PCN-LaunchDSI PROJECT 2017

DESK-REVIEW ON SITUATION ANALYSIS OF PATENT AND PROPRIETARY MEDICINES VENDORS OPERATION IN NIGERIA

Pharm N.A.E Mohammed
Pharm. I.B Ahmed
Pharm. Y.R Adamu
Pharm. T.O Ilupeju
Pharm. Maria Ochigbo
Pharm. A. Ibrahim Jatau
Pharm Viona Ologe

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Acronyms' List

ACT	Artemisinin – based Combination Therapy
ADDO	Accredited Drug Dispensing Outlets
APML	Association of Patent Medicines License
CEP	Continuing Education Programmes
CMS	Central Medical Store
DFID	Department for International Development
DPS	Directorate of Pharmaceutical Services
ESMPIN	Expanded Social Marketing Project in Nigeria
FDS	Food and Drug Services
FEFO	First Expired First Out
FIFO	First In First Out
FMOH	Federal Ministry of Health
FP	Family Planning
ICCM	Integrated Community Case Management
IMCI	Integrated Management of Childhood Illness
IPs	Implementing Partners
LGA	Local Government Area
LMOH	Lagos Ministry of Health
LMIS	Logistics Management Information System
Lo ORS/Zn	Low – Osmolarity Oral Rehydration Salt plus Zinc
LSMDA	Lagos State Medicines Dealers Association
MCH	Maternal and Child Health
MH	Maternal Health
MMR	Maternal Mortality Ratios
MOH	Ministry of Health
MOU	Memorandum of Understanding

MSH	Management Sciences for Health
NAFDAC	National Agency for Food Drug and Administration Control
NAPPMED	National Association of Patent Proprietary Medicines Dealers
NDHS	Nigeria Demographic and Health Survey
NDLEA	National Drug Law Enforcement Agency
NDP	National Drug Policy
NGO	Non-Governmental Organization
OP	Orientation Programme
ORS	Oral Rehydration Solution
OTC	Over The Counter
PBN	Pharmacists Board of Nigeria
PCN	Pharmacists Council of Nigeria
PIC	Pharmaceutical Inspection Committee
P.M.B	Private Mail Bag
PMS	Patent Medicines Shop
P.O.Box	Post Office Box
PPA	Poisons and Pharmacy Act
PPMV	Patent and Proprietary Medicines Vendor
PPMVL	Patent and Proprietary Medicines Vendor License
PSN	Pharmaceutical Society of Nigeria
RDT	Rapid Diagnostic Test
RH	Reproductive Health
RIRF	Requisition, Issue, and Report Form
SDP	Service Delivery Points
SMOH	State Ministry of Health
SOP	Standard Operating Procedure
TFR	Total Fertility Rate

UNFPA United Nations Population Fund

USAID United States Agency for International Development

EXECUTIVE SUMMARY

i. Introduction

The Pharmacists Council of Nigeria (PCN), a body corporate established under Act No. 91 of 1992 (now Cap, P17, LFN, 2004) is the government agency saddled with the responsibility of licensing, monitoring and controlling activities of PPMVs in all ramification.

PPMV was established as a child of necessity to fill in the gaps of inadequacy supply of pharmacists in the country. The patent medicines shops (PMS) are the most widely distributed, most readily accessible source of healthcare in Nigeria. By this, they remain the most available source of simple, essential medicines and can be leveraged upon if better repositioned, to initiate and strengthen referral/system in the health sector.

The PCN is at a point of developing and implementing a repositioned PPMVs Initiatives for Nigeria – Applying lessons learned from Tanzania's Accredited Drug Dispensing Outlets (ADDO) model. A part of the objectives is to conduct a situation analysis via survey pilot to understand the nature and size of the problem in other to proffer solutions.

The assessment will help validate an earlier desk review done on same subject matter of understanding the working operations, challenges and opportunities for intervention with the PPMVs. The recommendations from this assessment will serve as one source of information informing the development of a protocol and standard operating procedure (SOP) for scaling up the pilot activity.

ii. Methodology

The assessment spotlight six (6) states chosen across the six geopolitical zone of the country – Bauchi (North East), Edo (South South), Imo (South East),

Niger (North Central), Lagos (South West) and Kaduna (North West). In each state, an urban and a rural LGA were visited for the survey.

Questionnaires were developed to elicit as much information as possible from the respondents. The assessment drew on both quantitative and qualitative data.Data was gathered through interviews with participants; primarily PMS owners were targeted as respondents. (An average of 80 respondents per state was targeted).

