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Community Pharmacy Practice in Nigeria: The Dilemma of Regulation

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Abstract:
In Nigeria pharmacists are in chains everywhere in the practice of their chosen profession. This work sets out to unravel the contributions of the multiplicity of enactments on the subject, the use of committees, for example, the pharmacists inspection committee and executive officers as well as the abuse of powers by the agencies established under the enactments, to the miasma. In doing so, this work adopts the doctrinal method of research which involves the use of primary and secondary sources of law. Amidst other causes, this work observes that: (1) duplication and overlap of functions in the multiple enactments, (2) questionable provisions, (3) misconception and misapplication of the law, and (4) acts of abuses by the administrative agencies are the major contributors to the problems of the pharmacist in Nigeria. As to the solutions to the problems in pharmacy practice in Nigeria this work recommends: (1) refinement of the existing law, (2) pharmacists be exposed to the knowledge of administrative law; (3) pharmacists and chemists be made members of any legislative body or committee to enact laws or make regulations on drug matters.

Keywords: *Administrative process, discretionary power, plant or grow cocaine, use of committees by statutory bodies, infamous conduct*

1. Introduction

A balanced discussion of the topic calls for the examination of the legal and institutional framework for drug regulation in Nigeria. Under the legal framework some of the questionable provisions of the relevant Enactments will be x-rayed. Most importantly, the issue of duplication and overlap of functions in the pharmacy and Drug Legislations and the resolution of the seeming conflicts arising there from will be addressed. Under the institutional framework, the nature of and the exercise of discretionary powers by administrative agencies will be brought to the fore. Finally, the work will critically examine the misconception and misapplication of the provisions of the law by regulatory officers with emphasis on the closure of premises and other specific illegalities.

2. Legal Framework

2.1. Prelude

The regulation of pharmacy profession in Nigeria is of substantial antiquity. It began with dangerous drugs by the Dangerous Drug Ordinance (DDO)[i] which was enacted, 'to regulate the importation, exportation, manufacturing, sales and use of opium and other dangerous drugs'. The regulation was then extended to other drugs as well as the registration and inspection of premises as contained in the Poison and Pharmacy Act[ii], hereinafter referred to as the PPA. The regulation was then made complete by the Pharmacists Act[iii], which established the Pharmacists Board of Nigeria, which later became the Pharmacists Council of Nigeria (PCN) Act[iv] that introduced the registration of qualified members of the profession. These parent enactments have been variously amended and others enacted on related subject matters based on the exigencies of the time. In some areas the law has been so dynamic. For example, from 1935, beginning with the DDO till date, we have about twelve legislations regulating only hard drugs.

However, in other areas the volume of legislation is not that much. For the purpose of this paper, we shall lean heavily on the PPA, the PCN Act, the National Drug Law Enforcement Agency Act (NDLEA) Act[v] and the National Agency for Food and Drug Administration and Control Act, (NAFDAC) Act[vi], as amended.

2.2. Questionable Provisions

To say that Pharmacy and Drug laws in Nigeria are replete with obsolete, vacuous or nebulous provisions, which do not advance the interest of the profession in any way is to state the obvious. Only a few of such provisions will be considered in this work.

The PPA[vii] gives the Minister of Health the discretion to prescribe the licensing authority in respect of the Patent and Proprietary Medicine Vendors (PPMV). This provision has proved to be the greatest albatross of the Pharmacy profession. In the past, the exercise of the discretion as epitomised by Professor Olukoye Ransom Kuti has created invidious hiatus in the legal regulation of drugs and poisons in Nigeria. To avoid the emergence of another Ransom Kuti

who may decide to exercise his discretion in favour of District or Clan Heads, this work recommends the amendment of the section to vest the power in the PCN. This will enable the PCN effectively control the PPMVs who obviously are the bane of the profession. Without this step any pretence to amend the laws will amount to nothing but a sham.

Also the composition of the PCN under PCN Act[viii] is germane to the present discussion. It is not hard to point to instances in the past when the Directors of Pharmaceutical Services (DPS) exploiting their numerical strength in the PCN arm-twisted the PCN into making decisions, the implementation of which almost smuggled the regulation of the profession into the various State Ministries of Health. To move the profession forward therefore, this work the number of the DPS in the PCN must be pruned and the PCN should expedite action in establishing offices in the States.

Furthermore, this work maintains that the NAFDAC Act[ix] which provides for one month written notice of intention to commence suit against the Agency is redundant. This is because most of the actions against NAFDAC are likely to be fundamental human rights suits which by virtue of the Constitution of the Federal Republic of Nigeria (CFRN)[x] can even be commenced in anticipation of the breach of fundamental right. A person whose fundamental right has been, is being or is likely to be breached cannot be reasonably expected to serve one month notice before seeking redress in court. Also there are authorities to the effect that such pre-litigation notices do not apply to cases in contract. Having regard to the activities of NAFDAC and the likely injuries to would be litigants, the section is redundant. The section represents one of those impediments to access to court usually employed by military regimes which has no meaning in a civilian regime. Moreover, the NAFDC Decree now an Act of the National Assembly is *ultra vires* the Constitution in providing for pre-litigation notice.

