

# **BANGLADESH PHARMA MARKET & REGULATORY REPORT**



**Pharmaceuticals Export Promotion Council of India**

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

## CONTENTS

<b>DEMOGRAPHY:</b> .....	<b>3</b>
<b>MARKET REPORT</b> .....	<b>4</b>
<b>Introduction:</b> .....	<b>4</b>
<b>Latest Updates</b> .....	<b>4</b>
<b>Economic view</b> .....	<b>4</b>
<b>Market overview</b> .....	<b>4</b>
<b>Generic Drug Industry</b> .....	<b>5</b>
<b>Pharma Trade</b> .....	<b>5</b>
<b>Local drug Industry</b> .....	<b>5</b>
<b>Epidemiology</b> .....	<b>6</b>
<b>Statistics:</b> .....	<b>7</b>
<b>Imports of Bangladesh</b> .....	<b>8</b>
<b>REGISTRATION AND REGULATORY REQUIREMENTS</b> .....	<b>9</b>
<b>Regulatory Overview</b> .....	<b>9</b>
<b>About DGDA:</b> .....	<b>10</b>
<b>APPLICATION FOR DRUG MANUFACTURING LICENSE:</b> .....	<b>10</b>
<b>Recipe Assessment:</b> .....	<b>10</b>
<b>Recipe Approval:</b> .....	<b>11</b>
<b>IMPORTING DRUGS TO BANGLADESH:</b> .....	<b>12</b>
<b>Evaluation of the Recipe and Authorization:</b> .....	<b>12</b>
<b>Granting the Registration:</b> .....	<b>12</b>
<b>Regulatory Updates</b> .....	<b>13</b>
<b>REFERENCES:</b> .....	<b>13</b>

## DEMOGRAPHY:

SL. No	Parameter	Description
1	Region	South Asia
2	Country	Bangladesh
3	Capital	Dhaka
4	Population	162,650,853 (July 2020 est.)
5	Population growth rate (%)	0.98% (2020 est.)
6	GDP (purchasing power parity)	\$ 690.3 billion (2018 est.)
7	GDP - real growth rate (%)	7.4% (2017 est.)
8	GDP - per capita (PPP)	\$ 4,200(2017 est.)
9	Exchange rates	
10	Population below poverty line	24.3%
11	Age structure (%)	0-14 years: 26.48
		15-24 years: 18.56%
		25-54 years: 40.7%
		55-64 Years: 7.41%
		65 Years and above 6.82%

**Source: CIA World Fact Book updated to July 2020 on 2<sup>nd</sup> June 2020**

## **MARKET REPORT**

### **Introduction:**

As a populous country with a fast-growing pharmaceutical market, Bangladesh offers commercial opportunities for drug makers operating in the country. Local drug producers are geared up to meet most of domestic demand, while multinational drug makers that had manufacturing capacity in the country are increasingly reassessing their business models or shifting to drug importing arrangements. Bangladesh is poised well to take advantage of increasing global demand for generic medicines Produced in low-cost economies and is forecasted to see their export footprints rise over the next few years.

### **Latest Updates**

- As of reports in April 2020, Square Pharmaceuticals will set up a subsidiary company by investing USD 41.2mn to extend its foothold in the drug market and to meet the growing demand for its products.
- In March 2020, Beximco Pharmaceuticals signed a commercial agreement with Mylan for the distribution of certain Mylan products in Bangladesh. Under the terms of the agreement, Beximco will receive the exclusive rights to launch Mylan's portfolio of key monoclonal antibodies.
- Sanofi is reportedly considering shifting to an import/distributor model in Bangladesh as its current arrangement is not making the firm competitive with domestic companies, which make medicines at lower prices.
- In August 2019, Beximco Pharmaceuticals (A local company) launched its fifth product in the US market. The product is 20, 40 and 80mg nadolol tablets, is a generic version of Bristol-Myers Squibb's Corgard, indicated for treating hypertension and angina pectoris. This indicates Bangladesh Pharma industry's rapid strides towards development of quality Generics.