This assessment faced a number of minor limitations: In some cases the data that the assessment was able to acquire was not always complete; Additionally, due to time and resource constraints, the assessment team was only able to interview a limited number of respondents; Finally, as with any assessment, there is a possibility that respondents were bias based on their interest in seeing the pilot declared a success or a failure.

iii. Findings

The assessment established the following:

- PPMVs are more distributed in the rural areas than urban areas
- More PPMVs undergone apprenticeship in acquiring skills
- Most PPMVs attended secondary school (except Bauchi, where tertiary education is the bulk?)
- Most PPMVs have little or no knowledge of disease condition and treatment. However, most engage in all manners of interventions
- Majority of PPMVs source their stock from Drug market and Wholesalers
- Most PPMVs stock above the APML
- All PPMVs visited are dispensing
- Very few PPMVs registered with PCN, but most are registered with their association (NAPPMED)

- About half of the PPMVs are aware of the MOU between PCN and NAPPMED. However, most do not understand the content of the MOU and even less agreed with the spirit of the MOU
- Most PPMVs don't engage in referrals
- Majority of PPMVs don't keep documentations
- NAFDAC, NDLEA, NGOs, IPs and others tend to collaborate more with PPMVs than PCN. These organizations provide sensitization workshops and build capacity of PPMVs
- Less than 50% of PPMVs has attended the Orientation and Continuing Education Programmes of PCN

iv. Conclusion and Recommendations

The identified gaps above clearly create opportunities for PCN to better understand the workings of the PPMVs and to know how best to engage them through capacity building and reorientation. PCN needs a better engagement model with the PPMVs. Since PPMVs has a great regard for their association (NAPPMED), PCN should build on a better collaboration and partnering with the leadership of NAPPMED to get all the members compliant with PCN directives (MOU already in place).

Finally, the adoption and implementation of the ADDO initiative by PCN to reposition the PPMVs in Nigeria is a laudable one that if well implemented will raise the benefit of PPMVs to the teeming populace yearning for good services from this group of stakeholder who are widely spread across the nooks and crannies of the country as a stop gap to the inadequate supply of pharmacists

INTRODUCTION

COUNTRY CONTEXT:

Profile of Nigeria

The Nigeria's profile provided in this presentation draws most of its information from the Nigeria Demographic and Health Survey (NDHS) 2013.

Traditionally, the information contained in the NDHS is expected to assist policy makers and programme managers in monitoring and designing programmes and strategies for improving health and family planning services in Nigeria. Therefore, the information that would be made available through the report of the desk review shall be useful for programme planning and evaluation.