Also, this work is of the view that the NAFDAC Act[xi] was nebulously drafted with the dubious intension of weakening the hold of Pharmacists on the Pharmacy Profession. Apart from the vexatious role of the Minister under the section, the requirement that the Director-General shall be a person with good knowledge of pharmacy, food and drugs smacks of dishonesty. The section is deliberately couched in this manner to pave the way for a Medical Doctor, a Nutritionist or a Pharmacologist to become the Director-General.

As for the NDLEA ACT, it did not find it necessary to make a Pharmacist a member of the Agency at any given time. However, this deliberate omission is not without consequences. An Agency charged with the formulation and implementation of policies on technical subject matter without expert(s) is bound to goof. No wonder the NDLEA Act[xii] provides that any person who, without lawful authority plants or grows cocaine, LDS, heroin or any other similar drug shall be guilty of an offence. It is submitted that the section amounts to saying that any person who, without lawful authority plants or grows '*kernel', oil*, or the *juice* of an orange shall be guilty of an offence. Pharmacists need not be told that cocaine, LSD, heroin etc., as active ingredients (agents) in plants cannot be plated or grown. It is further submitted that the contextual error in the section was occasioned by the absence of inputs from pharmacists as experts in drug in the making of the law.

2.3. Duplication and Overlap of Functions

To a non-legal mind, the Pharmacy and Drug laws are replete with irreconcilable conflicts. The following provisions appear to support this claim, for example, the Long Title of the PPA states thus, 'An Act to regulate the sale and distribution of drugs and poisons. The PCN[xiii] charged the Council with the duty of, 'regulating and controlling the practice of the profession in all its aspects and ramifications'. At the same time the NDLEA Act[xiv] charged the NDLEA with the co-ordination of all drug laws and enforcement functions conferred on any person or authority including Ministers in the Government of the Federation. However, section 3 (q) limits the supervising, controlling, and coordinating functions of the NDLEA in relation to arrest, investigation and prosecution of offenders to illicit traffic in narcotic drugs and psychotropic substances. On the other hand, NAFDAC, is by its Act[xv] charged, *inter-alias*, with the following functions:

- Section 5(a) – to regulate and control the importation exportation, manufacture, advertisement, distribution, sale and use of drugs:
- Section 5 (f) – undertake the registration of drugs.
- Section 5 (j) – undertake measures to ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purpose.
- Section 5 (k) – grant authorization for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances.

The above provisions portray a conflict situation, more especially that the Legislations are co-ordinate; Acts of the National Assembly. However, the law is not as confused as pharmacists would want to believe. It has principles for addressing this kind of situation and only one is examined in this work. The principle is on special and general provisions in statutory interpretation. On the authority of Scroder v. Major[xvi], where there are two provisions, one special and other general covering the same subject matter, a case falling within the words of the special provision must be governed thereby and not by the terms of the general provision. By extrapolation the provisions of special legislation prevail over those of a general legislation.

Using the above principle, both the PPA, NDLEA Act and NAFDC Act are special legislations vis-à-vis the PCN Act which is enacted to regulate and control the practice of the profession in all its aspects and ramifications. In this connection, the PPA, NDLEA Act, and the NAFDAC ACT are supreme in those aspects of the practice of the profession on which they are enacted. For example, where the provisions of the PCN ACT and those of the NDLEA ACT are in conflicts in respect of narcotic drugs and psychotropic substances, those of the latter prevail. So also, are provisions of NAFDAC ACT on registration of drugs in relation to those PCN Act by virtue of the Food, Drugs and Related Products (Registration, ECT) Act[xvii], enforced by NAFDAC. In the same vein, the provisions of NAFDAC ACT prevail over those of the PPA on the

registration of drugs even though both legislations deal with the distribution and sale of drugs. However, on narcotic drugs and psychotropic substances, the law has charged the NDLEA and NAFDAC with the illicit and licit control respectively, and the provisions of their Enabling Act stand supreme in their respective domain.

3. **Institutional Framework**

3.1. Prelude

The institutional framework for the regulation of community pharmacy practice in Nigeria encompasses the activities of the various administrative agencies established under the statutes. The nature of an exercise of discretionary powers to make and enforce rules and regulations by these agencies will be considered in this segment of the work. The propriety of the use of committees, for example Pharmacists Inspection Committee, and executive officers as well as the abuse of powers by the agencies form substantial part of this segment.