### **Economic view**

Real GDP growth rate is estimated to be 8.1% during 2018-19. However Investment in Bangladesh is seen as low reward/high risk country

### **Market overview**

In 2019, Bangladesh's pharmaceutical market was valued at USD 3.1bn and is forecasted to grow by 7.6% in 2020 and reach \$3.54 billion. This market is dominated primarily by generic drugs which account for 71.4% of the total sales. This is followed by over the-counter drug sales, which account for 21.3%, while patented drugs make up a small segment of the total market at 7.3%. Notably, pharmaceutical spending per capita remains low at USD 18.9 in 2019.

Communicable diseases were the major part (70%) of epidemiology of this market till 2014, the profile now is shifting towards non-communicable diseases slowly but steadily. Among the non-communicable diseases, Cancer, musculo-skeletal disorders, chronic respiratory conditions and psychological disorders are predominant.

Key market growth drivers include growing public healthcare spending, rising healthcare spending in the private sector (as per capita wealth increases), improved access to health facilities and the adoption of modern marketing techniques by local drug manufacturers. Moreover, the rising awareness of and expectations around medical care, as well as the increasing burden of non-communicable diseases, will support sustained pharmaceutical market growth figures.

### **Generic Drug Industry**

Generic sector has good potential in Bangladesh. Government also encourages generic medicines. The generic drug market, accounts for 71% of total pharmaceutical sales in Bangladesh, and is likely to continue to expand over the next five years as increasing burden of non-communicable diseases, rising incomes and improving access to healthcare is foreseen.

In 2019, Bangladesh's generic market reached a value of USD 2.2bn. This is forecast to grow to USD 3.1bn by 2024, posting a compound annual growth of 6.5% .

Among the OTC products Paracetamol is the highest selling product. Among Prescription based products Chlorpheniramine, Omeprazole, Metronidazole and Vitamin C are the top selling products. All these products are made in House.

### **Pharma Trade**

Bangladesh remains import dependent for its Pharma requirement though not entirely for some more years. Due to its changing Scenario of epidemiology, the country may have to import increasingly in the next few years till its local industry catches with the pace as well as technology.

In the year 2018 the country has imported \$ 205.5 million and the estimates for 2019 are \$ 223 million. By 2023 imports are expected to touch \$2945 million with a CAGR of 7.4%. Leading drug import sources in 2015, include Denmark (27% of total imports), Belgium (11%), Switzerland (11%), Germany (8%), India (7%), the US (7%) and France (5%).

Bangladesh has also exported Medicines worth \$ 51 million. As patented products imported into Bangladesh are priced much lower when compared to many other countries, due to its status, these products are re-exported to other developed nations.

Bangladesh is also exporting APIs.

### **Local drug Industry**

Local industry is fairly developed. It makes drugs like Anti-infectives which constitute the largest therapeutic class of locally produced medicinal products, distantly followed by antacids and anti-ulcerants. Other significant therapeutic classes include non-steroidal anti-inflammatory drugs, vitamins, central nervous system medicines and respiratory products, which have developed to cater for changing domestic demand.

The domestic pharmaceutical industry currently meets 97% of local demand and also exports medicines and raw materials to over 150 countries. Improvements to Bangladesh's domestic

pharmaceutical landscape will support the government's economic development plans over the coming years.

There are around 150 companies (formulations making) in operation and 30 of them are involved in exports. They are around 40 companies involved in bulk drug manufacturing.

Local manufacturers dominate the industry, enjoying about 90% market share while multinationals hold 10%.

As of July 2017, 30 pharmaceutical companies export to 113 countries inclusive of infusions & injectables.

Bangladeshi pharmaceutical companies are investing heavily in upgrading manufacturing plants and obtaining certifications from the US, Australia, Canada and Europe, among other destinations. In value terms, exports are mainly concentrated in emerging markets.

