**Pharmaceuticals Export Promotion Council of India**

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

# REGULATORY & MARKET PROFILE OF NIGERIA

# DEMOGRAPHY

| SL. No | Parameter | Description |
|---|---|---|
| **1** | Region | Africa |
| **2** | Country | Nigeria |
| **3** | Capital | Abuja |
| **4** | Population | 190.632,261 (July 2017 est.) |
| **5** | Population growth rate (%) | 2.43% (2017 est.) |
| **6** | GDP (purchasing power parity) | $1.118 trillion (2017 est.) |
| **7** | GDP - real growth rate (%) | 0.8% (2017 est.) |
| **8** | GDP - per capita (PPP) | $5,900 (2017 est.) |
| **9** | Epidemiology | Malaria<br>Diarrheal disease<br>HIV/AIDS<br>COPD |
| **10** | Population below poverty line | 70% |
| **11** | Age structure (%) | 0-14 years: 42.54% |
| | | 15-24 Years: 19.61% |
| | | 25-54 years: 30.74% |
| | | 55-64 years: 3.97% |
| | | 65 years & over: 3.13% |
| *Source: CIA World Fact Book updated to july 2013* | | |

## Introduction

The Nigerian pharmaceutical and healthcare industry is underdeveloped by global standards and remains heavily dependent on imports especially Bulk Drugs.

It is estimated that total pharma market has come down from $ 717 million in 2016 to $ 607 mn in 2017 with negative growth of 15.6% which is mainly due to fall in crude oil prices.

## Latest updates

- In November 2017, at the 90th Annual National Conference of the Pharmaceutical Society of Nigeria (PSN), the President of the PSN announced the group's commitment to supporting 150 local drug makers in Nigeria, four of which already have WHO pre-qualification status.
- In November 2017, GlaxoSmithKline Nigeria partnered with the PSN to raise awareness about hepatitis B prevention in Nigeria.

## Strengths:

- One of the more developed African-Anglophone markets.
- Nigeria is one of Africa's largest economies and possesses considerable oil reserves.

## Weaknesses: Chronically under-funded healthcare sector, reliant on foreign aid.

## Opportunities

- The government's National Health Insurance Scheme is expected to improve healthcare services over the long term.
- Low-cost generic sector to drive overall market growth as demand patterns are framed by a cost-conscious government and a low-income population.

## Market overview

Nigerian Pharma market which is estimated at $ 607 mn in 2017 is dominated by OTC sector (43.1%) & Generic sector (38.9%). Rest of the 12% consists of patented sector. India participates in the larges 82% of the market.

Public health care due to its inadequate facilities is unable to meet the requirement. People mostly resort to Private health care.

## Epidemiology

Non communicable diseases dominate the Epidemiology profile of the country with HIV still a major issue. Government's National Action Committee on AIDS (NACA), has funded the local production of ARVs and their uptake has been substantially increased, while duties on imported ARVs have been cut to Fight **AIDS.**

According to the latest UNAIDS report, around **3.5mn people in Nigeria suffer from HIV/AIDS**, the majority of whom are adults. The prevalence and incidence rates vary significantly between geographical areas and gender; females report a higher incidence rate than males, and the HIV epidemic is concentrated in both rural and urban areas, including along major transport corridors. According to NACA, around 800,000 HIV patients in Nigeria receive government-sponsored ARV therapy annually, yet this figure is still markedly below the number of those eligible. UNAIDs estimate that approximately 180,000 Nigerians suffered HIV-related mortalities in 2016.

## Non communicable Diseases

Prostate cancer and breast cancer as two of the fastest growing cancer sub-types, with Globocan forecasting the number of new cases of prostate cancer to grow from 11,944 in 2012 to 17,469 by 2030, an increase of 46%; while the number of new breast cancer cases will increase by 67% - from 27,304 to 45,562.

In terms of mortality, it is liver cancer that is responsible for the greatest number of cancer-related deaths in Nigeria, responsible for 21% in 2016.

In Nigeria, chronic obstructive pulmonary disease (COPD) is dominant within this therapeutic area

## Generic Market:

Generic medicines will gradually gain a larger market share in Nigeria over the long term. Market growth will be driven by increased government spending. Local generic drugmakers in Nigeria will also be supported by the WHO, whose efforts to help more domestic drugmakers reach prequalification, will boost their competitiveness with foreign generic companies.

