

Original Research Article

Evaluation of pharmacy practice regulations in Nigeria: The pharmaceutical inspectors' perspective

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Abstract

Purpose: To evaluate pharmacy practice laws and regulations in Nigeria and recommend ways to overcome the challenges facing its implementation.

Methods: Semi-structured questionnaire of 19 questions was administered to pharmaceutical inspectors of the Pharmacists Council of Nigeria (PCN) to assess pharmacy practice laws and regulations in terms of its mandate, the challenges in implementation and recommendations for amendment for legislative attention. Data were analyzed using simple descriptive statistics.

Results: Respondents (87.5%) were not satisfied with the existing laws and regulations and 56.3% agreed that they were inadequate to regulate the practice of pharmacy profession in Nigeria. Some respondents (37.5%) agreed that the laws and regulations were not specific on many issues that require regulation and enforcement while all of them (100%) agreed that the laws did not adequately capture offences and penalties for offenders. Half of the respondents (50%) were of the opinion that the name of the regulatory body poses a limitation to the regulation of its sub-cadre while 43.8% agreed that consistent court injunctions and litigation that occurred had hampered regulation of pharmacy practice as a whole.

Conclusion: The existing laws and regulations are inadequate to regulate the current pharmacy practice in Nigeria. Need for speedy review in order to meet up with the current reality in practice, wide publicity, increase manpower, adequate funding and strong legal backing of PCN activities were recommended.

Keywords: Pharmacy practice, Drug laws and regulations, Pharmaceutical inspectors

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INTRODUCTION

The law regulating the practice of pharmacy in Nigeria dates back to 1878 when the Lagos Pilotage and Harbor ordinance was enacted [1]. This ordinance established the control and supervision of medicines and medical treatment respectively. Later, the hospital ordinance of

1881 and The Ereko Dispensary Rules of 1889 were enacted. As the numbers of dispensers and medicine stores increased, there was the need to standardize their practice. The Pharmacy Ordinance No.8 of 1902 was thus enacted to control the sales and distribution of drugs and poisons and was restricted to the colony of Lagos, the town of Calabar, Opodo, Warri,

Forcados and such other parts of the Protectorates as the Governor in the Council declared. Under this ordinance, the early dispensers and druggists were examined and granted certificates and licenses.

In 1923, the Poison & Pharmacy Ordinance of 1923 was enacted. This, in addition, provided the standards and skills to be attained by those wishing to be registered as Chemists and Druggists. Other laws enacted to regulate the practice included the Poison and Pharmacy Ordinance of 1927, Poison and Pharmacy Ordinance of 1936, the Poison and Pharmacy Act 152 of 1958, the Pharmacists Act No.26 of 1964 and the Pharmacists Council of Nigeria (PCN) Decree No. 91 of 1992 (now Act P.17 LFN 2004) [1]. The PCN Act P.17 LFN 2004 which repealed the Pharmacists Act of 1964 and dissolved the Pharmacy Board of Nigeria established by the former Act regulates pharmacists, pharmacy technicians, pharmaceutical premises and patent medicine shops across Nigeria. By this Act, the Pharmacists Council of Nigeria inherited all the assets, liabilities, registers, documents, regulations, functions, and employees of the defunct Board.

Pharmacists Council of Nigeria (PCN) is the statutory regulatory body for the pharmacy professions in Nigeria and is charged with the responsibilities of regulating and controlling the education and practice of pharmacy profession in all aspects and ramifications [2]. In discharging of statutory functions, Council had made regulations such as Regulation No. 79 of 2005 on Inspection, Location and Structure of Pharmaceutical premises and Regulation No.81 of 2005 on Registration of Pharmaceutical premises [3,4]. Since pharmacy laws must be properly enforced with appropriate penalties for violators [5], the Council uses its authority to impose appropriate penalties when necessary. Sanctions are sometimes simply corrective or punitive such as payment of fines or closing down the premises. Sometimes when a party has seriously contravened the law, an appropriate sanction could be determined to be the withdrawal of annual license to practice.

