PCL 314: Pharmacy Jurisprudence

There are many laws governing the regulation and control of the manufacture, sale, and distribution of drugs in Nigeria. They are as follows:

The Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act and Dangerous Drugs Act,

The Food and Drugs Act,

The Food, Drugs and Related Products (Registration etc) Act,

The National Agency for Food and Drugs Administration and Control Act,

The National Drug Formulary and Essential Drugs List Act,

The National Drug Law Enforcement Agency Act,

The Pharmacy Council of Nigeria Act,

The Poisons and Pharmacy Act.

(i) Poisons and Pharmacy Act, Cap 366 of 1990.
This Act regulates the compounding, sale, distribution, supply and dispensing of drugs and provides different levels of control for different categories of drugs and poisons.

(ii) Food and Drugs Act Cap 150 of 1990.
This Act prohibits the sale of certain foods, drugs, cosmetics and devices as treatment for certain diseases. The Act prohibits the importation, exportation, distribution and sale of specified drugs. It also prohibits practices such as misleading packaging, labelling, and advertising, as well as manufacturing food and drugs in unsanitary conditions. It conveys the power to appoint inspecting officers and food and drug analysts.

(iii) Counterfeit and Fake Drugs (miscellaneous provisions) Act, Cap 73 of 1990.
This Act prohibits the production, importation, manufacture, sale and distribution of any counterfeit, adulterated banned or fake drugs. It also prohibits persons to sell any drug in an open market without permission from the proper authority.

The World Health Organization (WHO) defines counterfeit medicines as those which are 'deliberately and fraudulently mislabelled with respect to identity and/or source.

NAFDAC has identified counterfeit drugs to be

- those with same quantity of active ingredient as the genuine brands that are unlikely to produce the desired therapeutic effects due to differences in their formulation and bioavailability when compared to the genuine brands
- Medicines with insufficient or without active ingredient, expired medicines as well as toxic or ineffective herbal preparations and medicines lacking the name and address of the manufacturer.
- Medicines which are not certified and registered by NAFDAC are also regarded as counterfeits

The following are general acts of counterfeiting;

- Products with insufficient or no active ingredients
- Products which do not contain the correct strength of the specified active ingredient
- Medicines with active ingredients different from what is stated on the package
- Medicines which do not contain any of the specified active ingredients despite what is written on the label
- Products with fake packaging
- Expired medicines relabelled with the purpose to extend the shelf-life
- Products without the name and address of the manufacturer
- Expired products
- Drugs with no expiry date
- Products which contain the different quantity of impurities

(iv) **Pharmacists Council of Nigeria**, Decree 91 of 1992, repealed the Pharmacists Act of 1964 which has now been repealed by the **Pharmacy Council of Nigeria** (Establishment) Act, 2022 No.31.

To regulate the standard of training and practice of Pharmacy ; and for other related matters.

Under this act, the Council shall in the public interest —

(a) Administer the provisions of this Act;

(b) regulate the standard of pharmacy practice and business in Nigeria ;

(c) determine the standard of knowledge and skills to be attained by persons seeking to become

registered members of the pharmacy profession and review such standards ;

(d) determine and set standards for the degree courses in faculties of pharmacy in Nigerian universities ;

(e) establish requirements and standards for registration of intern pharmacists for internship and any other experiential training to enable a person obtain practical experience in the practice of pharmacy ;

(f) establish requirements for the grant of licence to intern pharmacists to undergo internship training and engage in the practice of pharmacy in an approved institution under the direct supervision of registered pharmacists ;

(g) establish and maintain a register of persons entitled to practice as members of the pharmacy profession and publish the list of members ;

(h) inspect, approve, licence and regulate the registration and practice or operations in all pharmaceutical premises where drugs, medicines and poisons are manufactured, imported, exported, distributed, stored, dispensed or sold in Nigeria, based on Good Pharmaceutical Practice Standards (GPP) ;

(i) establish and maintain a register of premises used for the manufacture, storage, importation, exportation, distribution, sale and dispensing of drugs, poisons, medicines, and medical devices and accessories ;

(j) regulate, formulate, publish and review the code of conduct, ethics and practice of the pharmacy profession and code of conduct for pharmacy technicians, patent medicine vendors and pharmaceutical marketers ;