3.2. The Nature of Administrative Agency

Administrative agencies are to law what military regimes are to civilization, aberrations. This is because administrative agencies normally combine the functions of the three arms of government namely: the legislature, the executive and the judicially. This lack of separation of power, a concept that has been ingrained in our constitutional democracy, renders such bodies suspects in the eyes of the law. However, the technical nature of the subject matter handled by these agencies, the lack of time on the part of the of legislature vis-à-vis the bulk of legislation to be made, the desirability of testing new schemes to be introduced by government and the continuity of government at times of emergency adds up to make their existence tolerable. The above reasons coupled with the indeterminacy of the meaning of words and lack of human prescience to make laws aimed at taking care of a myriad of unforeseen situations for the benefit of the society make them necessary evils.

An administrative process is the carrying on of the business of government in the public interest or is the theory and practice of modern government while administration is the government machine by which policy is implemented.[xviii] This definition leads us to the consideration of the legal statutes of the regulation made by these agencies, exercise of discretionary powers and the use of committees and executive officers.

Usually, the legislature enacts law in board terms leaving the details to be filled in by administrative agencies or authorities in form of rules or regulations for application to a particular fact or set of circumstances in the future. In that wise the Interpretation Act,[xix] provides thus, *'... All orders, regulations and rules of the court shall have the force of law upon publication thereof, in accordance with the provisions of this section or from the date named therein'*. However, this provision does not entitle administrative agencies to make regulations or rules outside the scope of the enabling law; otherwise, they will be declared null for being *ultra-virus*.

Furthermore, the position of the law in the case of *Phoenic Motors Ltd v N. P. F. M. B*.[xx]is as follows:

> 'A statute cannot be amended or repealed by a subsidiary legislation. A Legal Notice (Regulation made by the PCN) being a subsidiary legislation does not have a legal life of its own in the sense that it can be made completely outside the enabling statute and stand alone as a separate piece of legislation'

So, where the PCN under Section 10 (2) of the Pharmaceutical Premises Regulation 2005 empowered Inspectors to prosecute offenders either in the High Court of a state or a magistrate, this work maintains that the making of the regulation is *ultra vires* for at least two reasons. First, prosecution by Pharmaceutical Inspectors is not provided for by the enabling Act (PCN ACT) and so any regulation on it is *ultra vires*. Secondly, by virtue of CFRN[xxi], the Federal High Court is the one with jurisdiction to try criminal cases arising from drugs and poisons. Whether the jurisdiction of the Federal High Court is exclusive or not is a matter beyond the scope of this work.

On the issue of the exercise of discretionary powers and its delegation, the law is well settled. The exercise of discretion must be regular and according to the rule of reason and law. After a long period of uncertainty in this area of the law, the Supreme Court, in the case of *Stitch v Attorney General (Federation)*[xxii], the Supreme Court came to the conclusion that the exercise of discretionary powers by administrative agencies is within its review-able power. Ordinarily, the courts will not interfere with the actions of administrative bodies that are within the power granted (*intra vires*). However, the desirability of reviewing administrative actions in a country like Nigeria that practices constitutional supremacy is based on many reasons, known as grounds for judicial control which includes express conditions or reasonableness, constitutional implications, sub-delegation, uncertainty and vagueness, relevant and irrelevant considerations, fault in the manner of performance, abuse of the principle of natural justice. Somehow, they must be forced into the mould of the *ultra vires* doctrine, otherwise the courts will have no basis for its intervention.

Related to the above is the principle on sub-delegation, that administrative powers must be exercised by the body, person or authority upon whom it is conferred by the enabling statute or law. This principle is supposed to be adhered to strictly even where it causes or poses administrative inconvenience. However, where upon a survey of a parent Act it is clear that the duty was intended to be delegated or sub-delegated those concerned may exercise such duties or functions. Where the parent Act is silent on the issue, the assumption is that such functions can be delegated. However, it must be stated that while legislative and executive functions may be delegated, judicial functions cannot[xxiii]. The concern of the law on delegation is that delegates (committee or executive officers) should merely carry out they duty of investigation and recommendations relating to a given function or duty; leaving the legal power of decision making to the body specifically authorized under parent Act. So, where the PCN insists on the endorsement by a State Official (PIC) before it can issue

annual practicing license, the courts will declare its action null and avoid for putting the decisive step (rate limiting step) in the hands of a wrong body.

4. Misconception and Misapplication of the Law

4.1. Prelude

Misconception under this head refers to a situation where the law makes provisions for regulating a particular activity of a pharmacist within and without a pharmacy shop. Furthermore, it encompasses situations where the officials of the PCN as inspectors subject pharmacists to hardships outside the purview of the law.

On the other hand, misapplication of the law arises from a situation where the PCN, contrary to the provisions of the PCN Act, makes a regulation and enforces same to the pharmacist and his premises. It is actually a situation of misconception and misapplication of the law.

One cardinal principle of our criminal justice system is that which provides thus:

'No person shall be held to be guilty of a criminal offence on account of any act or omission that did not at the time it took place, constitute such offence, and no penalty shall be imposed for any criminal offence heavier than the penalty in force at the time the offence was committed'[xxiv].

