EXAMINING NAFDAC GUIDELINES FOR THE IMPORTATION AND MANUFACTURING OF MEDICAL DEVICES IN NIGERIA

The National Agency for Food and Drugs Administration and Control (NAFDAC) (more particularly the Registration and Regulatory Directorate) is the agency in charge of issuing approvals for medical devices, amongst other classes of regulated products, in Nigeria.

According to the NAFDAC Act, LFN 2004, a medical device is any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of disease, disorder, abnormal physical state or the symptom thereof, in man or in animal.

It is important to note that NAFDAC requires that no medical device shall be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered according to NAFDAC regulations. To this end NAFDAC, based on its power to issue guidelines and regulations for regulated products, maintains the following regulations for the manufacture, importation and advertisement of medical devices:

- Guidelines for Registration of Medical Devices in Nigeria;
- Guidelines for Registration of Imported Medical Devices in Nigeria;
- The Guidelines for Advertisement of NAFDAC Regulated Products.

These guidelines provide the legal framework for the manufacture, importation and advertisement of medical devices in Nigeria, contravention of which attracts penalties and sanctions on erring entities.

MANUFACTURE OF MEDICAL DEVICES

Manufacturers of medical devices in Nigeria are required to register their products with NAFDAC. This requirement also extends to companies which have contract manufacturing arrangements with other companies. That is, companies who have outsourced part or all of the production process of any regulated products to other companies.

The "Guidelines for Registration of Medical Devices in Nigeria" specifies in details the application process and documents required for registering locally made medical devices.

Application Process and Required Documentation

The application process for locally manufactured medical devices is usually in three (3) stages:

- Submission of the application – An application letter, a registration form and other required documents are physically submitted at the NAFDAC office.

- Product approval meeting – upon satisfactory documentation review, Good Manufacturing Practice (GMP) Inspection of the production facility, and laboratory assessment of the products, an approval meeting is scheduled to determine if the products have satisfied the requirements for approval.

- Issuance of Notification – for products approved at the meeting, a notification of registration is issued to the applicant first, and subsequently a Certificate of Registration, which is valid for a period of five (5) years.

Documents required for an application for the manufacture of medical devices include the following:

- An application letter on the applicant's letterhead.
- A registration form for product registration. This form is to be printed from the NAFDAC website. Note that separate forms are required for multiple products.
- Contract manufacturing agreement (where applicable).
- Evidence of satisfactory inspection or GMP certificate for the product.
- Evidence of business registration, that is, CAC Certificate of Incorporation or Certificate of Business Name Registration as the case may be.
- Evidence of payment of registration fees.
- Evidence of registration of brand name with the Trademark Registry.
- Product labels/artwork.

- Comprehensive Certificate of Analysis. NAFDAC requires an applicant to carry out a comprehensive analysis of the product, report of which must be presented on the letterhead of the Quality Control Laboratory where the product was tested.

IMPORTATION OF MEDICAL DEVICES

Importers of medical devices manufactured outside Nigeria must comply with NAFDAC's requirements for importation as contained in the "Guidelines for Registration of Imported Devices in Nigeria".

Typically, before NAFDAC issues an Import permit for medical devices manufactured outside Nigeria, the application will pass through five (5) stages:

- Submission of the application – the application letter and other required documents are submitted physically at the NAFDAC office. The application letter must contain the common name and its brand name where these are different.

- Issuance of an Import Permit – an Import permit is issued after a successful review of the documents submitted. This will enable the applicant import samples of the product for vetting at NAFDAC.

- Product label vetting – the label or artwork of the product must conform to NAFDAC Medical Devices Labelling Regulations. One of the requirements is that the label or artwork must not contain any information which contravenes the information provided in the original application.

- Product samples analysis – the product samples are submitted at NAFDAC for analysis in its laboratory.

- Product approval meeting – upon satisfactory Good Manufacturing Practice (GMP) Inspection of the production facility abroad, vetting of the label, and laboratory assessment of the products, an approval meeting is scheduled to determine if the products have satisfied the requirements for approval.