As of April 2018, it is estimated that a total investment of USD300mn has been made in the pharmaceutical sector in the last five years

Bangladeshi pharmaceutical companies focus primarily on branded generic final formulations, while some are starting to emerge as competitors to Indian firms in some areas. Bangladesh manufactures more than 450 generic drugs for 5,300 registered brands. There are over 40 manufacturing units of active Pharmaceutical ingredients. The country is producing high-tech Anti-Cancer products also, though it is able to meet only 4% of its Anti-Cancer drug needs as of now.

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Bangladesh has five manufacturing units registered with USFDA. Sun Pharma has production unit in Bangladesh its local turnover was approximately \$ 350mn in Fy-17.

## **Epidemiology**

Bangladesh's pharmaceutical market major segments include (by share) alimentary and metabolism (36%), systemic anti-infectives (18%), nervous system (10%), cardiovascular system (9%), respiratory system (9%), and musculoskeletal system (5%). These figures are from 2016, the latest reported by the Bangladesh Association of Pharmaceutical Industries.

### **Key incentives include:**

- Unconditional tax-holiday to all APIs and laboratory reagents producers, both local and joint ventures, for five years from FY2017 to FY22. If a producer can manufacture at least five molecules every year, it would get 100% tax holiday from FY22 through to December 31 2032. Firms that produce at least three molecules will be entitled to a 75% tax holiday
- Waivers on advance income tax and tax deduction at source.

- Waivers on VAT and VAT deduction at source on purchase and sales of locally made APIs, laboratory reagents, all raw materials, immovable assets, and services up to 2032.
- A 20% cash incentive if producers add at least 20% value.
- 12-year tenure of term loans for factories and equipment instead of the six years at present.
- Export earning retentions of 40%.
- No single borrower cap.
- Back-to-back letters of credit facility.
- Priority in getting land at the industrial parks and economic zones.

The API policy aims at helping cut raw material manufacturing cost significantly and produce 370 key API molecules for exports. In 2017, the total number of locally produced API molecules and laboratory reagents stood at 41. The policy is aimed at cutting raw material import reliance from 97% in 2016 to 80% in 2032.

In the absence of local APIs, Bangladesh relies on imports from China, South Korea and India

Bangladesh has 285 drugs on essential list and prices of these products are controlled and fixed by Government only.

Bangladesh manufactures more than 450 generic drugs for 5,300 registered brands, which have 8,300 different forms of dosages and strengths. Prices of pharmaceuticals in Bangladesh are among the lowest in the world for four main reasons. First, under the WTO's TRIPS accord, the country has not been obliged to grant patents, which has meant that any innovative molecule can be lawfully re-engineered and sold legitimately. Second, given this loophole, many generic manufacturers are constantly engaged in a pricing war. Third, owing to low per capita income, branding has yet to make a significant impact in Bangladesh, which again forces down prices owing to the similarity of products. Finally, the country's flat terrain and extremely high population density mean that all of the top 20 manufacturers have extensive distribution networks, enabling them to supply pharmacies directly, which retain the margins and allow further price cuts.

### Statistics:

<b>India Pharma exports to BANGLADESH PR by Category \$ Million</b>					
<b>Category</b>	<b>2015-16</b>	<b>2016-17</b>	<b>2017-18</b>	<b>2018-19</b>	<b>Change%</b>
Bulk Drugs & Drug Intermediates	100.26	110.21	117.55	132.25	12.50
Drug Formulations & Biologicals	5.46	11.65	10.56	12.65	19.76
Ayush	0.40	0.27	1.50	1.72	14.40
Herbal Products	5.56	3.75	3.64	6.51	78.92
Surgical	9.30	8.21	10.92	12.82	17.37
Vaccines	15.18	19.47	18.49	25.65	38.73
<b>Total</b>	<b>136.15</b>	<b>153.56</b>	<b>162.67</b>	<b>191.60</b>	<b>17.79</b>