The PCN through his registrar and regulatory officers has taken the lead in violating this constitutional provision with regulatory officers of NAFDAC, NDLEA and the disbanded Task Forces showing flashes of the same trait. In this connection, this work will now deal with closure of pharmacy shops and other specific acts of illegalities by the regulatory bodies.

4.2. Closure of Pharmacy Shops

The closure of a pharmacy shop is a judicial act which makes the regulatory officer concerned the complainant, the prosecutor and the judge who has convicted, sentenced and executed his judgment or order. From the provision of the CFRN[xxv], it is clear that every offence has a penalty prescribed for it. The penalty is either contained in the same section defining the offence, in the subsection or in an omnibus punishment section. For example PPA[xxvi] provides that:

'A person guilty of an offence under this Act for which no special penalty is provided by this Act is liable on conviction to a fine of ₦200.00 or to imprisonment for a term of twelve (12) months or to both such fine and such imprisonment'.

This is the trend in all enactments including the PCN Act, NDLEA ACT, NAFDAC ACT, etc. So, a regulatory officer who upon entry into a premises noticed an offending act may:

- where the act amounts to a an offence proceeds against the pharmacist in a competent court through a legal officer employed by the agency in question or through a state council in the ministry of justice or a police officer qualified to prosecute in the relevant court.
- where the offending act is both an offence and a professional misconduct the regulatory officer may prosecute the pharmacist through the persons mentioned in paragraph (i) above and at the same time make a report to the PCN Disciplinary Tribunal for disciplinary proceedings as it was the case in. Esiagra and Unical[xxvii] and Denloye v Medical and Dental Practitioners Disciplinary Committee[xxviii]
- where the act is a professional misconduct (*simpliciter*), the proper body to try the matter is the PCN Disciplinary Tribunal (PCN-DT) and the penalties for infamous conducts in a professional respect are contained in the PCN ACT[xxix].

It is not possible in this work to itemize what acts are criminal offences and which are infamous conducts in a professional respect in a Pharmacy. However, any trial that may end in conviction and imposition of fine or imprisonment term or both is a criminal trial whereas a trial for professional misconduct either ends in the name of the Pharmacist been struck off the roll or his suspension from practice.

Professional misconduct is a nebulous concept which many professions have held against their members at entry point in the name of 'fit and proper person as in the case of *Okojo v Council of Legal Education*[xxx]. The only available examples of infamous conduct in a professional respect so far are, disclosure of professional methods and betrayal of one's profession as in the case of *Allison v General Council, Medical Education and Registration*[xxxi]. The proper procedure against a pharmacist who commits an offence in his registered premises is to prosecute him in a competent court. Where he is convicted, depending on the nature of the offence, the regulatory officer as a complainant, may then initiate his trial according to the Rules of the Tribunal.

This second trial does not in any way amount to double jeopardy. If the PCN-DT finds that the offence for which the registered pharmacist is convicted is incompatible with the status of a pharmacist, it may then direct the Registrar to strike his name off the relevant part of the register or to reprimand him. It is submitted that it is only when his name is struck off the register that the premises registered by him can be lawfully closed. Moreover, the direction of the PCN-DT is subject to the normal channels of appeal, beginning with the Court of Appeal.

However, where the regulatory officer chooses the course of abuse by ordering the immediate closure of the premises, the remedy available to the Pharmacist and the shop, as a limited liability company lies in a suit under fundamental human rights. In applying for the enforcement of his fundamental rights, the pharmacist usually will allege the breach of the twin principles of natural justice; *audi alteram partem* (the other party be heard) and *Nemo judexincausea sua (*no one shall be a judge in his own cause). No doubt the immediate closure of the shop is a violation of the principle of fair hearing as outlined in the CFRN[xxxii]. Note also that the regulatory officer is the complainant and by closing the shop he has convicted the pharmacist thereby acting as judge in his own cause. Even if the pharmacist's offence

was sale of expired drugs, the regulatory agency will not be allowed to set it up as a defence to the breach of the principles of natural justice. In essence, the whole trail may be concluded without the sale of expired drug being a fact in issue. The principles of natural justice are sacrosanct and must be followed as even the derogation from fundamental rights under the CFRN[xxxiii] does not affect them. Their universality suggests that they are from a higher source.

In relation to the above, further comments are required on the powers of the Task Force under the Counterfeit and Fake Drugs and Unwholesome Processed Foods (CFDUPF) (Miscellaneous Provisions) Act[xxxiv], which provides thus:

'The state Task Force shall have power to seal up any premises used or being used in connection with any offence under this Decree until such time as the drug, poison or unwholesome processed food product, as the case may be, in the premises has been removed by the state Task Force or until such reasonable time as the Minister may determine in the circumstances'.