A major issue with existing laws and regulations is that, some of them did not capture specific offences and penalties to be meted on offenders. The pharmaceutical inspectors are often limited in carrying out their activities. Today, the level of non-compliance with practice rules and regulations are on the high side. Over 50% of existing patent medicine shops in Nigeria practice illegally as they are unlicensed. There

are now many cases where licensed premises owners do not adhere to the premises they are licensed to practice and many premises licensed as wholesale outlets actually practice both retailing and wholesale. Likewise, nearly all patent medicine vendors engaged in illegal sales of ethical medicines rather than the over-the-counter medicines they are licensed to retail in their original packages. Furthermore, the advancement in the practice of pharmacy has created situations which were not covered in existing laws and regulations.

The objective of the study is to critically appraise the pharmaceutical inspectors perspective on the existing laws and regulations with a view to ascertain their continued relevance in current modern day practice of the pharmacy profession.

METHODS

Study design

A cross-sectional study was conducted in April 2013 among pharmaceutical inspectors who are staff of PCN across Nigeria.

Settings

PCN is an agency of the Federal Republic of Nigeria with its head office in Abuja, four (4) core departments, three (3) technical departments and two (2) units directly under the Registrar who is the chief executive of the organisation. The agency has decentralised and has offices located in thirty-five (35) states of the federation including the Federal Capital Territory (FCT) grouped into eight (8) zones [6]. The State and Zonal offices are headed by competent pharmacists with appropriate qualification and experience who are directly involved in pharmaceutical inspection activities among others while the Directors of Pharmaceutical Services in the State Ministry of Health (DPS, MOH) are delegated as the chairpersons of both the Pharmaceutical Inspection Committee (PIC) and Patent and Proprietary Medicine Vendors Licence (PPMVL), the two committees of Council involved in inspectorate activities for pharmacies and patent medicine stores. Due to inadequacy of Inspectors to carry out the inspectorate activities, pharmacists who are not staff of PCN that are of good standing were also appointed by PCN to work in collaboration with PCN in these activities under a Public Private Partnership (PPP) arrangement. A total of 53 pharmaceutical inspectors existed in the 8 zones and State offices including the head office.

Questionnaire design and data collection

Following approval from the chief executive of the regulatory body, a questionnaire was emailed to all PCN staff that are pharmaceutical inspectors across all states of the federation and FCT. Reminder was sent to them through text and email messages, as well as phone calls.

The questionnaire was design following review of both online data and other sources. The main piece of legislation forming the backdrop of regulation of pharmacy practice in Nigeria are Poison and Pharmacy Act, Cap 152 of 1958, PCN Act 91 of 1992 (Now Act P.17 LFN 2004), Inspection, Location and Structure of Pharmaceutical Premises Regulation No. 79, 2005 and Registration of Pharmaceutical Premises Regulation No. 81, 2005. It consisted of 19-items semi-structured questions with dichotomous Yes/No responses, 4-point Likert scale, and open-ended questions. The first part of the questionnaire was centred on socio-demographic characteristics of respondents such as sex, age, designation, position, years of experience post-graduation and as PCN inspector. Second part sought for perception of respondents on the existing laws and regulations in terms of their satisfaction, adequacy and ability to achieve PCN mandate while the third part which is an open-ended questions sort to know the challenges the respondents were facing in achieving PCN mandate through the Act and regulations. Respondents were requested to pinpoint relevant sessions that need amendments in the existing laws while making recommendations. Prior to administration to respondents, the questionnaire was subjected to expert review by two (2) experienced pharmaceutical inspectors. Responses were received from the respondents through email messages.

Data analysis

Data received were entered into Microsoft Excel and double checked. They were analysed using Statistical Package for the Social Sciences (SPSS) version 21.0 for simple descriptive statistics including tabular presentation of data, percentage and frequency.

RESULTS

Responses were received from 17 inspectors (32.1 %) but one of the questionnaire was discarded because information could not be extracted from the scanned copy. Table 1 shows that most of the respondents were male (68.8 %) and are in the senior pharmacist cadre (56.3%),

mostly State officers (62.5 %) and have been in the service of PCN for 10 years and below (87.5 %).

