IX ALL-RUSSIA GMP CONFERENCE

MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

# Access to Bangladeshi Pharmaceutical Market for Foreign Manufacturers

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# Bangladesh Pharmaceutical Market


- Market size: More than $ 5.0 billion
- Local Market Growth: 15%
- Export to 157 countries.

- Leading Foreign Pharmaceuticals:

-Novartis

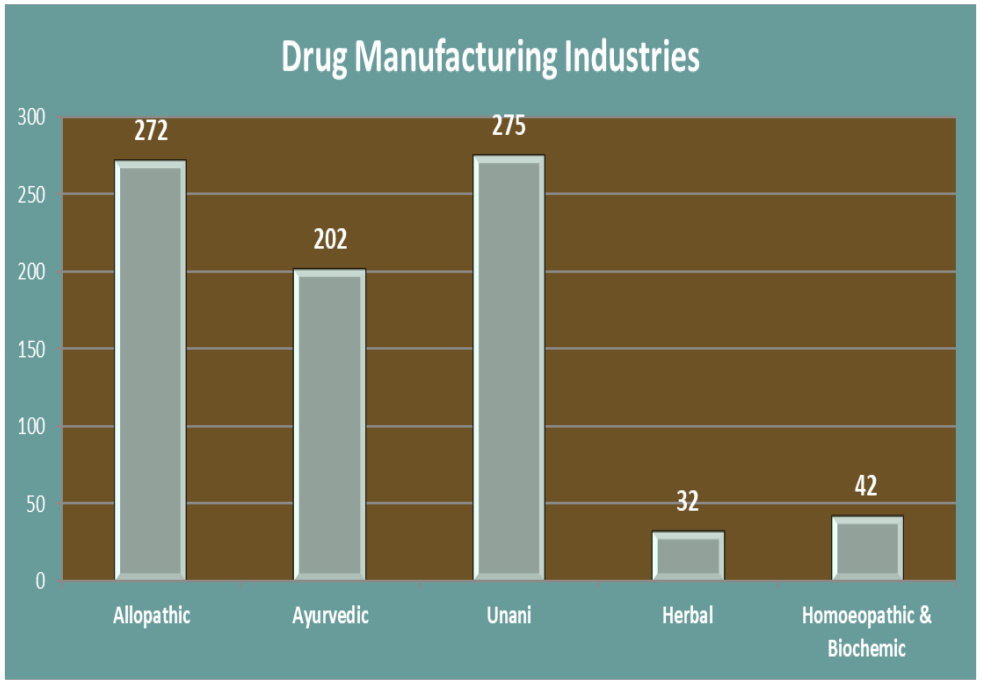
-Sanofi

-Novo Nordisk

-JMI

# Market Information

| Systems | No. of Production Units | Product | | No. of Pharmacy |
|---|---|---|---|---|
| | Total | Generic | No. of Reg. Brand | |
| Allopathic | 284 | 1549 | 30478 | 151768 |
| Unani | 282 | 484 | 6988 | 750 |
| Ayurvedic | 203 | 492 | 4367 | 504 |
| Homoeopathic | 71 | 519 | 2432 | 2548 |
| Herbal | 37 | 142 | 557 | 19 |
| Total : | 877 | 3186 | 44822 | 155589 |




- *Bangladesh is capable of producing of its 90% (approx) domestic requirement*
- *Bangladesh exports drugs to 157 different countries of the world including EU and USA.*

# Legal Framework of DGDA

## Legislation:

- The Drugs & Cosmetics Act 2023
- The Drug Rules 1945
- The Bengal Drug Rules 1946

## Regulations and mandate:

- The National Drug Policy 2016
- 65 guidelines
- 255 Standard Operating Procedures (SOPs)
- A number of manuals, forms, checklists and other documents.

## Condition for foreign manufacturers : (The Drugs & Cosmetics Act 2023)

**Manufacturing of drugs under licensing agreement, etc.—** (1) The Licensing Authority may, after specifying such conditions as may be necessary for the protection of public interest, permit any foreign establishment to manufacture any drug within Bangladesh under licensing agreement with any manufacturing establishment in Bangladesh:

Provided that before giving such permission, the Licensing Authority shall be ensured that any drug which is the research product of such establishment, is registered under the same brand name in any of the countries specified under sub-section (3) of section 41 .

(2) Any foreign company having no drug manufacturing factory in Bangladesh may manufacture all approved methods of drugs under contract manufacturing or loan license with its respective method company only for the purpose of export:

Provided that such manufactured drugs however shall not be marketed in local market by any means.

# Registration

## Documents Required for Imported Product Registration

1. The application for registration has to be made by a local authorized person of the manufacturer or foreign supplier or authorized agent to the DGDA.
2. Appropriate Fill up of Form DA-1/88
3. Fees
4. Company profile
5. Product Profile
6. CPP, FSC Signed by Health Authority of Manufacturing Countries
7. For Human Medicine Registration- (a) CPP/FSC of Country of Origin for the countries- Australia, France, Germany, Japan, Switzerland, USA, UK
   (b) Except above mentioned 7 countries- CPP/FSC of Country of Origin of own and CPP/FSC of any one above mentioned 7 countries.
8. For Veterinary Medicine Registration- (a) CPP/FSC of Country of Origin for the countries Australia, Austria, Belgium, Canada ,Denmark,Finland,France ,Germany, Hungary,ireland,Italy,Japan,Netherland,Norway,Singapore,Sweden,Switzerland,Spain, USA, UK, Russia, Polland, South Korea, Czechoslovakia
   (b) Except above mentioned 24 countries- CPP/FSC of Country of Origin of own and CPP/FSC of any one above mentioned 24 countries.
9. Sample of Packaging and Brochure.

# IMPORT AND EXPORT OF DRUGS

- **Import of drugs:**

  - license or beyond the conditions imposed under the license required.

  - Registered drug shall be imported with the prior approval of the Licensing Authority.

  - Registration or license for the purpose of importation of any drug for human or animal use, the drug has been registered under the same brand name in those countries

- **Procurement and import of raw materials of drugs, and packaging materials of drugs:**

  - Raw material for manufacture of registered drugs or packaging material of drugs shall be collected locally or imported with the prior approval of the Licensing Authority.

  - The Directorate may, in case of registration of importable raw materials for the manufacture of drugs or packaging materials of drugs, if necessary, inspect the manufacturing premises of manufacturing establishment, for verification of the Good Manufacturing Practice (GMP).

- **Export of drugs**

  - drug shall be exported with obtaining a license from the Licensing Authority.

  - The Licensing Authority may, for the purpose of export, register any kind of drugs.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