Product Registration in Nigeria

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The National Agency for Food and Drug Administration and Control (NAFDAC) is empowered by law to regulate and control the manufacture, importation, exportation, advertisement, distribution and sale of regulated goods like cosmetics, drugs and food in Nigeria.

Regulated products manufactured both locally and outside Nigeria must meet certain requirements as approved by NAFDAC to qualify to be registered in Nigeria. As part of its functions, NAFDAC carries out inspection of imported goods in various ports and monitors companies that manufacture these goods in Nigeria to ensure that they comply with these requirements.

Currently, NAFDAC registers products in two categories: drugs and food.

- Drugs include medical devices, vaccines, chemicals and pesticides, veterinary products, nutraceuticals and supplements, herbal preparations and cosmetics. Clinical trials of drugs are also regulated by NAFDAC.
- Food products include processed and semi-processed food, bottled or sachet water, alcoholic and non-alcoholic drinks, etc.

No such goods can be imported/sold in Nigeria without written approval from NAFDAC. NAFDAC approval is granted for each specific product. This means that two products from the same source will require different approvals and registration numbers – in fact, two different packages of the same product are processed as different products.

As mentioned above, both locally manufactured and imported goods must be registered. However, an application for registration can only be initiated by the Nigerian manufacturer for a locally manufactured product or by a Nigerian representative of the foreign manufacturer for products manufactured outside Nigeria – i.e. the applicant for the NAFDAC application must be based in Nigeria. The applicant is expected to possess the capacity to control the circulation and recall of the product.

Product registration can be divided into two stages and although the required documentation varies for different drug and food categories, the general procedure is similar. The first stage is applying and obtaining approval to import samples (not applicable if the product is locally manufactured), while the second stage is the full registration of the product.

Requirements for procurement of samples

During the registration process, NAFDAC will require samples of the product. NAFDAC therefore grants special authorization to import such samples if manufactured outside Nigeria. Documents required for clearing and taking delivery of samples must be submitted to NAFDAC, particularly a Certificate of Analysis issued by the manufacturer and a Certificate of Manufacture and Free Sale issued by the appropriate regulatory authority in the country of origin. Samples must also conform to stipulated product labelling regulations.

Requirements for full registration of product

The full registration procedure starts with the procurement and completion of an application form for each product.

In practice, it takes approximately one month to complete the first stage and about two months from the second stage to issuance of the NAFDAC registration number.

Pursuant to law, NAFDAC has published several guidelines to aid applicants in product registration. Each guideline provides the requirements for the registration of a regulated product in Nigeria. The following guidelines have been published: Food, Drug, Chemicals, Medical Devices, Biological, Cosmetics, Herbal, Global Listing, Clinical Trial and Veterinary Guidelines. Copies of these guidelines can be provided, as necessary.

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