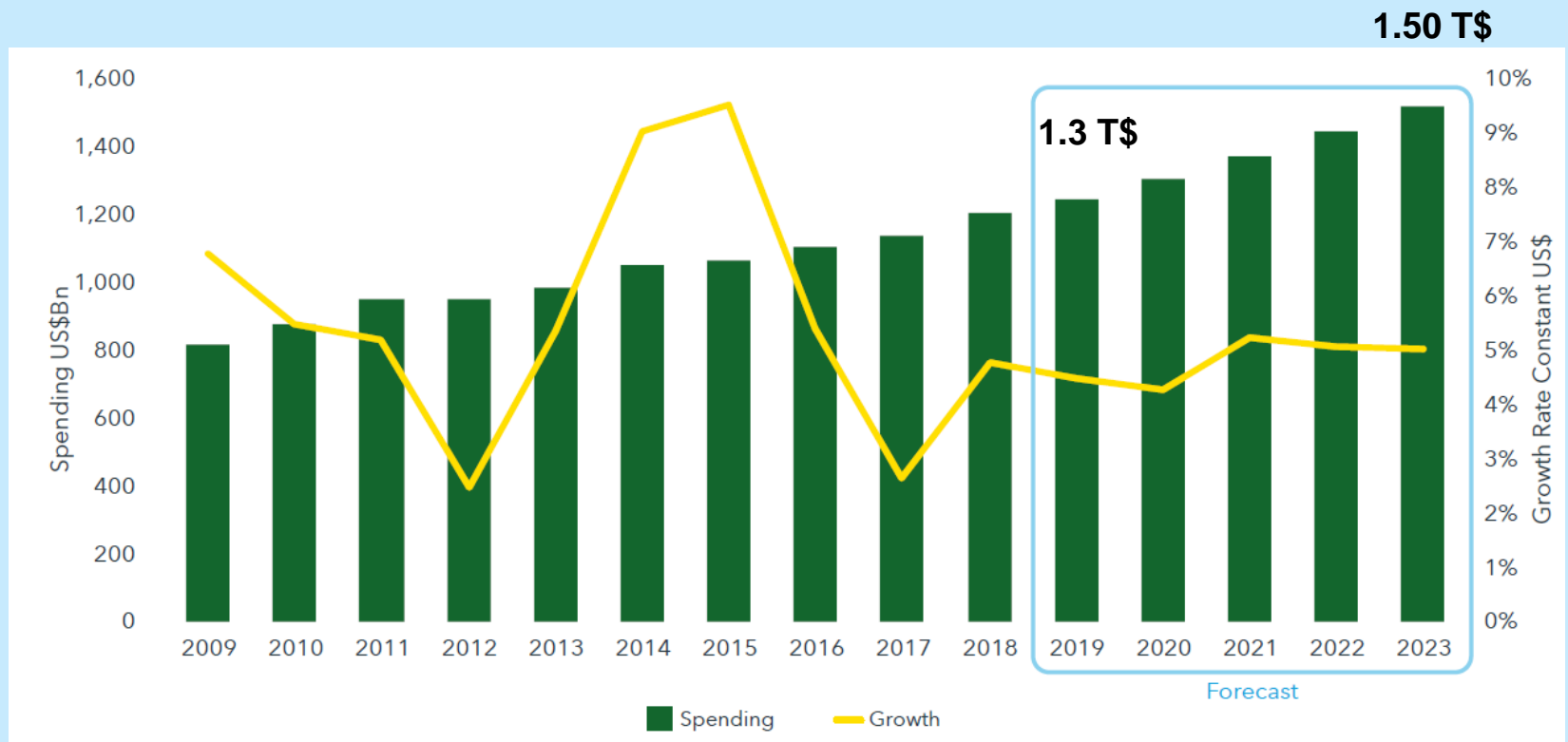


Global Generic Export



Global Medicine Spending and Growth

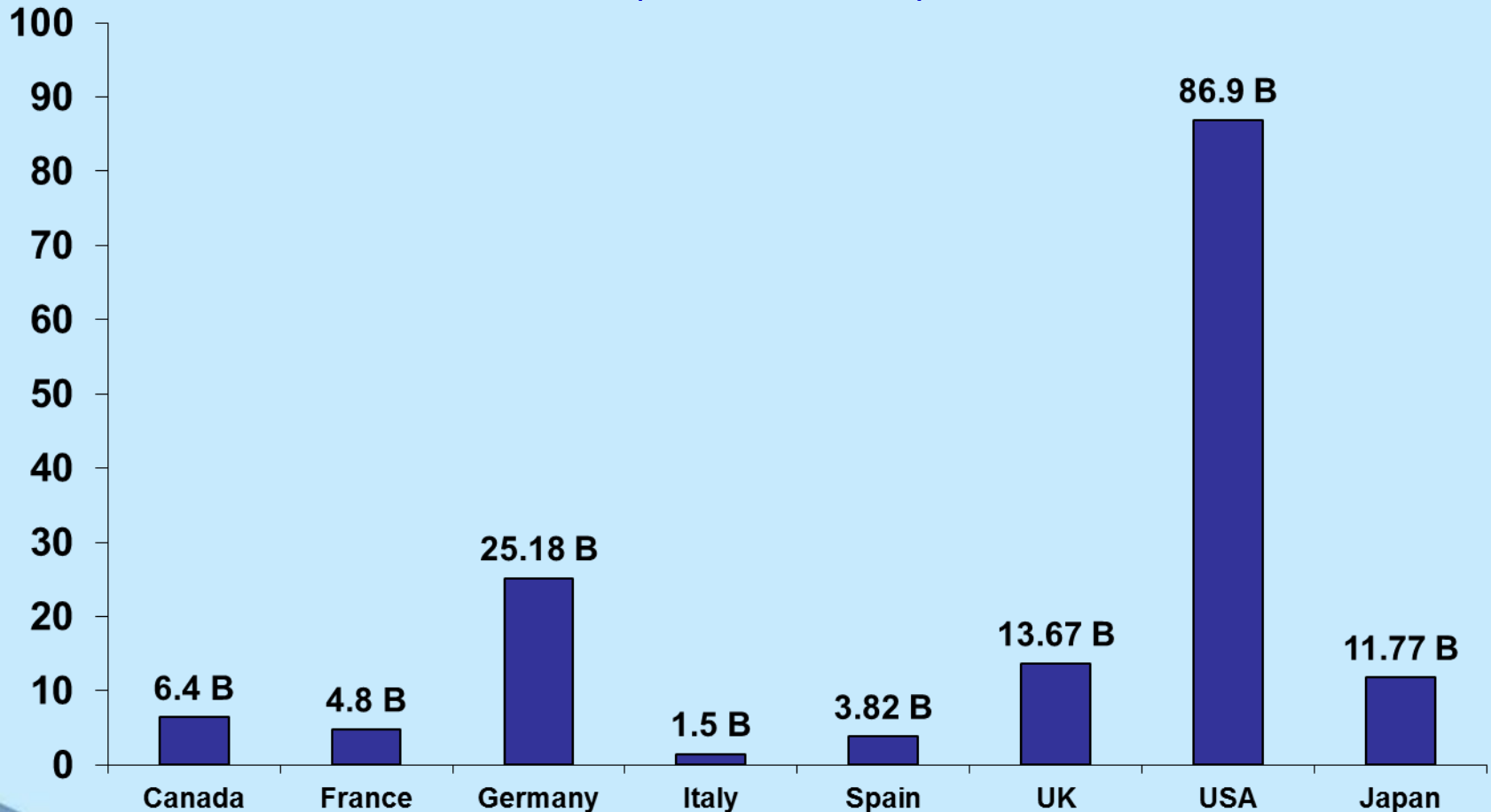
- Global spending on medicines reached just under \$1.3 trillion by 2019, with 4–5% growth globally. Global spending is expected to exceed \$1.5 trillion by 2023.