- Issuance of Notification or Listing – for products approved at the meeting, a notification of registration is issued to the applicant first, and subsequently a Certificate of Registration, which is valid for a period of five (5) years.

Documents required for an application for the importation of medical devices include the following:

- An application letter on the applicant's letterhead.
- A registration form for product registration. This form is to be printed from the NAFDAC website, and separate forms are required for multiple products.
- Power of Attorney or Contract manufacturing agreement. An applicant applying on behalf of a manufacturer outside Nigeria must file an evidence of Power of Attorney from the manufacturer which authorizes him to apply on his behalf. Additionally, an applicant is required to submit the contract manufacturing agreement where it has outsourced the production of the medical device to another company outside Nigeria
- Certificate of manufacture and free sale. This is required as proof to show that a manufacturer outside Nigeria is licensed to manufacture medical devices, and that the sale does not constitute a contravention of the laws of that country.
- Comprehensive certificate of analysis. Apart from the laboratory analysis which will be carried out by NAFDAC at some point in the application process, an applicant is expected to have carried out a laboratory analysis of the product first, and submit a certificate of analysis presented on the letterhead of the Quality Control Laboratory where the product was tested.
- Evidence of business registration, that is, CAC Certificate of Incorporation or Certificate of Business Name Registration as the case may be.
- Evidence of payment of registration fees.
- Evidence of registration of brand name with the Trademark Registry.
- Product labels/artwork.
- Letter of invitation for GMP inspection. The manufacturer is required to write a letter inviting the NAFDAC officials to inspect the factory abroad. This letter must contain both the manufacturer's and local agent's information.

ADVERTISEMENT OF MEDICAL DEVICES

Registration of a product with NAFDAC does not automatically confer an advertising permit, therefore, NAFDAC requires a separate application process for the advertisement of medical devices.

According to the Guidelines for Advertisement of Regulated Products, no person shall advertise a product unless same has been registered by NAFDAC. NAFDAC

however allows a simultaneous submission of both an application for registration and an application for advertisement.

All holders of Certificate of Registration must therefore obtain Advertisement approval from NAFDAC and other regulatory bodies before production or airing of all commercials.

An application for advertisement approval must be submitted on the applicant's letterhead include the following documents:

- A completed application form;
- Evidence of product registration;
- Letter of introduction of the advert agent;
- Script/storyboard/artwork depending on the advert media, that is, TV, Radio, Outdoor, Print, Online or SMS;
- Recorded advert messages in CD/VCD/DVD.

The application is generally processed within twenty (20) working days subject to any compliance directives raised by NAFDAC, and where all requirements have been satisfactorily met, an approval for advertisement is granted. This approval is valid for a period of one (1) year from the date it is issued.

BREAKDOWN OF FEES

Subject to review by NAFDAC, the following is the current tariff applicable to obtaining an approval for medical devices in Nigeria.

	ITEM	DESCRIPTION	FEES IN NAIRA
1.	Application form	Per product	2,500
2.	Facility inspection		30,000
3.	Inspection of imported products at the Ports	Per 20ft container	27,000
4.	Permit to Import	Per product	11,000
5.	Registration of medical devices such as diapers and sanitary pads	Locally manufactured	20,000

6.	Registration of medical devices such as diapers and sanitary pads	Imported	415,150
7.	Registration of other medical devices	Locally manufactured	20,000
8.	Registration of other medical devices	Imported	356,250
9.	Laboratory analysis for medical devices such as diapers and sanitary pads	Locally manufactured products	29, 700
10.	Laboratory analysis for medical devices such as diapers and sanitary pads	Imported	101,250
11.	Laboratory analysis for other medical devices	Locally manufactured	29,700
12.	Laboratory analysis for other medical devices	Imported	67,500
13.	Advert for a single product		15,000
14.	Advert per variants		5,000

CONCLUSION

Generally, navigating the various compliance requirements at NAFDAC appears straightforward however obtaining the much needed approval can be a daunting and very complicated task. It is therefore advisable to enlist the services of a consultant who can utilize their expertise, vast experience and network to ensure a seamless application process.

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