First, only the members of the Task Force, not every regulatory officer of NAFDAC are vested with this power. So where the Task Force has not been dully constituted, the power to act under the Section is at large. Secondly, the sealing up of the premises must be distinguished from closure. It is limited to a time sufficient to enable the Task Force remove the drug or poison in question. So where the counterfeit and fake drugs in question are a few tins of paracetamol and chloroquine, the sealing up of the premises for a whole day or days will be held unreasonable. However, where the items concerned are bulky, the availability of the means of removal may be a factor. Either way, it will be a matter of evidence to decide where liability lies. This analysis is necessary and should be noted because sealing up of the premises is not the penalty for the offence but a fine of N50,000 or imprisonment for a term not less than 6 months or both as contained in the CFDUPF[xxxv]. The CFDUPF[xxxvi] merely empowers the Task force to take a particular action if confronted with a specific situation in the exercise of its functions. The section is akin to the power of a policeman to use reasonable force to arrest a recalcitrant criminal but which power does not exist were a criminal willingly submit to arrest. So too, sealing up a premises in circumstances which do not justify same will surely attract liability, more so that the task Force will only be acting on suspicion at that point. Thirdly, being an Act of the National Assembly, the constitutionality of the provision vis – a - vis the principle of fair hearing in the CFRN[xxxvii] is doubtful.

Finally, immediate closure of premises by regulatory officer has not been prescribed as penalty for any offence in the Pharmacy and Drug Laws and even if it has been, the courts will not infuse 'life' into the provision for want of its constitutionality. The closure of premises and the striking off the Pharmacist's name in the Pharmacy profession is akin to 'death penalty' which can only be imposed through a judicial process. It is submitted that no regulatory officer of any agency can lawfully close a pharmacy shop except through the process earlier outlined. This submission has its root in the Latin maxim, *eodo modo quo, eodo modo desuviter.* In other words, since a pharmacist premises come into existence through a legal process of registration it can only go out of existence through a legal process.

4.3. Renewal of Annual Licence

For an effective discussion on renewal of annual licence or re-certification of a pharmacist, the law as found in the PCN Act[xxxviii] is hereby reproduced:

'Every fully registered pharmacist who has paid his registration fee (practicing fee) as prescribed in subsection (1) above or is exempted from payment of registration fee (practising fee) as in subsection (2) of this section, shall be entitled to an annual practicing licence authorizing him subject to any regulation in force to import, mix, compound, prepare, dispense, sell and distribute drugs and prisons'.

The crucial issue here is whether the duty of the PCN under the section is ministerial or discretionary. It is submitted with utmost vehemence that the PCN has no discretion under the Section. In other words, once a fully registered pharmacist has fulfilled the singular requirement under the section, payment of annual practising fee in respect of any years, the issuance of annual licence to him becomes a matter of course. This position is re-enforced by the provision of subsection (6) thus:'any pharmacist who in respect of any year without paying practising fee practices as such is guilty of an offence and is liable on conviction'.

Regrettably, in practice, many conditions are attached to the issuance of annual licence either by the PCN or its surrogates. It is submitted that no other condition, not even the requirement of good character, fit and proper will entitle the PCN to refuse to act under the section. This is because after full registration, who is a 'fit and proper person' is no longer within the competence of the PCN to determine but that of the PCN-DT and the courts. The point I am struggling to make here is that after full registration, whatever the PCN may consider sufficient to prevent its issuance of annual licence can either amount to an offence against the PCN Act or an infamous conduct in a professional respect and the procedures for addressing such have been outlined under paragraph 4.2 above. Ultimately, once a fully registered pharmacist has tendered to the PCN the practicing fee in respect of any year, the prerogative order of mandamus will issue against it for refusing or neglecting to issue the licence.

When in 2008 the excesses of the PCN became intolerable the author of this work, then a practising pharmacist as the 1st plaintiff and his pharmacy shop (Beam Pharmacy Nig. Ltd.) as the 2nd plaintiff approached a Federal High Court in Lafia, Nasarawa State, Nigeria, to challenge the ever growing requirements for the annual renewal of a pharmacist's licence to practice. The stage for the challenge was set when in 2005 the PCN purportedly made a Regulation to the effect that unless a practicing pharmacist earns a certain amount of credits in its Mandatory Continuing Professional Development (MCPD) his annual licence to practice will not be renewed, which in the opinion of the plaintiffs is *ultra vires* the PCN Act and therefore void. The plaintiffs in the case before the Federal High Court, found the jurisdiction to challenge the Regulation of the PCN in the CFRN[xxxix], which provides thus:

'Notwithstanding anything to the contrary contained in this Constitution and in addition to such other jurisdiction as may be conferred upon it by an Act of the National Assembly, the Federal High Court shall have and exercise jurisdiction to the exclusion of any other court in civil causes and matters-

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(m) drugs and poisons,

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…… '.