(k) determine and set standards for the training of pharmacy technicians in schools and colleges of health technology approved by the Council ;

(l) determine the standards of knowledge and skills to be attained by persons seeking to become pharmacy technicians and patent medicine vendors, and review such standards ;

(m) establish requirements for continuing education and development for pharmacists, pharmacy

technicians, patent medicine vendors and other cadres in practice in institutions and centres recognised by it, including the determination of acceptable continuing educational and developmental courses ;

(n) register, licence, regulate and control the practice of pharmacists, pharmacy technicians or such other cadres as may be recognised by the Council in Nigeria ;

(o) register, licence, regulate and control the activities of patent and proprietary medicine vendors and Satellite medicine facilities, pharmacies, pharmaceutical manufacturing, importation, exportation, storage, distribution of pharmaceutical products and veterinary products in Nigeria ;

(p) regulate and control the practice of pharmaceutical marketing and representations ;

(q) regulate and control pharmacy practice in all its aspects and ramifications

(r) do such other things that are necessary to ensure the efficient performance of the functions conferred on the Council under this Act.

Registration of pharmacists.

Registration of a provisional member or a member.

Registration of Nigerian citizen who qualified outside Nigeria.

Registration of non-Nigerian Pharmacists.

Offences include:

a. Obstruction of a Pharmaceutical Inspection Officer and breaking of seal.

b. Operating a pharmacy without registration.

(v) National Agency for Food and Drug administration and control (**NAFDAC**) was established by Decree 15 of 1993 as amended by Decree 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria, 2004. This Act mandates NAFDAC to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices and packaged water (also known as regulated products).

The Agency performs the following functions ;

(a) Regulate and control the importation, exportation, manufacture, advertisement, distribution, sale, and use of food, drugs, cosmetics, medical devices, bottled water and chemicals,

(b) Conduct appropriate tests and ensure compliance with standard specifications designated and approved by the council for the effective control of the quality of food, drugs, etc., as well as their raw materials and production, including processes in factories and other establishments.

(c) Undertake appropriate investigations into the production premises and raw materials for food, drugs, etc. and establish relevant quality assurance systems, including certification of the production sites and regulated products.

(d) Undertake inspection of food, drugs etc.

(e) Compile standard specifications and regulations and guidelines for the production, importation, exportation, sale and distribution of food, drugs, etc.

(f) Undertake registration of food, drugs, etc.

(g) Establish and maintain relevant laboratory or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions. The Federal task force on counterfeit and fake drugs established under the provisions of the counterfeit and fake drugs (miscellaneous provisions) Act operates within NAFDAC.

(I) make pronouncements on the quality and safety of food, drugs, cosmetics, medical devices, bottled water and chemicals after appropriate analysis;

(j) undertake measures to ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes;

(k) grant authorisation for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances;

(l) collaborate with the National Drug Law Enforcement Agency in measures to eradicate drug abuse in Nigeria;

(m) advise Federal, State and local governments, the private sector and other interested bodies regarding the quality, safety, and regulatory provisions on food, drugs, cosmetics, medical devices, bottled water and chemicals;

(n) undertake and co-ordinate research programmes on the storage, adulteration, distribution and rational use of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(o) issue guidelines on, approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(p) compile and publish relevant data resulting from the performance of the functions of the Agency under this Act or from other sources;

(q) sponsor such national and international conferences as it may consider appropriate;

(r) liaise with relevant establishments within and outside Nigeria in pursuance of the functions of the Agency;

(s) determine the suitability or otherwise of medicines, drugs, food products, cosmetics, medical devices or chemicals for human and animal use;

(t) carry out such activities as are necessary or expedient for the performance of its functions under this Act.

(vi) **Drugs and related products (registration) Decree No. 19 of 1993**. This decree makes provisions for the prohibition of the manufacture, importation, exportation, advertisement, sale or distribution of drugs, drug products, cosmetics or medical devices unless it has been registered in accordance with the provisions of the decree. It also stipulates the procedure for applying for registration of a drug product, conditions under which information supplied by an applicant is disclosed, and provisions for the suspension or cancellation of certificates of registration and clinical trials. Penalties for contravention of provisions of this decree are also stipulated therein.