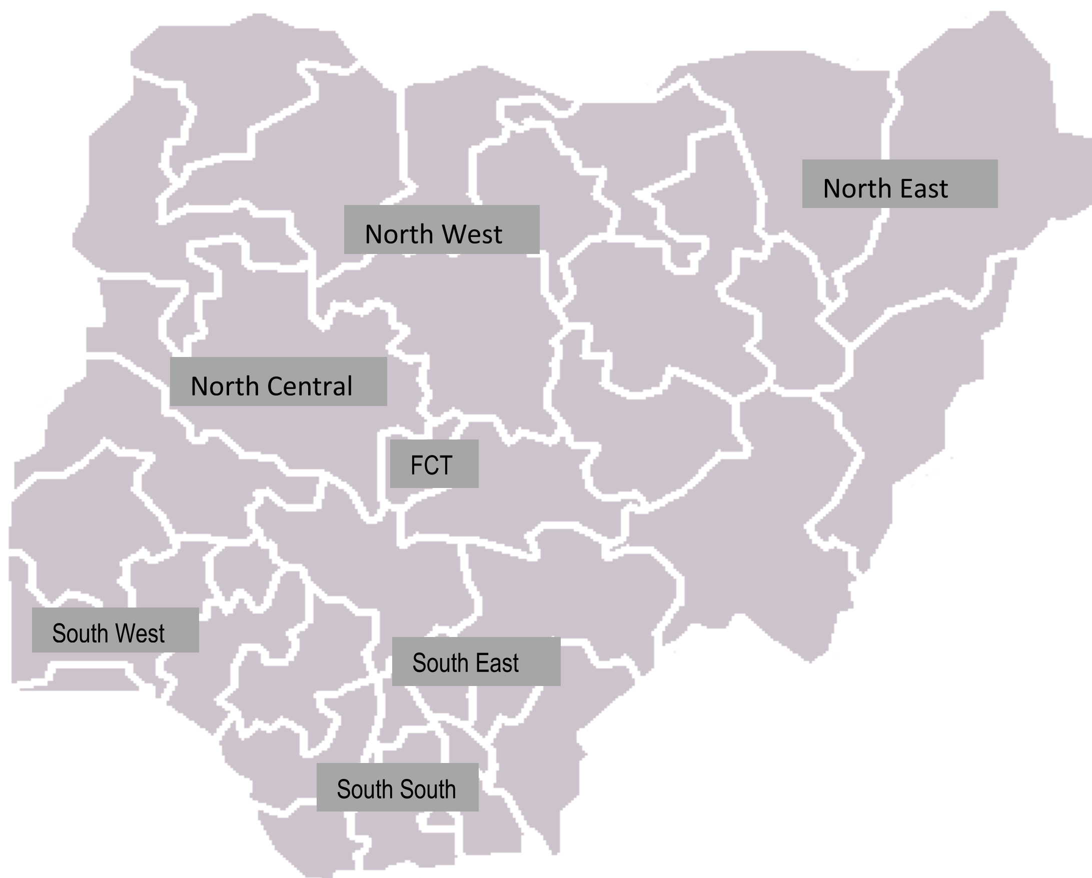

Fig 1. Geopolitical zones of Nigeria

Nigeria occupies approximately 923,768 square kilometers of land stretching from the Gulf of Guinea on the Atlantic in the South to the fringes of the Sahara Desert in the North. The country's 2006 Population and Housing Census placed the country's population at 140,431,790, with a national growth rate of 3.2 percent per annum.

With this population, Nigeria is the most populous nation in Africa, as noted, and the seventh most populous in the world according to Population Reference Bureau, 2013. Nigeria has a tropical climate with wet and dry seasons.

Its climate is influenced by the rain-bearing south-westerly winds and the cold, dry and dusty north-easterly winds, commonly referred to as the harmattan. The dry season occurs from October to March with a spell of cool, dry and dusty harmattan whilst the wet season occurs from April to September. The temperature in Nigeria oscillates between 25^0c and 40^0c, and rainfall ranges from 2,650 millimeters in the Southeast to less than 600 millimeters in some parts of the North. The vegetation consists of mangrove swamp forest in the Niger Delta and Sahel grassland in the North.

There are about 374 identifiable ethnic groups in Nigeria with Hausa, Igbo and Yoruba as the major groups. Presently, Nigeria is made up of 36 States and a Federal Capital Territory, grouped into six (06) geopolitical zones: North-West, North-East, North-Central, South-West, South-South and South-East.

Agriculture used to play a dominant role in the economy in terms of the country's foreign-exchange earnings before and immediately after independence but today, the country's economic strength is derived largely from its oil and gas reserves.

1.2 *Population and Health Policies*

The National Policy on Population for sustainable Development, 2004 recognises that population factors, social and economic development, and environmental issues are irrevocably interrelated and are therefore critical to the achievement of sustainable development in Nigeria.

The overall goal of the National Policy on Population for Sustainable Development is to improve the quality of life and standard of living of the Nigerian population.

This policy operates on the principle that achieving a higher quality of life for people today should not jeopardise the ability of future generations to meet their own needs. To guide policy, programme planning and implementation, the following targets were set, among others:

(i) Reduce the national population growth rate to 2 percent or lower by 2015;

(ii) Reduce total fertility rate by at least 0.6 children every five years by encouraging child spacing through the use of family planning;

(iii) Increase in the contraceptive prevalence rate (CPR) for modern methods by at least two percent points per year through the use of family planning;

(iv) Reduce the infant mortality rate to 35 per 1,000 live births by 2015;

(v) Reduce the child mortality rate to 45 per 1,000 live births by 2010;

(vi) Reduce the maternal mortality ratio to 125 per 100,000 live births by 2010 and to 75 by 2015;

(vii) Achieve at least a 25 percent reduction in HIV/AIDS adult prevalence every five years.

The overall long term goal of the revised National Health Policy is to provide adequate access to primary, secondary and tertiary healthcare services for the entire Nigerian population through a functional referral system. The overall objective of the policy is to strengthen the national health system such that it will be able to provide effective, efficient, quality, accessible and affordable health services that will improve the health status of Nigerians.

The policy identifies primary healthcare as the framework to achieve improved health, for the population. The primary healthcare services to

be offered include family planning, disease control, and provision of essential drugs, among others.

1.3 History of Patent and Proprietary Medicines Vendors (PPMVs) in Nigeria

The granting of licenses to sell patent and proprietary medicines and packed goods was first introduced in Nigeria through the Poisons and Pharmacy Ordinance of 1936 which set up the Pharmacy Board of Nigeria and the power to issue the license for stocking and sale of patent and proprietary medicines was statutorily vested on the Pharmacy Board of Nigeria (PBN).

In line with the provisions of the ordinance, there were only two classes of persons who could sell patent and proprietary medicines. They were:

(i) a registered Pharmacist (who were then largely known as Druggists and Chemists, Druggists and selling Dispensers) and;

(ii) a person who holds a patent and proprietary medicines vendor's license (PPMVL).

The patent and proprietary medicines vendor licenses were issued as a matter of necessity, to those who were not by law qualified to deal with the sale and distribution of drugs and poisons. The first group of persons to deal in patent medicines in Nigeria were the French Medicines Stores and Waterloo Medicines Stores in Lagos. They were allowed and provisions were made in the law to protect the sale of patent medicines all over the country.

In order to obtain a patent and proprietary medicines vendor's license an applicant must adduce evidence to the satisfaction of the PBN, which was the licensing authority, that:

(i) He or she is not less than twenty one years old.