Generic market was around $ 279 million in 2016 and accounted for 38.9% of the total market, and is estimated to have negatively grown in 2017 by over 14%.

## OTC market:

This is the largest segment with over 43% share and was put at $ 310 million in 2016. This sector negatively grew by 17% in 2017.

## Pharma Trade:

Pharmaceutical imports, which reached a value of USD299mn in 2016, are expected to grow by CAGR of -0.2% to reach USD296mn by 2021.

Like the majority of African countries, Nigeria's pharmaceutical market is extremely reliant on importing its medicines. Nigeria's key pharmaceutical import partners include India, China and the US. The naira's devaluation against foreign currencies will lead to imports becoming more expensive in local currency terms, which in turn creates the risk of more frequent drug shortages as imports will subsequently be reduced in terms of volume.

## Local Industry

Nigeria's poor pharmaceutical regulatory environment and sporadic power supplies to energy-heavy industries are major drawbacks to foreign direct investment (FDI). The country's inability to provide its own reliable high-capacity pharmaceutical sector contradicts its own rationale behind banning imported drugs.

The National Agency for Food and Drug Administration and Control (NAFDAC), the World Health Organization (WHO), and the Pharmaceutical Society of Nigeria (PSN) are continually working towards raising the standards of locally produced medicines and supporting Nigerian drugmakers in their pursuit of WHO prequalification status. However, as of November 2017, only four local drugmakers, namely May & Baker, Chi Pharmaceutical, Evans Pharmaceuticals and Swiss Pharma Nigeria have obtained WHO prequalification status to produce drugs in accordance with its Good Manufacturing Practice (GMP) standards.

## Current Pricing issue

Nigerian drug prices are controlled mostly by market forces, with government tariffs, taxes and distribution mark-ups accounting for a significant proportion of the final price. Medicine pricing has become increasingly complicated in 2017 as a result of the lack of foreign currency needed by local drugmakers for imports. The introduction of a 20% 'Import Adjustment Tax' in Nigeria, which applies to medicines under HS Codes 3003 and 3004, has exacerbated issues brought about as a result of scarce foreign exchange.

The impact of a lack of pricing control is still being passed onto local manufacturers and consumers through higher medicine prices. A number of Nigerian pharmacy retailers are reporting up to a 40% rise in the cost of medicines as the combined effects of the naira's devaluation and import tariffs are in full flow. Three of the dominant players in the industry, namely **Union Diagnostic/Clinical Services**, **Pharma Deko** and **Evans Pharmaceutical**, have also reported a downturn in production in 2017.

As the prices of Crude has gone up (To a fairly comfortable level), the tone of the above info may have been simmered.

## Statistics:

| India's Pharma exports to Nigeria in $ mn | | | | |
|---|---|---|---|---|
| Category | 2014-15 | 2015-16 | 2016-17 | Gr% |
| AYUSH | 1.46 | 1.68 | 1.56 | -7.17 |
| BULK DRUGS AND DRUG INTERMEDIATES | 42.90 | 46.27 | 48.57 | 4.98 |
| DRUG FORMULATIONS AND BIOLOGICALS | 371.61 | 382.63 | 344.09 | -10.07 |
| Herbal Products | 0.06 | 0.01 | 0.04 | 325.23 |
| Surgicals | 4.47 | 6.02 | 4.33 | -28.16 |
| **NIGERIA** | **420.50** | **436.61** | **398.59** | -8.71 |

## REGISTRATION AND LICENSING REQUIREMENTS

| | | |
|---|---|---|
| ➢ Regulatory Authority | : | **National Agency for Food and Drug Administration and Control (N)** |
| ➢ Website of regulatory Authority | : | http://www.nafdac.gov.ng/ |
| ➢ Fees for Drug Registration | : | USD 1100 |
| ➢ Normal time taken for registration | : | 12 Months |
| ➢ Registration Requirement [Dossier Format] | : | Non CTD |
| ➢ Whether plant inspection is mandatory | : | Yes |
| ➢ Requirement of Local agent/ Subsidiary | | Subsidiary is Required to operate locally |

### NAFDAC Organization :

The National Agency for Food and Drug Administration and Control (NAFDAC) was established by Decree No. 15 of 1993 as amended by Decree No. 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004 to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of Food, Drugs, Cosmetics, Medical Devices, Packaged Water, Chemicals and Detergents (collectively known as regulated products). The agency was officially established in October 1992.