India's exports to Bangladesh \$ Million			
Category	Fy-19	Fy-20	Change%
Bulk Drugs & Drug Intermediates	132.25	146.60	10.85
Drug formulations & Biologicals	11.91	17.87	50.02
Ayush	1.72	1.98	15.24
Herbal Products	8.41	12.17	44.76
Surgical	13.48	13.48	-0.03
Vaccines	26.15	58.77	124.77
<b>Total</b>	<b>193.91</b>	<b>250.87</b>	<b>29.37</b>

During Fy-20 Growth in vaccines is Predominant and Exports of Bulk drugs has fared better than last year.

### Imports of Bangladesh

Bangladesh has not reported its imports of 2016, 2017 & 2018 to UN comtrade

India is 4th importing partner of Bangladesh as far as formulations are concerned with 9.34% contribution. However Exports by all countries to Bangladesh which are reported to UN comtrade suggests in 2017 India is the second largest importing Partner of Bangladesh next to Belgium as shown below.

Top Ten formulation Exporting Countries to Bangladesh \$ Million						
Rank	Country	2015	2016	2017	Gr%	Contbn%
1	Belgium	57.27	53.91	61.59	14.24	22.62
2	India	23.72	33.37	32.54	-2.47	11.95
3	China	15.91	26.31	30.05	14.20	11.03
4	Switzerland	22.06	19.60	24.95	27.29	9.16
5	Rep. of Korea	32.04	27.33	20.82	-23.79	7.65
6	USA	10.84	12.79	15.69	22.61	5.76
7	France	24.48	17.14	15.61	-8.89	5.73
8	Germany	9.61	12.15	14.36	18.14	5.27
9	Singapore	3.41	11.09	13.24	19.39	4.86
10	Netherlands	20.19	3.92	6.36	62.42	2.34
	Total of the above	219.52	217.61	235.22	8.09	86.37
	<b>Grand Total</b>	<b>254.24</b>	<b>260.46</b>	<b>272.33</b>	<b>4.56</b>	100.00



## REGISTRATION AND REGULATORY REQUIREMENTS

- Regulatory Authority : The Directorate General of Drug Administration (DGDA)
- Website of regulatory Authority : <https://www.dgda.portal.gov.bd/>
- Fees for Drug Registration : BDT 1500
- Normal time taken for registration : 12 Months
- Registration Requirement [Dossier Format] : CTD
- Whether plant inspection is mandatory : No
- Requirement of Local agent/ Subsidiary : Local agent is required for registration

### **Regulatory Overview**

The safety, efficacy and quality of medicines in Bangladesh were formerly controlled by the Directorate of Drug Administration (DDA), which operated under the Ministry of Health and Family Welfare (MOHFW). The Directorate General of Drug Administration (DGDA) replaced the DDA. The DGDA comprises several units, such as the Drug Control Committee and the Pricing Committee, which are tasked with different responsibilities relating to issues such as approval, regulation and import of pharmaceuticals.

**On December 18 2016**, the Cabinet approved National Drug Policy 2016, which replaced Drug Policy 2005.

Thus, the updated policy supersedes the one created almost a decade ago and focuses heavily on controlling substandard, counterfeit and adulterated drugs. To support this, the policy evolves towards a more regulated pharmacy channel with the introduction of 'Model Pharmacies' and a structured over-the-counter (OTC) category. The new policy aim is to ensure that the manufacturing of medicines is in compliance with international standards to increase export of pharmaceutical products. The law also updated the pricing Regime.

The latest law states that only 39 of Allopathy drugs, 23 Ayurveda drugs and 48 of Unani system only could be dispensed over the counter and the rest needs a prescription from the relevant specialists.