(ii) He or she possesses the ability to read and write.

(iii) He or she is of good character. In practice, such an applicant will require two references that he or she is of satisfactory character, and

(iv) In the case of body corporate, that the nature of the business warrants the sale of patent medicines in the premises.

It was one of the duties of the licensing authority (the PBN) as it still is, to grant such a license or if not satisfied, reject the application. Also, the licensing authority would in the event of being satisfied with the particulars adduced by the applicant, grant a license which must be, at all times conspicuously exhibited in the applicant's **place of business**.

A license so granted is not transferable and expires on the 31st December of the year in which it is issued and should be renewed during the month of January of every subsequent year while still in business.

After Nigeria attained independence in 1960, the Pharmacy Board of Nigeria transferred the issuance of the Patent and Proprietary Medicines Vendors License to the States Ministries of Health in line with the provisions of the Poisons and Pharmacy Act (PPA) Cap 152 of 1960. This Act was an offshoot of the Pharmacy Ordinance Cap 152 of 1958, which strengthened the establishment of the Pharmacy Board of Nigeria with the authority to issue the Patent and Proprietary Medicines Vendors License.

At this time, the PPA Cap 152, 1960 placed the issuance and licensing fees for patent and proprietary medicines vending under the control of the States Ministries of Health and the fees varied from State to State. This function automatically became that of the Directorate of Pharmaceutical Services upon its creation and the function was spelt out

in the schedule of duties of the Directorate vide the Circular letter Reference Number MH.2790/8 of July 07, 1980.

It is however worthy of note that in spite of the fact that the provision of the PPA Cap 152, 1960 vested the licensing authority on various States of the Federation, the same legislation also make provisions that the licensing authority (in this case, the States) shall:

a. Ensure that the persons who hold the patent and proprietary medicines licenses should exhibit (display) conspicuously such licenses in the licensed place of business;
b. See to it that no one sells or deals in substances beyond the scope of the license issued to him;
c. Keep a register of all persons granted licenses to sell patent and proprietary medicines, and;
d. Submit the list of licensed patent and proprietary medicines vendors to the Registrar, Pharmacy Board of Nigeria (PBN), in January of every year so that the Registrar can enter it in the relevant register.

In addition, the same legislation (PPA Cap 152, 1960) also provides that, "a person aggrieved by the refusal of the licensing authority to enter his name on the register or by the removal of his name from the register by the licensing authority, may appeal against the refusal or removal to the Board (PBN), whose decision shall be final. This again corroborates the zenith of the regulatory authority by the PBN over the operations and activities bordering on patent and proprietary medicines vending.

The sale and distribution of patent and proprietary medicines in Nigeria in those days and even up till now, by a person holding PPMVL is such that, he shall only sell a patent medicine in its original container as it comes from the manufacturer. Such a person shall not dispense out of

the container and shall not remove or replace the original label on the container.

As events began to unfold, there were as many regulatory frameworks as was the number of States that were exercising licensing authority over patent medicines. The scope of approved patent medicines list also varied from State to State. The situation therefore progressed to a chaotic drug distribution system in the country. The unacceptable situation became more deplorable with preponderance, fake, counterfeit and sub-standards drug products everywhere in Nigeria. This situation became worse, when on July 10, 1963 the issuance of the PPMVL was suspended throughout the Federation. However, the suspension was lifted shortly in 1964 through the invocation of the Pharmacists Act No. 26 of 1964.

The Pharmacists Act No. 26 of 1964 that established the Pharmacists Board of Nigeria (PBN) was the Act that changed the name of the Pharmacy Board of Nigeria (PBN) to the Pharmacists Board of Nigeria (still PBN). The Act sought to make better provision for the regulation of the pharmacists and for purposes connected therewith.[7]

Informed by the chaotic drug distribution system, the Federal Government through the Federal Ministry of Health (FMOH) streamlined the approved patent medicines list and published the first of its kind called, Approved Drugs List in 1990 and the second edition in 1994, hoping that this would address the issue of PPMVs operating outside/beyond the scope of drugs they can stock and sell.

Local Government Area (LGA) Councils were authorized for the first time and possibly the last time too, to issue the PPMVL in 1990 by the (then) Minister of Health. Unfortunately, the issuance of the PPMVL suffered perhaps the highest level of abuse since that date and precipitated the

return of the authority for issuing the PPMVL to the PCN in 1992 by the then Minister of Health. However, this action was challenged in court resulting in an injunction stopping the issuance of PPMVL.

In view of the need to further address the chaotic drug distribution system characterized with fake, counterfeit and sub-standard medicines, and taking full cognisance of the scheduling of Drugs and Poisons in the Exclusive Legislative List of the Constitution of the Federal Republic of Nigeria, the licensing authority for patent and proprietary medicines was reverted to the PCN in April 14, 2003 vide a Ministerial fiat. Since then the PCN has remained the only agency of Government charged with the statutory mandate to issue PPMVL and to regulate and control the activities of patent and proprietary medicines vendors.