Source: The Global Use of Medicine in 2019 and Outlook to 2023. IQVIA formerly known as IMS Health - 2019

Pure Generic Market in \$ Billion

(2021-2022)

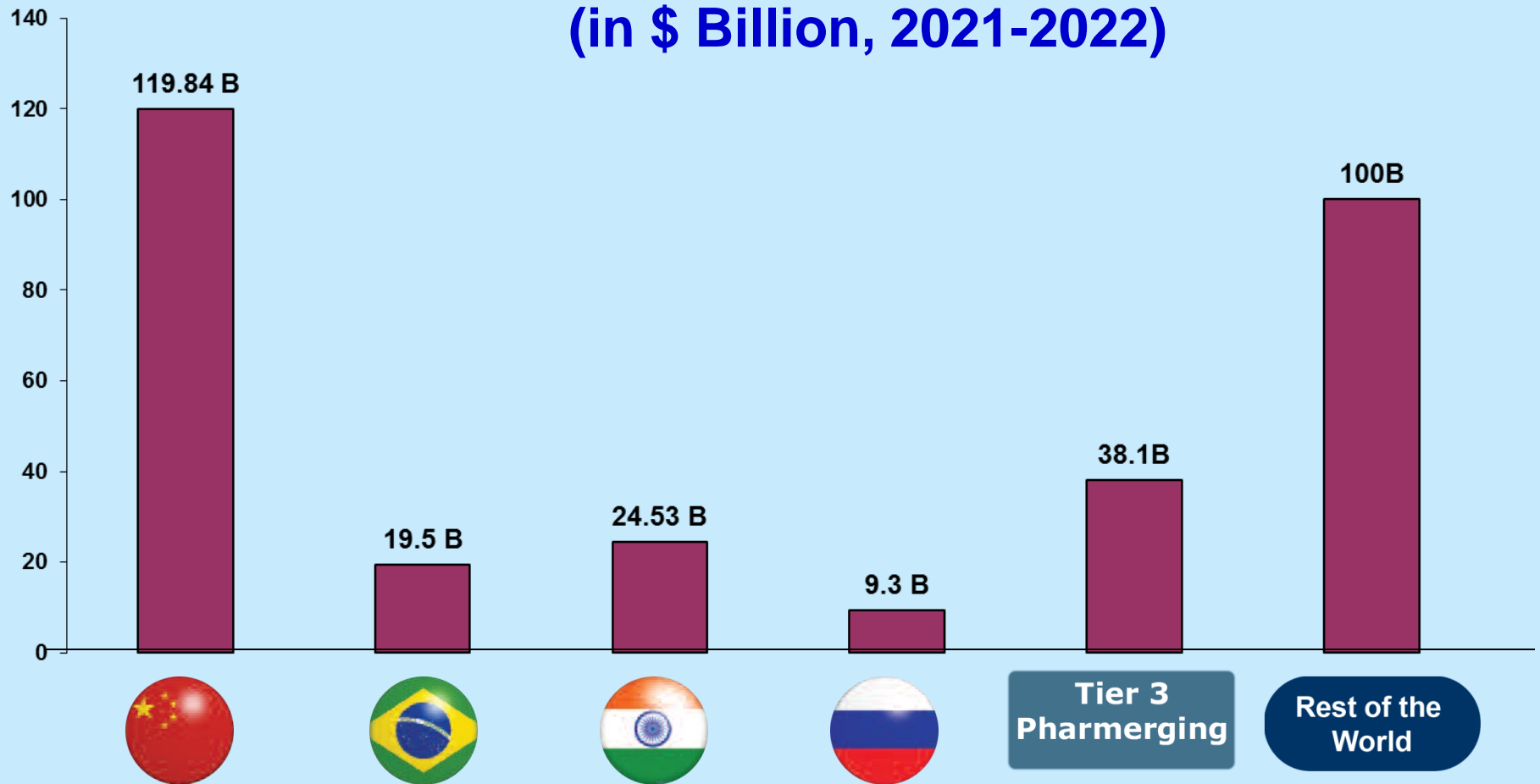


Total = 154 B\$

Source: RESEARCH AND MARKETS (researchandmarkets.com) & statista.com

Branded Generic Countries & market

(in \$ Billion, 2021-2022)