The respondents identified the stakeholders to be regulated as pharmacists, pharmacy technicians (PT), patent medicine vendors (PMVs), non-pharmacist group operating pharmacy, pharmacies/pharmaceutical premises, patent medicine shops, Faculties of Pharmacy, Schools of Health Technology offering PT training and traditional medicine practitioners. None of the respondents was satisfied with the existing laws and regulations even though only 37.5 % of them had made suggestions on the need for amendments (Table 2). They were all of the opinion that the existing laws and regulations were inadequate to regulate the practice of pharmacy in Nigeria. Only 6.3 % of the respondents agreed that the 2005 regulation was able to resolve the inadequacy of 1992 Act and perceived that the present law and regulations have the ability to achieve the PCN mandate.

Table 3 shows the challenges of the existing laws and regulations and in implementing the laws and regulations. All the respondents agreed that the offences, punitive measures and penalties were inadequately specified, weak, outdated and/or weakly implemented while half of them concur that the laws do not specifically include regulation of all stakeholders and 37.5 % believed that the mandate was not clearly defined and does not represent current reality. Challenges in implementing the laws and regulations include poor funding and logistics (56%), implementation of PCN mandate under the state government which is subject to political interference (50%), unresolved court cases and delay in judicial proceedings (43.8%) and safety and security backup for inspectors (31.3 %).

Respondents noted important relevant session for amendment which should include offences and penalties (62.5 %), name and composition of PCN to indicate regulation of all stakeholders (43.8 %) and the need to clearly state the detail of PCN mandate and standard operating procedures (31.3 %) (Table 4). Respondents' suggestions on the challenges observed in the existing law, its implementation and sessions that need amendment are provided in Table 5.

DISCUSSION

In this study, PCN inspectors were of the opinion that the existing laws and regulations were inadequate to regulate the practice of pharmacy profession in Nigeria.

Table 1: Socio-demographic characteristics of the respondents

Variable	Frequency N=16	%
Sex		
Male	11	68.8
Female	5	31.2
Age (years)		
30-39	10	62.5
40-49	5	31.3
No response	1	6.3
Designation		
Pharmacist	4	25.0
Senior pharmacist	9	56.3
Chief pharmacist	3	18.8
Deputy director	1	6.3
Position		
Zonal officer	1	6.3
State officer	10	62.5
Unit head	5	31.3
Years of qualification post-graduation		
1-5	3	18.8
6-10	5	31.3
11-15	2	12.5
Above 15	5	31.3
No response	1	6.3
No. of years in PCN service		
1-5	9	56.3
6-10	5	31.3
11-15	2	12.5
Above 15	0	0

Table 2: Respondents' perception of the existing law and regulations

Variable	Frequency, N=16	Percentage, %
Satisfaction with existing law and regulations	0	0
Previous suggestion to make amendment to the laws	6	37.5
Adequacy of the existing law & regulation in regulating the practice	0	0
Adequacy of 2005 regulations to resolve inadequacy of the 1992 Act (LFN, 2004)	1	6.3
Ability of the present law and regulations to achieve the PCN mandate	1	6.3

They suggested the need for speedy review of existing laws for ease of implementation, having realized that many offences were not captured and penalties were very inadequate to make any correction to offenders.

Respondents' perception that the existing laws and regulations are inadequate to regulate the practice is in compliance with one of the studies on drug regulation in Nigeria where it was concluded that laws governing the manufacture, sale, distribution, importation and exportation of drugs are not adequate enough to control the illegal manufacture and sale of drugs in Nigeria [7].

All the respondents (100%) were of the opinion that many of the offences were not captured in the laws and regulations, and penalties were very inadequate as of the view of respondents in a similar study conducted in Nigeria [7] where

they viewed the penalties for the offenders as being too light and expressed that the penalties should be increased both in monetary terms and severity. They were of the opinion that laws were not being enforced to its maximum hence they suggested the establishment of proper mechanism to implement this aspect of the regulation, separate enforcement department of the PCN and strengthening of its legal unit to adequately tackle the issue.