Consequent upon the reversion of the licensing authority to the PCN in 2003, the Council (PCN) published the Guidelines for issuance of PPMVL and a revised edition of the Approved Patent Medicines List, in order to facilitate seamless regulation and transparency.

Recently, the approved patent medicines list has been expanded by the PCN to include some health commodities in line with the Integrated Community Case Management (ICCM) and Integrated Management of Childhood Illnesses (IMCI) Concepts and the adoption of the recommendations of the United Nations Commission on Life-Saving Commodities.

These commodities include:

1. Artemisinin-based Combination therapy (Artemeter-Lumefantrine and ArtesunateAmodiaquine) for treatment of malaria;
2. Rapid Diagnostic Test (mRDT) Kit for testing all suspected cases of malaria;

3. Low-Osmolarity Oral Rehydration Salt plus Zinc (Lo ORS/Zn) for treatment of diarrhoea;
4. Amoxillin Dispersible Tablet for treatment of pneumonia in children under five years of age;
5. Chlorhexidine gel (4%) in 25g tube for cord care.

1.4 Laws/Policies for the Establishment and Regulation of the Operations of PPMVs in Nigeria

A lot has been mentioned about the laws that established the operations of the patent and proprietary medicines vendors. However, the extant laws and policies in this regards are:

(i) Poison and Pharmacy Act Cap 535, LFN, 1990;
(ii) Pharmacists Council of Nigeria (PCN) Act Cap P17, LFN, 2004;
(iii) Other relevant Pharmacy and Drug laws;
(iv) Guidelines for Issuance of Patent and Proprietary Medicines Vendors License;
(v) Approved Patent Medicines List;
(vi) Ministerial fiat on Reversion of the Licensing Authority to PCN.

1.5 The Place of the PPMVs in the Healthcare Delivery System

The place of the PPMVs was that of a stop gap mechanism where the patent and proprietary medicines vendors licenses were issued to those who are not by law qualified to deal with the sale and distribution of simple household medicines, which are also known as over the counter (OTC) medicines. The attempt was to redress the lopsided distribution of the very few healthcare facilities as well as the dearth of pharmacists in the country.

Today, the situation which necessitated the innovation of patent and proprietary medicines vending has not changed. Hence, the need for continued operation of the PPMVs.

Also, the existence and operations of the PPMVs is a strive to achieving the main objective of the Nigeria's National Drug Policy, which is to ensure adequate supply, accessibility to and availability of essential medicines that are safe, efficacious and of good quality as well as rational use of same.

It is also noteworthy that the achievement of the universal health coverage in Nigeria is being driven through the primary health care delivery - a constituency to which the patent medicines vendors belong.

In addition, reports of research findings have shown that the patent medicines shops are the first port of call for accessing healthcare by majority of Nigerians.

The patent medicines shops are the most widely distributed, most readily accessible source of healthcare in Nigeria. By this, they remain the most available source of simple, essential medicines and can be leveraged upon if better repositioned, to initiate and strengthen referral/system in the health sector.

In summary, the place of PPMVs in the healthcare delivery system is that of most readily available source of simple essential medicines for healthcare service delivery and provision of referral service.

2.0 REGULATORY MECHANISMS

2.1 Guidelines for PPMV Operations

The Pharmacists Council of Nigeria (PCN) takes the challenge of adequate provision, accessibility and availability of essential drugs seriously and has mobilised all resources at its disposal to effectively address it. The *Guidelines of PPMV operations* demonstrate the commitment of the PCN towards facilitating the delivery of simple medicinal remedies at the grass root level in every nook and cranny of Nigeria.

(i) Scope

The *Guideline*are designed to address the issuance of Patent and Proprietary Medicines Vendor's License (PPMVL) in Nigeria, under the following sub-themes:

(i) The Licensing Authority
(ii) Eligibility
(iii) Requirements for an Application
(iv) Application Fee Required
(v) Issuance and Renewal of the License
(vi) Validity of the License
(vii) Mandatory Orientation and Continuing Education for Holders of the Patent and Proprietary Medicines Vendor's License, and
(viii) Monitoring and Inspection

(ii) Licensing Authority

By virtue of the Poisons and Pharmacy Act Cap 1958, the Poisons and Pharmacy Act Cap 535 LFN, 1990 and the Pharmacists Council of Nigeria

(PCN) Act 91 of 1992, **the Licensing Authority is thePharmacists Council of Nigeria (PCN) established** under Act No. 91 of 1992 (now Cap, P17, LFN, 2004).

(iii) Eligibility

An applicant for the Patent and Proprietary Medicines Vendor's License (PPMVL) shall produce evidence to the satisfaction of the licensing authority.