Total = 311 B\$

Source: RESEARCH AND MARKETS (researchandmarkets.com), statista.com, imarcgroup.com, reach24h.com

Competitive advantage of Bangladesh in global market

- Confidence in producing high quality products
- Technology
- Human Resource
- Language (English Speaking)



Pharmaceutical Export from Bangladesh

Now,

Bangladesh Pharmaceutical Industry is successfully exporting its quality products to about 157 countries in -

- ❖ Asia
- ❖ Africa
- ❖ North America
- ❖ South America
- ❖ Europe



Export from Bangladesh

157 Countries

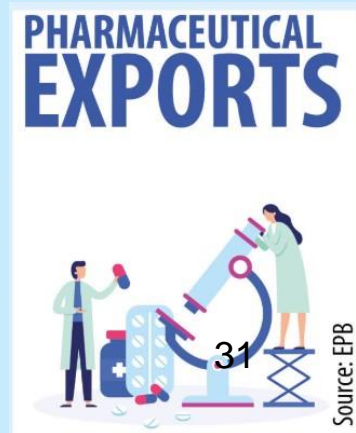
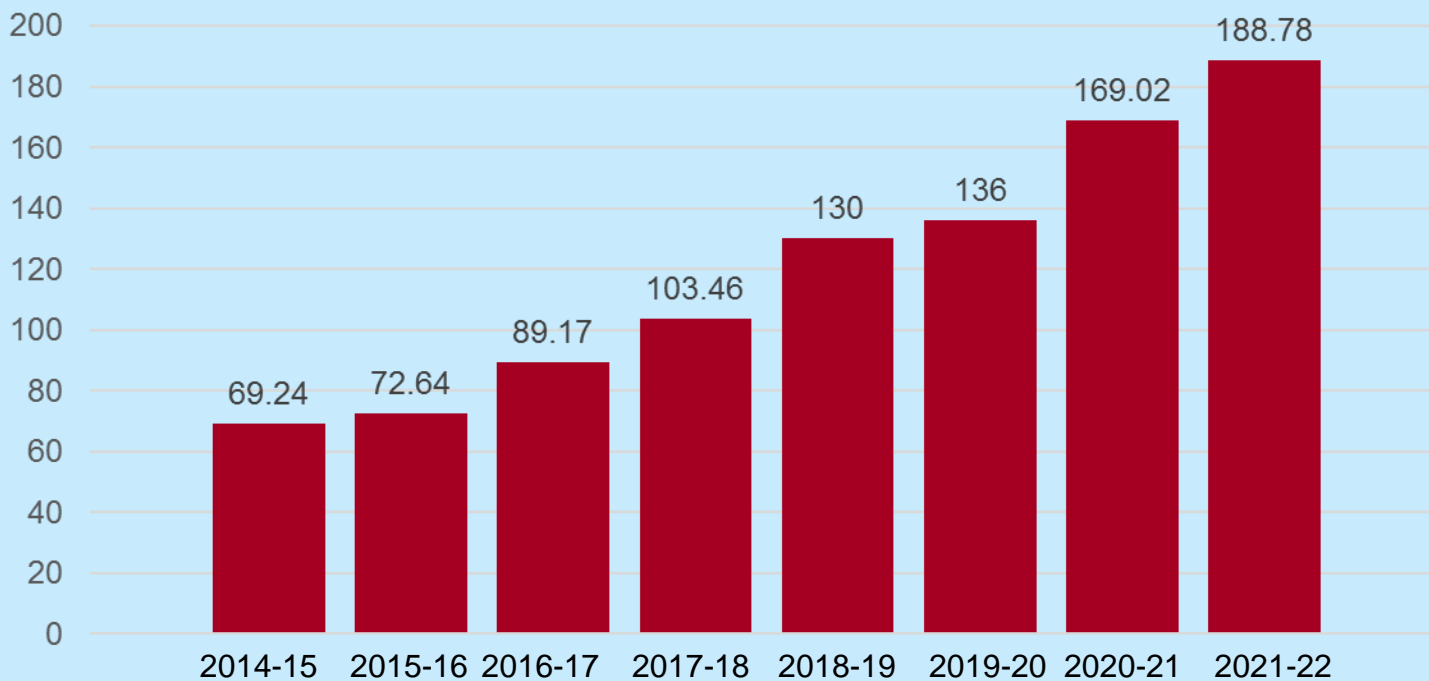
Ref: DGDA