The respondents (50%) noted that PCN as the statutory regulatory body has challenges with its stakeholders apart from pharmacists because the mandate establishing PCN did not specify other stakeholders to be regulated e.g. pharmacy technicians (PTs), patent medicine vendors (PMVs), etc. The phrase 'regulating and controlling the practice of the profession in all aspects and ramifications' has been used by PCN to cover its regulatory activities to

encompass all areas of pharmaceutical regulation, however, this has been challenged in different quarters by pharmacy sub-cadre (PTs), PMVs and even premises where veterinary medicines are being produced and sold. Respondents were of the opinion that the name of the regulatory body also posed challenges to the above, hence respondents (43.8%) proposed that the name could be changed to "Pharmaceutical or Pharmacy Council of Nigeria" as in other

countries like U.K., Ghana and South Africa [8-10] where the composition reflect the stakeholders being regulated.

As stated by some of the respondents, the roles and responsibilities of PCN were not well captured in its mandate stipulated in the PCN law. Even though the regulations were able to give further explanation to some aspects of the law, many areas were still left behind, hence

Table 3: Challenges in achieving PCN mandate through the Act and Regulations

Response theme	Frequency, N=16	Percentage, %
Challenges of the existing laws and regulations		
They do not specifically include regulation of all stakeholders	8	50.0
Offences, punitive measures and penalties were inadequately specified, weak, outdated and/or weakly implemented	16	100.0
Hospital pharmacy regulation was not well captured	3	18.8
Mandate was not clearly defined and does not present current reality	6	37.5
No difference in the role specification in premises registration certificate	2	12.5
Challenges in implementing the laws and regulations		
Unresolved court cases and delay in judicial proceedings: NAPPMED & NAGPPE	7	43.8
Implementing the 200m distance between two pharmacies made difficult by pharmacists	3	18.8
Compliance of pharmacists to one job very difficult	2	12.5
Adherence to an area of practice	2	12.5
Lack of political will by government to implement law	1	6.3
Implementation of PCN mandate under the state government is subject to political interference	8	50.0
Inadequate staff strength	9	5.3
Poor funding and logistics	9	56.3
Low level of public awareness on PCN mandate	4	25.0
Societal corruption	1	6.3
Level of commitment of inspectors	3	18.8
Safety and security backup for inspectors	5	31.3
The name PCN limits the jurisdiction of regulation	1	6.3
Chaotic drug distribution channel	1	6.3
NAPPMED association posing as regulatory body to patent medicine vendors	1	6.3

Questions were open-ended and summation was based on multiple responses received

Table 4: Relevant sessions of the laws that need amendment

Response theme	Frequency, N=16	%
Seizure of drugs from unauthorised premises and its automatic forfeiture	4	25.0
Review of offences and penalties	10	62.5
Establish process of prosecuting offenders	2	12.5
Establish enforcement unit of PCN to ensure proper enforcement	1	6.3
Name and composition of PCN to indicate regulation of all stakeholders	7	43.8
Detail of PCN mandate and standard operating procedures should be clearly stated and spelt out	5	31.3
Law to allow pharmacists in hospital/administration/public sector to register premises with adequate regulation	1	6.3

Questions were open-ended and summation was based on multiple responses received

Table 5: Recommendations

Response theme	Frequency, N=16	Percentage, %
Suggestions to PCN management/ Council		
Speedy review of existing law	5	31.3
Public enlightenment of PCN mandate	6	37.5
Creation of enforcement department	1	6.3
Strengthening of legal unit	3	18.8
Urgent attention to all court cases to bring them to logical conclusion	1	6.3
Put in place a mechanism to implement the law and regulation	6	37.5
Seek for political will to implement law	2	12.5
Involve all stakeholders in amendment process	1	6.3
Enlighten the judicial on PCN mandate	1	6.3
Ensure implementation of existing laws	2	12.5
Revert all PCN activities to PCN office from state MOH to reduce political interference	3	18.8
Suggestions to policy makers		
Speedy hearing as well as accelerated passage of reviewed law	8	50.0
Amend law to favour more funding of PCN activities	4	25.0
Amend law to improve the pharmacy profession as well as live and health of the people in particular		6.3

inspectors had to use their discretion so many times to make decision. For example, the inspection, location and structure of pharmaceutical premises regulation specify some requirement that leads to approval for registration, yet the detail of hospital pharmacy regulation was not well captured. Respondents, however, suggested that details of the PCN mandate and standard operating procedures should be clearly stated and spelt out in the amendment.