(a) That the applicant has attained the age of twenty-one (21) years.
(b) That the applicant is of good character and certified as such by two satisfactory referees, and
(c) The applicant is able to read and write in the English Language.
(d) Possession of a Pharmacy Technician's certificate from a PCN accredited School will be an added advantage.

(iv) Requirements for an Application

(i) An application shall be made in the applicant's own handwriting, indicating the exact location and address where the intended business is to be undertaken. A Post Office Box (P. O. Box) or a Private Mail Bag (P.M.B) shall not be accepted as a valid address.
(ii) The application shall be addressed to the **Registrar, Pharmacists Council of Nigeria(PCN)** and submitted at the PCN State Office where the applicant intends to operate the business.

(iii) The applicant shall attach copies of the Pharmacy Technician Certificate obtained from a PCN Accredited Institution and current Annual Permit.

(iv) Letters of recommendations from two (2) reputable referees; one of whom shall be a registered and currently licensed Pharmacist.

(v) Three passport photographs, all of which shall be endorsed by one of the applicant's referee, shall be attached to the application.

(vi) The applicant shall produce a current income tax clearance certificate.

(vii) Each application shall be accompanied with a non-refundable application fee as specified by the PCN.

2.2 Registration and Licensing

(i) Procedure for the Issuance of the License

The following procedure shall be adopted for the issuance of the Patent and Proprietary Medicines Vendor's License (PPMVL):

(a) Submission of a duly completed application form;

(b) Interview of the applicant by the State PPMVL Committee;

(c) Payment of the prescribed inspection fee;

(d) Inspection of proposed shop by the State PPMVL Committee;

(e) A satisfactory report to the PCN by the State PPMVL Committee;

(f) Issuance of the license by the PCN on payment of prescribed registration fee;

(g) The applicants shall be issued a booklet containing the list of medicines approved for sale by the licensing authority (PCN), and;

(h) The applicant's mandatory attendance of a Patent and Proprietary Medicines Vendors' (PPMV) orientation course.

Note

(a) The PCN reviews the application and inspection report forwarded by the state PPMVL committee in respect of every applicant to ensure that it's content is consistent with laid down rules before approval of the applicant and issuance of license.

(b) A PPMVL holder shall conspicuously display the license in their shop, as well as their business name on a signpost in front of their premises. The business name shall also carry the wordings: "Patent Medicines Shop". The use of such names as "Drug Stores" or "Medicine Stores", etc., is prohibited.

(ii) Licensing Fee

The license fee shall be as specified by the PCN and the Council reserves the right to review the fees from time to time.

(iii) Conditions for the Renewal of License

The following conditions shall guide the renewal of the PPMV license:

(a) All applications for the renewal of the license must be submitted on or before the **31st of January of the year**;

(b) The license must be renewed annually, subject to a satisfactory inspection report;

(c) All licensed shops for the sale of patent and proprietary medicines shall be subject to the periodic inspection by pharmaceutical inspectors appointed by the Pharmacists Council of Nigeria.

(d) Evidence of attendance at a Continuing Education Programme (CEP), at least once in every two years;

(e) Payment of the prescribed fees, and;

(f) Satisfactory performance by the licensee.

(iv) Validity of the License

The license shall expire on the 31st of December of the year of issuance. However, the licensing authority reserves the right to revoke a license during its validity period if there is any breach of the conditions for granting it or proof of false declaration or documentation.

2.3 **Orientation Programme and Continuing Education Programme**

Every new PPMV license holder shall be required to attend an orientation programme. Thereafter, the license holder shall be required to attend a Continuing Education Programme, at least once in every two (2) years. The Pharmacists Council of Nigeria, in collaboration with the State PPMVL Committee, shall organize such programme at State level.

2.4 Monitoring and Inspection

Licensed shops shall be subject to periodic monitoring and inspection by accredited Pharmaceutical Inspectors who shall submit their reports to the Pharmacists Council of Nigeria.

2.5 Activities of PPMV Inspection Committees

(i) Composition of State PPMVL Committee

Membership of the Committee shall consist of:

(a) The Director of Pharmaceutical Services (DPS) of the State (Chairman);
(b) The Director Pharmaceutical Services, State Hospital Management Board (Member);
(c) The Head of the Pharmaceutical Inspectorate Unit in the State's Directorate of Pharmaceutical Services (Member);
(d) The Chairman of State Chapter of the Pharmaceutical Society of Nigeria (PSN) or his representative (Member);
(e) The Chairman of State Chapter of the Association of Community Pharmacists of Nigeria (ACPN) or his representative (Member);
(f) One representative of NAFDAC (Member);
(g) A member of the Civil Society nominated by the PCN (Member), and;
(h) The PCN Zonal/State Officer and/or his representative (Member and Secretary).