1	Afghanistan	26	Ethiopia	51	Liberia	75	Republic of Dominican	99	Tunisia	124	Ireland
2	Algeria	27	Fiji	52	Libya	76	Rumania	100	Turkey	125	Oman
3	Armenia	28	France	53	Lithuania	77	Russia	101	U.A.E	126	Turkmenistan
4	Australia	29	Gabon	54	Macau	78	Samoa	102	Uganda	127	Kazakystan
5	Austria	30	Gambia	55	Malaysia	79	Serbia	103	UK	128	Bahrain
6	Azerbaijan	31	Germany	56	Maldives	80	Seychelles	104	Ukraine	129	Brunai Darus Salam
7	Barkina Faso	32	Ghana	57	Mauritius	81	Siera Leone	105	USA	130	Peru
8	Belarus	33	Guam	58	Mexico	82	Singapore	106	Uzbekistan	131	Suriname
9	Belgium	34	Guatemala	59	Moldova	83	Slovenia	107	Vanuatu	132	Benin
10	Belize	35	Guyana	60	Mongolia	84	Solomon Islands	108	Venezuela	133	Congo
11	Bhutan	36	Honduras	61	Morocco	85	Somalia	109	Vietnam	134	Mauritania
12	Botswana	37	Hong Kong	62	Mozambique	86	South Africa	110	Yemen	135	Somali Land
13	Brazil	38	Hungary	63	Myanmar	87	Spain	111	Palestine	136	Abkhazia
14	Burundi	39	India	64	Nepal	88	Sri Lanka	112	Lebanon	137	Bulgaria
15	Cambodia	40	Indonesia	65	New zealand	89	Sudan	113	Kuwait	138	Macedonia
16	Canada	41	Iraq	66	Nicaragua	90	Swaziland	114	Qatar	139	Bosnia
17	Chad	42	Iran	67	Nigeria	91	Switzerland	115	Argentina	140	Finland
18	Chile	43	Italy	68	Pakistan	92	Taiwan	116	Montenegro	141	Transnistria
19	China	44	Jamaica	69	Palau	93	Tajikistan	117	Egypt	142	Georgia
20	Colombia	45	Japan	70	Panama	94	Tanzania	118	Lesotho	143	Cypras
21	Costa Rica	46	Jordan	71	Papua New Guinea	95	Thailand	119	Malawi	144	Kosovo
22	Denmark	47	Kenya	72	Philippines	96	The Netherlands	120	Mali	145 to 157	Others
23	Ecuador	48	Kiribati	73	Poland	97	Togo	121	Senegal		
24	Eritrea	49	Korea	74	Portugal	98	Tonga	122	Laos		
25	Estonia	50	Latvia					123	Kyrgyzstan		

Export from Bangladesh

- Export revenue for 2021-2022 was **USD 188.78 million**, Growth rate of **12%**
- Pharma Export grew almost **three (03) folds** in last 7 years

Pharma Export Revenue (Million USD)



Export opportunities from Bangladesh



- According to “Research And Markets” (an Ireland based research company), Bangladesh’s exports will increase to 450 million dollars by 2025.
- World generic market is about 400 billion USD, if Bangladesh can take 1% of this value then pharma export will reach 4 Billion USD. This is highly achievable considered by majority of experts.
- Then, in next step if we can take 10% of the share, it will be 40 Billion USD every year.
- It is not only the revenue but it gives security for the country which is over depended on RMG sector.