## **About DGDA:**

DGDA has number of committees for carrying out different function of DGDA. Those committees are:

- Drug Advisory Committee
- Drug Appellate Authority
- Drug Control Committee
- Drug Technical Sub- Committee
- Drug Pricing Committee
- Drug Pricing Technical Sub- Committee
- Manufacturing Project Evaluation Committee
- Standing Committee for Import
- Herbal Drug Advisory Committee
- Adverse Drug Reaction Advisory Committee

## **APPLICATION FOR DRUG MANUFACTURING LICENSE:**

The applicant company will need to submit the application for drug manufacturing. The application should be submitted with the documents described in the checklist by the Drug Administration.

Recipes of the proposed items need to be submitted with the application. After that an inspecting team is formed after receiving the application to visit the factory of the company. The inspecting team is instructed to submit a report on the necessary production and quality control system of the proposed items in the factory. The report should also contain their opinions on approving the recipes of the items after assessing overall facilities and providing the drug (organic/inorganic) manufacturing license.

### **Recipe Assessment:**

After receiving the report on the opinions of the inspecting team, recipes of the proposed common drugs are presented to the Recipe Assessment Committee and recipes of the uncommon drugs are presented to the Drug Control Sub-committee.

### **Recipe Assessment Procedure:**

I. Recipe Assessment of Common Drugs: Recipes of the common drugs are presented in the meeting of Recipe Assessment Committee of the Drug Administration. Recipes are recommended based on the approval by DCC and the manufacturing and quality control system for the proposed drugs.

II. Recipe Assessment of Uncommon Drugs: Recipes of non-regular drugs recommended by the Drug Control Sub-Committee are presented to the Drug Control Committee. Drug Control Committee recommends the approval of the recipes based on safety, efficacy and necessity of the drugs.

### **Recipe Approval:**

Recipes recommended by the local Recipe Assessment Committee and Drug Control Committee are approved by the drug licensing authorities and the applicant company is informed by sending a letter. The recipe has an expiration period of one year. After one year, it can be renewed for one additional year by submitting the necessary fee

### **Approval on collecting the raw materials and packaging contents for import:**

After the company submits a distribution list following the fixed format of collecting the raw materials and packages for import, The above distribution list is presented in the standing committee of drug and raw materials related to drugs. The standing committee approves the distribution list. Distribution list of locally prepared raw materials and packaging contents are approved by the Directorate.

### **Inclusion of items/Registration Approval:**

After receiving the letter on recipe approval, the company submits the documents described in the selected check list for inclusion of item(s) in the license.

### **Inclusion of Items included in the pharmacopeia:**

The company applies to the Drug Administration for approval of draft packaging of recipe approved items for inclusion of their items that are included in the pharmacopeia. After getting the approval for packaging contents, the company applies for item inclusion/registration with the inclusion fee, sample test and analysis fee and results of local testing. Approval is given if all documents are considered proper and then the company is sent the approval letter with the annexure on related items. It is instructed in the letter to submit samples from first commercial batch for testing and analyzing.

#### **Table: Steps To Establish A Pharmaceutical Manufacturing Unit And Obtain A Drug Manufacturing Licence**

- Submission of a new project profile needs to be evaluated by the New Project Evaluation Committee after inspection of the site by a team of inspectors from DGDA and the committee.
- Submission of application for a Drug Manufacturing Licence (DML) that lists composition of items to be initially manufactured. Recipes need to be evaluated by the Drug Control Committee after inspection of the manufacturing plant by a team of inspectors. Items similar to approved ones will be evaluated by an internal committee of the DGDA after inspection of the manufacturing units by a team of inspectors from the DGDA.
- Submission of application for packaging and promotional materials. The DGDA officers examine the submitted materials and papers and may inspect the manufacturing unit again.
- The DML may be issued at this stage and the product may be registered with the condition that the manufacturer must use the price approved by the DGDA.
- Submission of block list (details of raw and packaging materials to be imported) for prior approval. The block list needs to be approved by the standing committee for import.
- Submission of samples of first commercial batch for test and analysis by the government laboratories and submission of proposed price for the items. Only the price of 117 essential generic drugs needs to be fixed by the price committee. All other medicines use the indicative price, which needs to be certified by the DGDA.