2.6 Signpost (Compliance and Reasons for Non-Compliance)

The PCN has approved signpost for patent medicines shops (PMS). The holders of PPMVL are expected to obtain the signpost from the PCN and mount at the front of their shops, but many of them are not complying with the use of the signpost. The reasons for non-compliance from records include the following:

(i) Not designed with input from stakeholders

(ii) Issues of cost
(iii) Issues of quality
(iv) Issues of design
(v) Inadequate advocacy
(vi) Low patronage and use

2.7 Memorandum of Understanding (MoU) with Stakeholders

The PCN has engaged dialogue in its regulatory activities over the operations of the PMVs. The dialogue has culminated in the signing of memorandum of understanding (MoU) with the relevant associations of the PMVs. (Annex 3)

2.8 Enforcement Activities

In accordance with the MOU, PCN undertook extensive enforcement activities in year 2016. A total of 3,506 PPMVs with various infringements on regulatory requirements were closed down.

3.0 RECORDS AND STATISTICS OF PPMVL

3.1 Preamble

The PPMVL unit of the registration and licensing department is saddled with the responsibility of issuing licenses to both prospective and existing vendors.

Vendors who have undergone the necessary inspection and fulfilled the criteria are advised to go to the state and zonal offices of the PCN to pick up forms **M1** in order to commence the registration process. Currently, a total fee of sixteen thousand five hundred (**N16,500**) naira is to be paid to the PCN account and other relevant documents are to

accompany the registration form **M1** as stipulated by PPMVL guidelines. The state and zonal offices will now forward the forms along with the inspection report to the Registry for licensure.

The Registry has the final say whether a premises is to be licenced or not.

3.2 Statistics and records of PPMVs

Table 1.0 shows the statistics of the records of PPMVs regarding the registration and licensure as at December 2016.

Table 1.0 Records of PPMVs Registration/Licensure as at December 2016

	Total number	Percentage (%)
Registration	56,905	
Licensure	10,002	17.6
Ratio of registered PPMV per Nigerian population of **188 Million**(growth rate of 3.2 % per year)	Registered PPMV : 3,303	0.03