LDC Pharma Intellectual Property (IP) Waiver Until 2033 Approved By WTO TRIPS Council

Patent waiver for Bangladesh: 2033 (2026)

Source: The Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS)



Impact on the pharmaceutical industry of the country due to the loss of the TRIPS exemptions/ waivers after graduation from the LDC category in 2026



1. What will happen to those products which have valid patent but already introduced in Bangladesh?
2. What will happen to affordable access to medicine after 2026?

Fate of those products which have valid patent but already introduced in Bangladesh

- Already introduced products in local market should be considered as prior art as these are already available in public domain
- Thus patent can not be implemented for products already introduced in Bangladesh within 2026

NOVELTY



Probable impact on medicine price and availability after 2026



- Patented product price will be expensive
- In light of this high price, the experts may feel certain interventions are needed. In that case required provisions may be introduced in the patent law to mitigate the problem
- Some complex biologics may not be available in the country



Measures and initiatives to prepare for the loss of the TRIPS waiver

- Negotiate with WTO for extending the TRIPS transition period relating to pharmaceutical even if the country graduates from the LDC status.
- On 07 March'23, Hon. Prime Minister Sheikh Hasina advocated for at least six-year extension of preferential market access for graduating LDCs like Bangladesh.



Global Integration and Post-LDC Market Opportunities

- Already government has invested heavily to accelerate the development of API park
- 27 companies have obtained plots for setting up factories in the industrial park
- In the mean time, companies are building up their finished formulation manufacturing capacity. Finished formulation includes both small molecule synthetic drug and complex biologics & Vaccines



Global Integration and Post-LDC Market Opportunities

- If we can implement our plans then Bangladesh can effectively become a global hub of generic medicine
- Production of the selective items which are currently patented will provide us valuable data for “First to File”
- These items will be available from Bangladesh only at competitive price



Global Integration and Post-LDC Market Opportunities

- For generic drugs, in addition to western regulated market we should also focus on potential API markets
- Target countries which has large formulation base but no API industry. Countries in Latin America, Indonesia, Pakistan, Egypt, Kenya etc.
- Diplomatic efforts should be started so that once API is available, we have a ready market



Global Integration and Post-LDC Market Opportunities

- Robust pharmaceutical sector with API and biologics manufacturing facility in addition to synthetic small molecules. In terms of skilled manpower and cost, very few countries will be able to compete with Bangladesh
- Bangladesh will have enough data to file application to become first time generic manufacturer of various patented molecules as soon as their patent expires, in various developed countries



Global Integration and Post-LDC Market Opportunities

- Not many countries in the world has pharmaceuticals manufacturing capability like Bangladesh
- India is considered as pharmacy for the world
- Everyone is looking for an India Plus One, where Bangladesh has tremendous opportunity



Global Integration and Post-LDC Market Opportunities

- China is mainly into intermediates and chemical industry
- In the scenario of current global geopolitical situation, supply from China may face constraint.
- Bangladesh can carter to all markets with -
 - ✓ Pure Generics
 - ✓ Branded Generics
 - ✓ API



Global Integration and Post-LDC Market Opportunities

- China is supplying to its local market which is already as big as 220 B\$.
- India has a local market of 40 B\$ which is also increasing in good rate
- Both, India and China may not be enough to meet such huge global demand as these two countries have significant local need



Global Integration and Post-LDC Market Opportunities

- All these geopolitical situations are creating huge opportunities for Bangladesh in global export of -
 - ✓ API
 - ✓ Pharmaceutical Formulation
 - ✓ Biosimilar
 - ✓ Vaccine
 - ✓ Medical Device



Conclusion



- Bangladesh has surplus human resources for the pharma industry
- Many of the companies have received regulatory approvals, which will make us a global supplier of medicines.
- There are visible competitive advantage for Bangladesh in global market place



Conclusion



- Bangladesh Pharma industries aims to capture 10% of the global generic market
- 7 to 9 companies have received approval from highly regulated authorities like MHRA, EU countries, US FDA, WHO PQ etc. This number will increase to 20 very soon.
- New Opportunities like, API, Biosimilars, Vaccine, Oncology products, Medical Devices, etc are already in place.





Bangladesh is becoming
a major global hub for
High Quality, Low Cost
generic medicines



Thank You