The core of the plaintiff's grievances is that the provisions of the PCN Act on renewal of practising licence and that of its Regulation PCN.EdT.009 are incompatible and therefore the Regulation is void to the extent of the inconsistency. The facts of the case as presented before the court are contained in a letter written by the 1st plaintiff to the Registrar of the PCN and is hereby reproduced:

'The Register
Pharmacists Council of Nigeria
Abuja.
Sir,
NON-ISSUANCE OF ANNUAL LICENCE TO PHARM. MOSES EDIRU IN 2008
We wish to bring to your notice that Pharm. Moses Ediru, the superintendent pharmacist of Beam Pharmacy (Nig) Ltd, No. 76 Doma Road, Lafia, Nasarawa State duly filled out Forms B and J and paid the necessary fee for registration vide Bank Draft No. 00008741 in respect of 2008, before 31/1/2008 and submitted same to the PCN designated official in the State (see Exhibit 'A' annexed to this letter). Surprisingly however, the PCN neither issued the licence and certificate for the year nor communicated its failure and/or refusal and the reasons therefor to us. When we inquired from the designated official in the State and the officials of the PCN at the 2008 Annual Conference held at Abuja on 3/11/08, the responses were uniform. Are you MCPD complaint?

We did not consider the reason official until we received from the PCN Inspection Committee of the State, a letter titled: Forwarding of 2009 PCN Renewal documents herein marked Exhibit 'B', stating among other things, the requirements for registration as:

- MCPD Compliance
- PSN Dues
- ACPN dues

Our position is that these requirements are extraneous to the duty of the Registrar to issue licences and certificates under the PCN Act. Moreover, since the designated state official is insisting on these requirements, we have decided to package our completed Forms B and J for the 2009 registration and to tender the fee in respect thereof directly to the PCN.

TAKE NOTICE that if after one (1) month of the service of this letter, together with the completed Forms and the fee rendered vide PCN First Bank Deposit Slip No. 0020975 of 22/01/09 on you, we do not hear from you, we shall immediately approach the Court to ventilate our grievances against the PCN, PSN and ACPN over the registration requirements.

TAKE FURTHER NOTICE that the issuance of the licence and certificate without delay is the only way to avert the legal pugilism that is sure to erupt from this matter.
Yours faithfully,
Pharm. Moses Ediru
At the Federal High Court the plaintiffs in the originating summons submitted the following questions or issues for determination by the Court:

- '1. Whether Forms B and J (Exhibits 'F' and 'F1' respectively) are legal forms under the Pharmacists Council of Nigeria (PCN) Act, Cap P-17, Laws of the Federation of Nigeria, 2004.
- 2. Whether paragraph 5 subparagraph (b) of Exhibits F and F1 are impediments to access to Court and therefore null by virtue of Section 6 subsections 6(b) of the 1999 Constitution.
- 3. Whether the Pharmacists Council of Nigeria Act provides for Mandatory Continuing Professional Development (MCPD) programme for re-certification of pharmacists.
- 4. Whether payment of capitation/conference and Journal fee to the PSN and MCPD compliance are conditions-precedent for annual licence to practice as a pharmacist under Section 14(3) of the PCN Act and the retention of premises on the register of premises under Section 3 of the Poisons and Pharmacy Act Cap 152, L & F, 1959'.

Based on the issues submitted, the plaintiffs claimed the following reliefs:

- A DECLARATION that Forms J and B (Exhibits F and F1) are not legal forms under the Pharmacists Council of Nigeria (PCN) Act and/or paragraph 5 subparagraph (b) thereof are contrary to S. 6(6)(b) of the 1999 Constitution and therefore null.
- A DECLARATION that the imposition of the Mandatory Continuing Professional Development (MCPD) on pharmacists by the 1st defendant is *ultra vires* its enforcement functions under the PCN Act and therefore null.

- A DECLARATION that the payment of capitation/conference and journal fees to the PCN and MCPD compliance are not conditions – precedent for the issuance of annual licence and certificate of retention of premises under S.14(3) of the PCN Act and S. 69(1)-(b) of the Poisons and Pharmacy Act (PPA) CAP 152, L & F 1958 respectively.
- A DECLARATION that the sole requirement for the issuance of annual licence and certificate of retention of premises under S. 14(3) of PCN Act and S. 23(1)-(3) of the PPA respectively is the tendering of the prescribed fees for the year in question.
- A DECLARATION that the refusal, failure and/or neglect by the 1st defendant to issue the plaintiffs with licence and certificate after tendering the fees for 2008 is illegal and unconstitutional.
- AN ORDER of the Honourable Court compelling the 1st defendant to issue the annual licence and certificate of retention of premises for 2009 to the 1st and 2nd plaintiffs respectively and for subsequent years upon tendering the necessary fees until and unless S. 14(3) of the PCN Act is amended otherwise.
- AN AWARD of Eight Million (N8,000,000.00) Naira only as general damages against the defendants'.