The NAFDAC's organization consists of the Director General's Office and fourteen (14) directorates overseeing the functions of the agency: They are

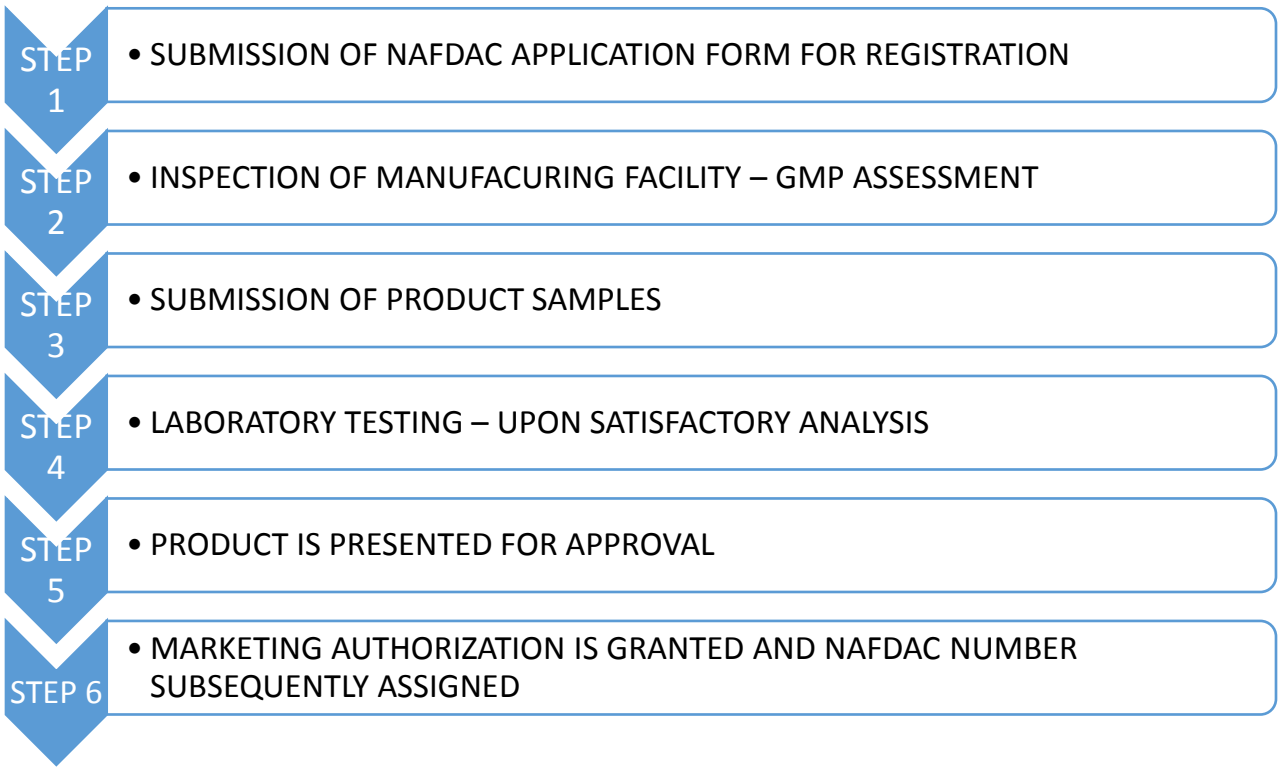
- Registration and Regulatory Affairs (R&R)
- Drug Evaluation and Research (DER)
- Food Safety and Applied Nutrition (FSAN)
- Pharmacovigilance and Post Marketing Surveillance (PVG/PMS)
- Laboratory Services (LS)
- Veterinary Medicines and Allied Products (VMAP)
- Narcotics and Controlled Substances (NCS)
- Admin & Human Resources (Admin & HR)
- Planning Research and Statistics (PRS)
- Investigation and Enforcement (I&E)
- Finance & Account (F&A)

- Port Inspection Directorate (PID)
- Legal Services
- Chemical Evaluation and Research (CER)

**Registration and Regulatory Affairs Directorate (R & R),** undertakes Registration of foods, drugs, cosmetics, medical devices, Chemicals, detergents and packaged water. Other functions are as follows:

- Formulating, updating, compiling and periodic review of standard specifications, regulations and guidelines for the production, importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water and Chemicals.
- Approval and control of advertisement of food, drugs, cosmetics, medical devices, bottled water and Chemicals to ensure that advertisements are not exaggerated, deceptive or detrimental to the consumer.
- Monitoring of advertisement to ensure compliance and identify illegal advertisements.