## **IMPORTING DRUGS TO BANGLADESH:**

A local (Bangladeshi) representative nominated by the foreign medicine manufacturing institution needs to submit an application to register medicines for importing.

The following documents need to be submitted for the application-

- Documents and information included in Form DA-1/88 and Form DA-2/88
- Main copy of treasury invoice worth of BDT 1500 as recipe evaluation fee
- Company Profile
- Product Profile
- CPP/FSC signed by Health Authority of manufacturing country and attested by the embassy of Bangladesh
- If the manufacturing country is Australia, France, Germany, Japan, Switzerland, USA or the UK in that case CPP/FSC of the Country of Origin (Attested by the Embassy of Bangladesh) need to be submitted. If the manufacturing country is outside the above mentioned 7 countries, then country of origin and FSC/ CPP of any one of the seven countries mentioned above.
- Sample and dossier of the packaging of the item printed in English or Bengali

### **Evaluation of the Recipe and Authorization:**

The recipes of the proposed common medicines (recommended by the Drug Control Committee) are presented in the meeting of local Recipe Evaluation Committee. Recipes recommended by the local Recipe Evaluation Committee are approved by the licensing authorities (drugs) and the applicant institution is informed later with a letter. The expiration time of the approved recipe lasts for 1 year and by submitting the necessary fees it can be extended to another additional year after the expiration. The recipes of non-regular medicines are presented in the Sub-Committee of Drug Control. The non-regular medicines recommended by the Sub-Committee of Drug Control are presented in the Drug Control Committee. Drug Control Committee recommends approves the recipes based on safety, efficacy and necessity. Licensing Authorities (of Drugs) approve the recipes recommended by the Drug Control Committee and the applicant institution gets informed with a letter. The expiration time of the approved recipe lasts for 1 year for non-regular drugs as well and with necessary fees this can also be extended to another additional year after the expiration.

### **Granting the Registration:**

The local (Bangladeshi) institution submits the application along with the registration, test and analysis fee, final packaging materials and the main FSC/ CPP. The Licensing Authorities grant the registration after assessing all the documents.

## Regulatory Updates

- **A product manufactured by four and more local companies is not permitted to be imported. This is a major non-tariff barrier of this market.**
- Most of the local companies adhere to WHO standards.
- In May 2018, Bangladesh announced a corporate tax holiday for active pharmaceutical ingredient (API) and laboratory reagent manufacturers until 2032, among other incentives to encourage local manufacturing of drug ingredients.
- In April 2018, the commerce ministry announced that it drafted a policy that will offer several incentives to encourage local manufacturing of raw materials for the pharmaceutical sector.

### REFERENCES:

- [CIA world fact book last updated in March 2020.](#)
- [Review article on Pharmaceutical Industry of Bangladesh by EBL securities ltd.](#)
- Report on pharmaceutical sectors in Bangladesh submitted by MRC Bangladesh Ltd
- [An A-Z of Pharma industry review: Bangladesh perspective By AK Moinuddin Faculty of Pharmacy, World University of Bangladesh.](#)
- [Guidelines for the submission of Bangladesh common technical document general guidelines by Ministry of Health and Family welfare - DGDA](#)

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**Details of Indian Embassy abroad:** <https://www.hcidhaka.gov.in/>

**Details of importing country Embassy in India:** <http://bdhcdelhi.org/>

**List of local pharma organization abroad:**

- |                      |                  |   |
|----------------------|------------------|---|
| Bangladesh<br>Samity | Aushad<br>Shilpa | <ul style="list-style-type: none"><li>• <a href="http://www.bapi-bd.com/">http://www.bapi-bd.com/</a></li><li>• Address: 214 Bir Uttam Mir Shawkat Sarak,<br/>Dhaka 1208, Bangladesh</li><li>• Phone: +880 2-58816767</li></ul> |
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