At the end of the case, Hon. Justice I. N. Buba of the Federal High Court, relying on the case of *Phoenic Motors Ltd v N. P. F. M. B.*[xl]answered the four (4) questions or issues thus:

'In the instant case I think the defendants cannot decide the ambit of their powers. I think on a proper interpretation of Section 14 of the PCN Act in the instant case, I am satisfied that the plaintiffs have produced evidences and have proffered argument and none of the defendants made any submissions on the merit of the application. The 2nd defendant labored to make submissions on issues that are not before the Court and left the issues before the Court. In the circumstances, the case of the plaintiffs becomes unchallenged on the merit and the Court can accept the case of plaintiffs. That: A statute cannot be amended or repealed by a subsidiary legislation. A Legal Notice (Regulation made by the PCN) being a subsidiary legislation does not have a legal life of its own in the sense that it can be made completely outside the enabling statute and stand alone as a separate piece of legislation.

I shall not delve into other irrelevant issue. In sum, the case of the plaintiffs succeeds and for the avoidance of doubt, I answer question 1 in the negative. I answer question 2 in the affirmative. I answer question 3 in the negative and 1 also answer question 4 in the negative.

In effect the case of the plaintiffs succeeds and I make the following orders'.

In line with the resolution of the issues, the Court granted reliefs 1-6 of the plaintiffs but declined relief 7.

It is the opinion of this work that the relevance of the instant case to this work is embedded in the arguments of the parties; hence, the need to touch on the arguments, albeit briefly. From the answers to the questions or issues by the Court, it is clear that the Court considered issue 3, which is, '*whether the PCN Act provides for Mandatory continuing professional Development (MCPD) for re-certification of pharmacists'*as the core of the dispute before the Court. For a better understanding of the arguments on the issue the provisions of the PCN Act[xli] and the vexed regulation PCN-EdT.009: MCPD Programme for the Re-certification of Pharmacists in Nigeria[xlii] are hereby reproduced:

- 'Every fully registered pharmacist who has paid his registration fee as prescribed in subsection (1) above or is exempted from payment of registration fee as in subsection 14(2) of this section shall be entitled to an annual practicing licence authorizing him subject to any regulations in force to import mix compound, prepare, dispense, sell and distribute drugs and poisons' (*Emphasis supplied)*
- Every pharmacist is expected to attend and obtain the required 30 credit units within each re-certification period. Note also that as from January 11, 2016 a pharmacist in default would lose the right to the renewal of his practice licence and if in employment of any company or establishment, such companies or establishments would be operating in breach of the law.

The above provisions bring to bear the need to consider the relationship between an enabling Act and subsidiary legislation such as a Regulation before delving into the dilemma of regulation of the pharmacy profession in Nigeria by considering the arguments of the parties in the instant case.

On the relationship between an enabling Act and a Regulation, the Court in the instant case after a thorough consideration of the issues and arguments of parties, relied on the following authorities in reaching its decisions. The Court relied on the work of J. M. Events,[xliii] which stated that:

'Despite the greater fluidity of the Court's approach to the interpretation of legislation and the inherently limited utility of general principles that have to be applied to widely varying contexts, the common law presumptions retain a great deal of their vitality. The greatest of these presumptions is that parliament does not intend to deprive the subject of his common law rights except by express words or necessary implication. This is the generic presumption of which the following are species; that, statutory powers must as far as is reasonably practicable, be so exercised as to avoid injury or to minimize the scope of any injury that must inevitably be caused, to the rights of others; …. Of the common law presumptions the most influential in modern administrative law is that which preserves the ultimate jurisdiction of the Courts to pronounce on the matter of law. Accordingly, only in the most exceptional circumstances will the Courts construe statutory language so as to endow a public body with exclusive authority to determine the ambit of its own powers'. (*Emphasis supplied)*

At this juncture, it is expedient to throw up the salient arguments on the issue of MCPD compliance as a prerequisite for re-certification of practising pharmacists. In the course of the trial the argument of the plaintiffs on the issue which the Court accepted is that the payment of the practising fee provided for in the PCN Act[xliv] is the sole requirement for the renewal of annual licence. They further argued that the PCN cannot by any Regulation add to the requirements stipulated by the enabling Act and cited the case of *Musa v INEC*[xlv], where **S. 74(2)** of the Electoral Act, 2001, reproduced the provisions of the CFRN[xlvi] spelling out the conditions on registration of political associations and added

conditions (g) and (h), the Court declared conditions (g) and (h) of S. 74(2) of the Electoral Act 2001 null and restrained INEC from basing the registration of political association on the offending provisions of the Electoral Act.

In like manner, the PCN Act[xlvii] has provided the restrictions to the right to practice; hence, any attempt to add to the restrictions by the PCN in its regulation PCN.EdT.009 with the requirement of MCPD compliance suffers the same fate as in Musa's case above. Also, the law as found in the case of *Olaniyan v University of Lagos*[xlviii] is that any act by administrative authority outside the statute or instrument defining its powers, in this case the PCN Act, is *ultra vires* and therefore null. With the above authorities the plaintiffs submitted at trial that the payment of the renewal fee as contained in the PCN Act[xlix] is the sole requirement for renewal of annual licence.