## REGISTRATION STEPS



# GUIDELINES FOR REGISTRATION OF IMPORTED DRUG PRODUCTS IN NIGERIA (HUMAN AND VETERINARY DRUGS)

(Ref: Doc. Ref. No: R&R-GDL-OO5-OO of R&R Directorate, NAFDAC w.e.f 01/06/2018)

1. **General**

1.1. These Guidelines are for the interest of the general public and in particular Importers of Pharmaceutical and Veterinary Drugs in Nigeria.

1.2. It is necessary to emphasize that, no drug shall be manufactured, imported, exported, advertised, sold distributed or used in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations and the accompanying Guidelines.

2. **Applications**

2.1. A written application for registration of imported drug should be made on the company's letter head paper to the Director-General (NAFDAC), ATTENTION: The Director, Registration & Regulatory Affairs (R & R) Directorate, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, and Lagos State.

2.2. The application letter should include the generic name of product and brand name (where applicable).

2.3. An online application form for Product Registration should be purchased at; http://registration.nafdac.gov.ng and completed.

2.4. A separate application form should be submitted for each product.

**Step 1**

3. **Documentation**

3.1. The following documents (all originals) and two (2) sets of photocopies (including print-out of the completed online Registration form) are to be submitted at the Liaison Office of the Director (LOD), R & R Directorate, Ground Floor, NAFDAC Office Complex, Oshodi-Apapa Express Way, Isolo, Lagos State or any NAFDAC Office (outside Lagos):

3.1.1. Notarized Declaration (Appendix I). To be completed (typed), signed by Declarant and notarized by a Notary Public in Nigeria.

3.1.2. Power of Attorney or Contract Manufacturing Agreement. An applicant on behalf of a manufacturer outside Nigeria must file an evidence of Power of Attorney from the manufacturer which authorizes him to speak for his Principal, on all matters relating to the latter's specialties. The Power of Attorney shall be:

3.1.2.1. Issued by the manufacturer of the product.

3.1.2.2. Signed by the Managing Director, General Manager, Chairman or President of the Company, stating the names of the products to be registered. The Power of Attorney shall also state 'Authority to register product with NAFDAC'.

3.1.12.3. State ownership of Brand name(s)/Trademark.

3.1.12.4. Notarized by a Notary Public in the Country of manufacture.

3.1.12.5. Valid for at least five (5) years.

3.1.3 Contract Manufacturer Agreement. An applicant filing an application on behalf of his company, and being the owner of the product, shall provide a Contract Manufacturing Agreement. The Agreement shall be:

3.1.3.1. Notarized by a Notary Public in the country of manufacture.

3.1.3.2. Signed by both parties stating names and designations of the signatories with the names of all the products to be registered and other relevant clauses clearly explained in an unambiguous language.

3.1.4 Evidence of Business Incorporation of the importing Company with Corporate Affairs Commission in Nigeria.

3.1.5 Manufacturing License/Certificate of Free Sale

3.1.6 Evidence that they are licensed to manufacture drugs for sale in the country of origin (Manufacturer's Certificate). The license shall be issued by a relevant Health/Regulatorybody in the country of manufacture.

3.1.7 Certificate of Pharmaceutical Product (COPP-WHO Format)

3.1.8 There must be evidence by the competent Health Authority, that the sale of the product does not constitute a contravention of the drug laws of that country. The Certificate of Pharmaceutical Product (COPP) should;

3.1.8.1. Conform to WHO format.

3.1.8.2. Be issued by the relevant Health/Regulatory body.

3.1.8.3. Be authenticated by the Nigerian Embassy or High Commission in the country of origin. In countries where no Nigerian Embassy exists, any Commonwealth or ECOWAS country can authenticate the COPP.