About half of the Respondents (56.3%) noted that the regulatory agency is often crippled by manpower shortages that severely curtail their ability to perform designated tasks. Capacity shortage has been identified as a key factor influencing the ability of regulation to achieve its stated goals [11]. A comparative 10-country study on effective drug regulation concluded that 'the shortage of qualified staff is the main problem faced by regulatory authorities' [12]. Inadequate manpower has led to the delegation of the inspectorate activities to the office of DPS, MOH before establishment of the PCN state and zonal offices and PPP arrangement whereby pharmacists working in other areas of practice were incorporated into the inspectorate activities similar to what is obtainable in Zimbabwe, Tanzania and South Africa where part-time evaluators were employed [13].

Half of the respondents noted that the above had also led to the political interference in the state through the office of the DPS and sometimes compromise by other inspectors incorporated. The physical location of the Medicine Control

Council (MCC) within the Department of Health in South Africa is perceived by stakeholders to be a significant limiting factor on its ability to meet its responsibilities [13]. Hence the need to employ more inspectors for PCN, a statutory regulatory authority to be totally autonomous.

Poor remuneration of part-time inspectors has for a long time been identified as one of the contributing factors in slowing down the inspectorate and enforcement activities because the inspectors do not get adequate compensation for their time and expertise, they are not often motivated as noted by our respondents and in a previous study in South Africa [13]. Since PCN is a government regulatory body, engagement of staff is based on public service rule and availabilities of fund to employ more inspectors by government, hence, there are challenges in recruiting more experienced staff within the PCN.

Funding of regulatory activities can be very expensive in terms of provision of vehicular movement, fueling and honorarium for inspectors, provision of security and insurance for inspectors as noted by respondents. Previous study had also shown that poor funding had led to the loose control systems by the drug regulatory body which was being exploited by unscrupulous persons to manufacture, import, and distribute fake and adulterated products [7]. Respondents were of the opinion that more funding should be dedicated to regulatory activities by government to prevent compromise and slowing down of activities.

Less than half of the respondents noted that the ongoing legal tussles had led to a deterioration of the relationships between stakeholders and the regulator especially in the case of patent medicine vendors who constantly institute litigations against the PCN on the power to regulate them. Also, the controversy that accompanied new regulation of 2005 allowing only pharmacist to own retail pharmacy had caused legal conflict between PCN and the non-pharmacist owners of retail pharmacies. This is similar to what happened in South Africa whereby controversy accompanied new regulations allowing for compulsory licensing and parallel importation led to the pharmaceutical industry engaging the state in extensive litigation [14].

In South Africa, the Industry Task Group (ITG) was established in order to create a forum to bring together Pharma industry representatives and the pharmaceutical regulators with the aim to improve communication and enhance regulatory effectiveness [13]. The PPMVL committee of PCN has in its membership a member of the public ably represented by a member of National Association of Patent and Proprietary Medicines (NAPPMED) to improve communication of PCN mandate and to ensure oversight and regulatory functions over the patent medicine vendors but this is yet to yield a positive and lasting solution.

The regulatory body needs to invest massively in public enlightenment for the people to know and be able to make informed decisions about their health and where to access safe and effective medicines. The awareness is also expected to span to the patent medicine vendors as the executive members and the association sometimes parade themselves as a regulatory body extorting monies from its ignorant members.

Limitations of the study

The response rate in this study is low (32.1 %). However, studies involving top management or organizational representatives are known to often have lower response rates (average 36% with standard deviations of 18.8 to 33.3 % [7,15,16]. This has led to the suggestion that a distinction should be made between surveys directed at individual participants and those targeting organizational representatives [17]. Most of the responses were received from southwestern part of the country where inspectors were mostly concentrated. Since other inspectors outside PCN and stakeholders were not involved in the study, the findings cannot be generalized.

CONCLUSION

Pharmaceutical inspectors are not satisfied with the pharmacy practice laws and regulations in Nigeria. They are of the opinion that the existing law and regulations are not adequate for regulating the practice of pharmacy in the light of current challenges. The need for speedy review of the current laws and regulations to address the deficiencies observed, creation of enforcement division in PCN, wider publicity of PCN activities, increased manpower and adequate funding of the agency are highly recommended.

DECLARATIONS

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Competing interest

The author declares that there is no conflict of interest

Contribution of authors

We declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors.

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