On the part of the 1st and 4th defendants, their submission on the issue is that the use of the phrase, 'subject to any regulation in force', in the PCN Act[l] implies that the payment of prescribed fees is in itself subject to any regulation or requirement that the PCN have put in place for the time being. The plaintiffs, in their written address attached to their further affidavit countered the 1st and 4th defendants' submission thus:

'From the provision of the PCN Act[li] reproduced earlier, it is clear that it is not the payment of the prescribed fee and the issuance of the licence but the authority to practice conferred by the annual practising licence that is subject to any regulations in force. In other words, the pharmacist is to practice subject to any regulations in force. Moreover, such regulations, which must relate to the activities, listed i.e. import, mix, compound… drugs and poisons can only restrict or limit what the pharmacist does with the licence and not the payment of the fees or issuance of the licence by the PCN.

Furthermore, regulations in force under the section do not and cannot refer to regulation providing for MCPD as the regulations are limited to regulations on the listed activities under the section. Assuming without conceding that it is included, the regulation itself will be *ultra vires* the PCN Act, which has not provided for any form of continuing education for practising pharmacists.

Still on the above issue, the counsel to the 2nd and 3rd defendants cited a section of the PCN Act[lii] as the source of the authority of the PCN in imposing the MCPD on pharmacists. The section provides thus:'…charged with the general duty of- ... (d) regulating and controlling the practice of the profession in all its aspects and ramifications'.

The question, which the 2nd and 3rd defendants failed to answer at the trial, is whether the section gives the PCN a blank cheque to regulate and control the pharmacy profession outside the law.

In reply the plaintiffs submitted that in law, the whole essence of the establishment of administrative bodies, like the PCN is to apply the provisions of its enabling Act to specific situations through the making of regulations. Any regulation on any matter not covered by the PCN Act i.e. the so-called regulation on MCPD is *ultra vires* the powers of the PCN.

In alliance with the plaintiffs in that case this work submits that it is only after the PCN has renewed the licence of a pharmacist that it can exercise control over the pharmacist by enforcing the provisions of any Regulation.

Finally, on the state of the law the Court declared that the payment of the necessary fee is the sole requirement for the re-certification of a practising pharmacist and as well declared the MCPD illegal, amongst other reliefs. The defendants in this case appealed to the Court of Appeal but could not file their brief for a period of more than 9 years and the appeal was dismissed by the Court of Appeal without the possibility of re-listing according to the law, making the decision of the Federal High Court the position of the Law in Nigeria as at today.

Regrettably, with the above position of the law the PCN is as at today still running the MCPD in disobedience to the decision of the Courts which makes the imposition of the MCPD compliance the utmost dilemma in the regulation of the pharmacy profession in Nigeria.

5. Conclusion

It is sad that from the introduction through the main body of this work the deficits in both the contents of the enactments on community pharmacy practice in Nigeria, as well as the understanding and application by regulators are the main baneof the profession. The profession is the most regulated in the clime but yet, there is nothing to applaud in the areas of organization and service to the public. This adverse commentaries on the profession as evident in the body of this work are engendered by the following factors:

- non-refinement of the existing laws,
- non-inclusion of pharmacists and chemists in legislative bodies or committees to enact laws or make regulations on drug matters,
- no knowledge of administrative law on the part of pharmacists,
- lack of in-depth knowledge of pharmacy and drug laws in pharmacy curriculum.
- It is the summation of the above factors that put community pharmacists in chains even as they handle life's utensils on the floor of the pharmacy.

6. Recommendations

It is axiomatic that no amendments to pharmacy and drug laws proposed by any governmental agency will be in the interest of pharmacists. This is evident from the procedural requirements for such amendments. Therefore, the Annual General Meeting(AGM) of the Pharmaceutical Society of Nigeria (PSN) should constitute a committee for the singular purpose of overhauling the pharmacy and Drug Laws using democratic lens with a view to presenting a private Bill to the National Assembly.

To properly empower members of the Association of Community Pharmacists in Nigeria (ACPN) in their chosen sphere of practice, the knowledge of administrative law is recommended. Administrative law, amongst other things, deals

with the control of the powers of administrative agencies. In this wise, pharmacists will be in better position to know when, how and what questions to ask or the appropriate action to take in the face of any provocation or intimidation by any administrative agency. The requisite knowledge can be acquired by introducing Administrative law into the pharmacy curriculum.

7. References

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vi. Cap N-1, LFN 2004
vii. S. 36
viii. S. 3(1)
ix. xix. S. 26(1)
x. 1999, S. 46
xi. S. 9(1)
xii. S. 10(a)
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