3.1.9 Current Good Manufacturing Practice (cGMP) of the manufacturing facility. This is to be:

3.1.9.1. Valid at the time of submission.

3.1.9.2. Be issued by the relevant Health/Regulatory body.

3.1.9.3. Be authenticated by the Nigerian Embassy or High Commission in the country of origin. In countries where no Nigerian Embassy exists, any Commonwealth or ECOWAS country can authenticate the document.

3.1.9.4. Reference the Manufacturer's License Nos Form 25 and Form 28

3.1.10 Dossiers; The applicant shall submit two (2) copies of the Dossiers which should be;

3.1.10.1. In a Compact Disc (CD).

3.1.10.2. Searchable Portable Document Format (pdf).

3.1.10.3. Common Technical Document (CTD) format

3.1.11 Evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment. This should be registered in the name of the owner of the Trademark/Brand name as the case may be (Trademark Class 5 for Drugs).

3.1.12 Copy of valid Annual License to practice for the Superintendent Pharmacist issued by Pharmacists Council of Nigeria.

3.1.13 Evidence of valid Premises Retention License for the facility.

3.1.14 Comprehensive Certificate of Analysis for product(s)

3.1.15 The Certificate of Analysis must be presented on a letter-headed paper of the quality control laboratory where the sample was tested/evaluated and should contain the under listed information:

3.1.15.1. The brand name of the product

3.1.15.2. The batch number of the product

3.1.15.3. The manufacturing and expiry dates

3.1.15.4. The name, designation and signature of the analyst

3.1.16 Label or artwork of the product

3.1.17 Letter of Invitation for Good Manufacturing Practice (GMP) Inspection: A letter of invitation to inspect the factory abroad shall be written by the manufacturer and shall state the following:

3.1.17.1. MANUFACTURER INFORMATION: Name of Company, full location address of factory (not administrative office address), e-mail, and current phone no. Details (name, phone number and email) of contact person overseas.

3.1.17.2. LOCAL AGENT INFORMATION: Name of company, full location address, functional phone no., e-mail address. Details (name, phone number and email) of contact person. Names(s) of product(s) for registration.

**Step II**

4. **Import Permit and Label vetting**

4.1. Upon successful screening of documentation and review of supporting documents, an Import Permit shall be issued after which products are submitted for vetting.

**STEP III**

5. **Submission of samples for laboratory analysis**

5.1. After successful vetting of product labels, laboratory samples are submitted. The following documents are included;

5.1.1. Evidence of payment to the Agency

5.1.2. Certificate of analysis.

5.1.3. Evidence of submission for vetting.

**Step IV**

6. **Product Approval meeting**

6.1. Upon satisfactory Dossier review, satisfactory GMP of the production facility and satisfactory laboratory analysis of product, products are presented for Approval Meetings.

6.2. For products labels with compliance issues, compliant artworks may be submitted with a commitment letter from the manufacturer (stating that the commercial products will be in compliance).

**Step V**

7. **Issuance of Notification**

7.1. For products approved at the meeting, Notification of Registration or Listing is issued to the applicant while compliance directive is issued to those not approved.

8. **Labelling Guidelines for Imported Drugs**

8.1. Labelling should be informative and accurate.

8.2. Minimum requirements on the package label in accordance with the Drug Labelling Regulations include:

8.2.1. Name of product (brand name) where applicable and generic name.

8.2.2. Name and full location address of the manufacturer.

8.2.3. Provision for NAFDAC Registration Number on product label

8.2.4. Batch No., Manufacturing date and Expiry date.

8.2.5. Dosage form & strength

8.2.6. Indications, frequency, route, conditions of administration (Over the counter; OTC drugs).

8.2.7. Dosage regimen on the package (Over-the-Counter; OTC drugs).

8.2.8. Patient Information Leaflet (PIL)

8.2.9. Prescribing information (for POM).

8.2.10. Net content of product

8.2.11. Quantitative listing of all the active ingredients per unit dose

8.2.12. Adequate warnings where necessary.

8.2.13. Where a brand name is used, there MUST be the generic name which should be conspicuous in character, written directly under the brand name.

8.2.14. Any drug product whose name or package label bears close resemblance to an already registered product or is likely to be mistaken for such registered product, shall not be considered for registration.

8.2.15. Any drug product which is labelled in a foreign language shall NOT be considered for registration unless an English translation is included on the label and PIL (where applicable).

8.2.16. See the Agency's Drug Labelling Regulations and other relevant Regulations for specific details.

9. **Tariff**

9.1. Please see Tariff section.

10. **Note**

10.1. For New Chemical Entities (NCE), there must be evidence that Clinical Trials have been undertaken in the relevant population. Such clinical trial reports must be submitted and reviewed

10.2. No combination drug product shall be registered or considered for registration unless there is scientific documented evidence to prove that such a product has clinical advantage over the single drug available for the same indication(s).

10.3. Failure to comply with these requirements may result in the disqualification of the application or lead to considerable delay in the processing of registration.

10.4. A successful application will be issued a Certificate of Registration with a validity period of five (5) years.

10.5. Registration of a product does not automatically confer Advertising Permit. A separate application and subsequent approval by the Agency shall be required if the product is to be advertised. Simultaneous submission of registration and advertisement applications are allowed.

10.6. NAFDAC reserves the right to revoke, suspend or vary a certificate during its validity period.

10.7. Filing an application form or paying an application fee does not confer registration status.

10.8. Failure to respond promptly to queries or enquiries raised by NAFDAC on the application (within 90 working days) will automatically lead to the closure of the Application.

10.9. The time line for product registration from acceptance of submissions to issuance of Registration number is one hundred and twenty (120) working days.

10.10. Please note that the clock stops once compliances are issued.

All correspondences should be addressed to:-

Director-General (NAFDAC),
**Attn:** The Director, Registration and Regulatory Affairs Directorate,
National Agency for Food and Drug Administration and Control,
Ground Floor, NAFDAC Office Complex
Isolo Industrial Estate
Apapa-Oshodi Expressway, Isolo, Lagos

## DOCUMENTS TO BE SUBMITTED FOR DRUG REGISTRATION

- Duly completed Drug Registration Form
- Application letter for Registration of product(s)
- Power of Attorney/Contract Manufacturing Agreement
- Manufacturing Licence
- Certificate of Pharmaceutical Products (CoPP) – WHO Format
- Current Good Manufacturing Practice (GMP) Certificate of the manufacturing facility
- Certificate of Registration of Brand Name
- Certificate of Business Incorporation of the importing company with the corporate affairs commission in Nigeria
- Comprehensive Certificate of Analysis.
- Current Superintendent Pharmacists License to practice
- Valid Pharmaceutical Premises License
- Dossier in CTD – WHO Format
- Notarized Declaration
- GMP Invitation letter
- Copy of Expiring Certificate/License – Renewal Application

## National Drug Policy:

- The government is committed to national self-sufficiency in terms of pharmaceutical production, which is stimulated by assistance for Nigeria's pharmaceutical manufacturing sector and by attempts to curb the influx of inexpensive counterfeit drugs. The recently introduced National Drug Policy (NDP) aims for 70% national self-sufficiency in drugs, which is to be achieved through greater local production of generic drugs and the raising of tariff and non-tariff barriers on imported drugs. In May 2017, Nigeria's Vice President, Yemi Osinbajo, signed an executive order that mandates all ministries, departments and agencies (MDAs) to give preference to locally-produced medicines in their procurement activities. According to the pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN), around 40% of expenditure by the MDAs must be targeted towards pharmaceuticals manufactured by local drug makers.

- Current uncompetitive local drug makers in Nigeria are supported by government in the form of the development fund and the World Health Organization (WHO)'s efforts to help local drug makers reach prequalification. The WHO's assistance to local manufacturers is to improve the quality of medicines and make the companies more competitive with foreign generic drug makers, particularly those from India and China.

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Details of importing country embassy in India: **http://www.nigeriahcindia.org/**

Contact details of Indian Embassy abroad: **http://hcindia-abuja.org/index.php**

**List of Local Pharma Associations:**

- Pharmaceutical Society of Nigeria
  Anthony Village, 32 Faramobi Ajike Street, Lagos, Nigeria.
  Ph:(+)234 1 734 8287
  www.psnnational.org

- The Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN)
  Website: http://pmgman.com/