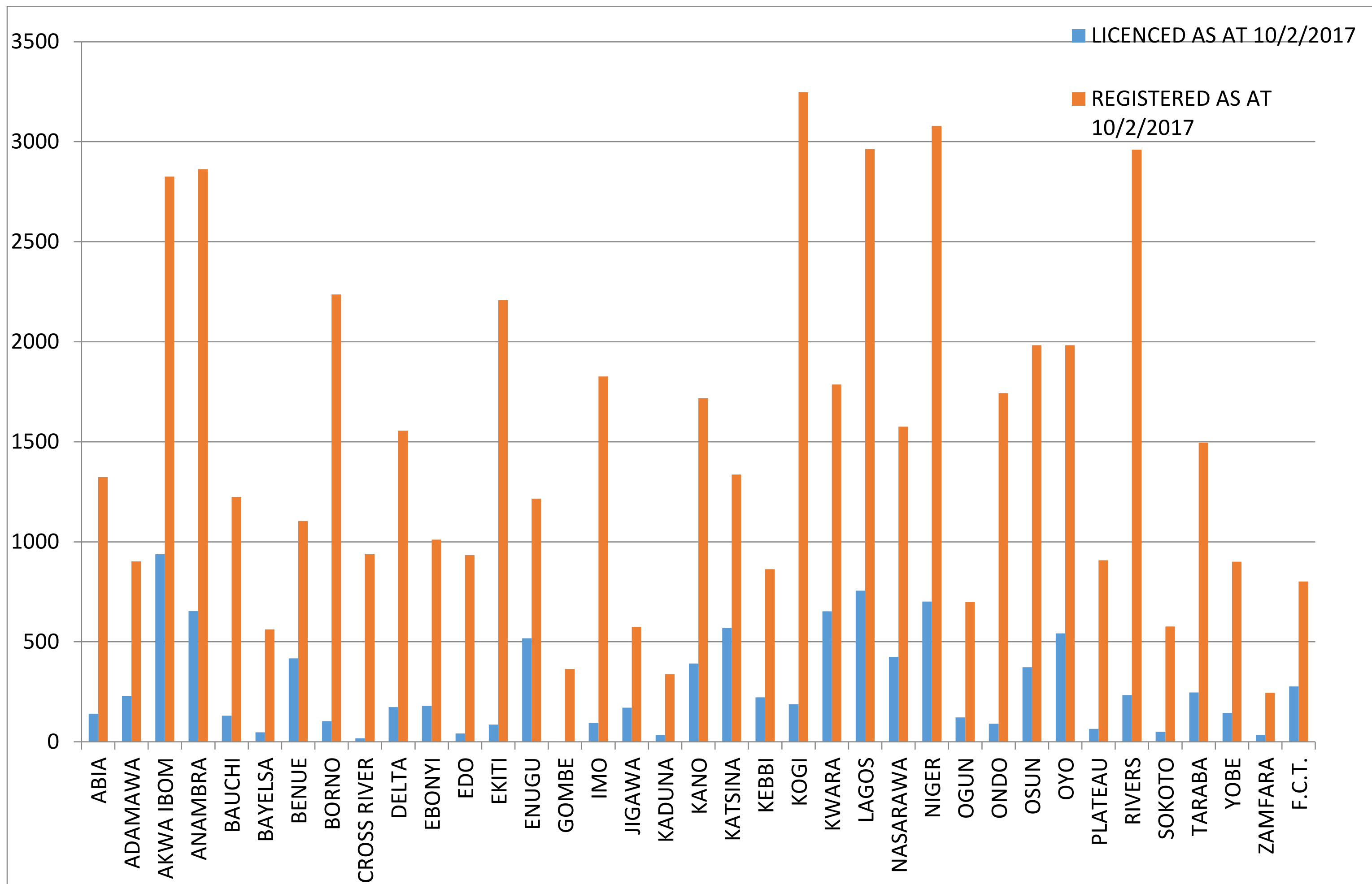

Fig 2. Distribution of records of PPMVs' registration/licensure per state

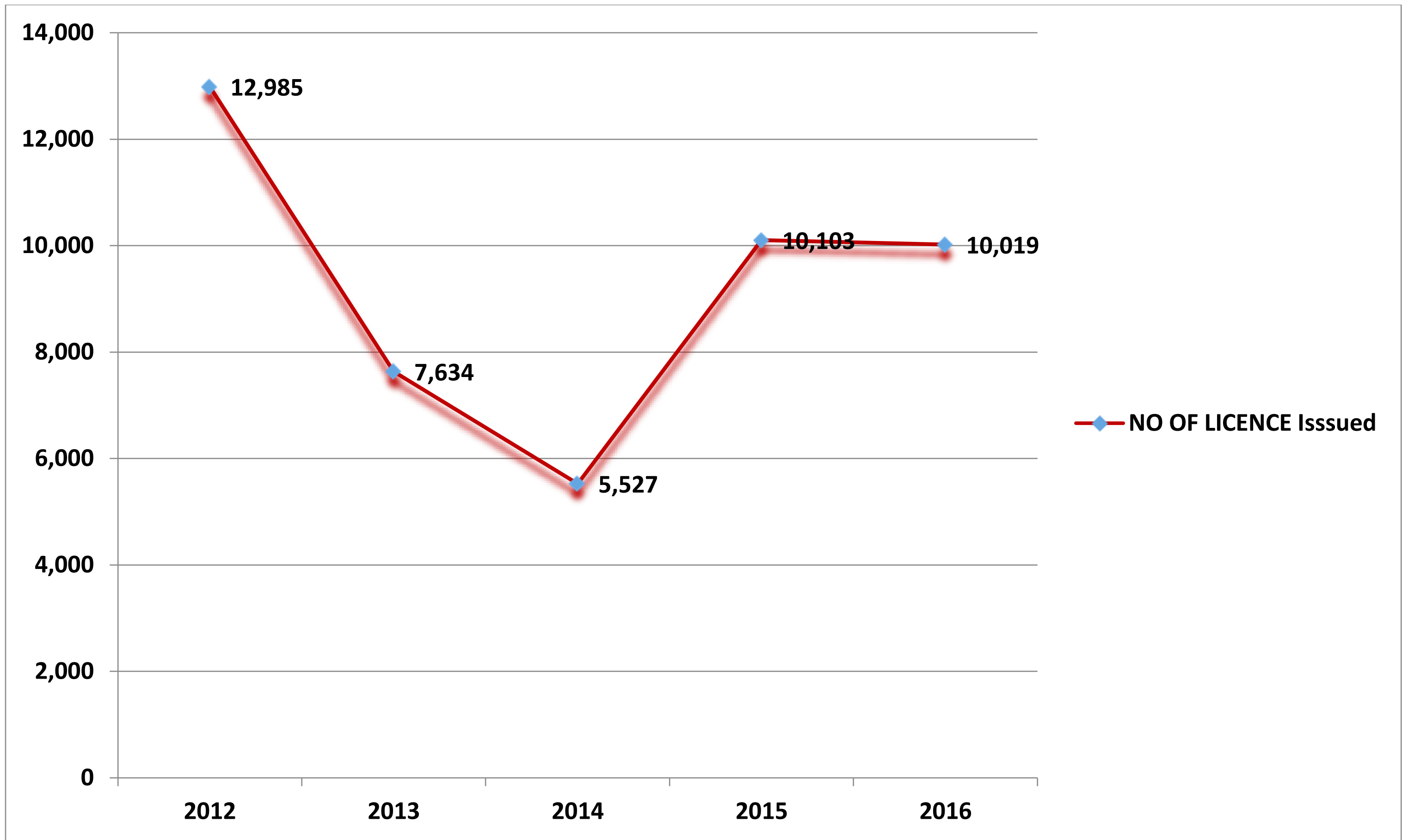

Fig 3.Trend of License Issued from 2012 to 2016

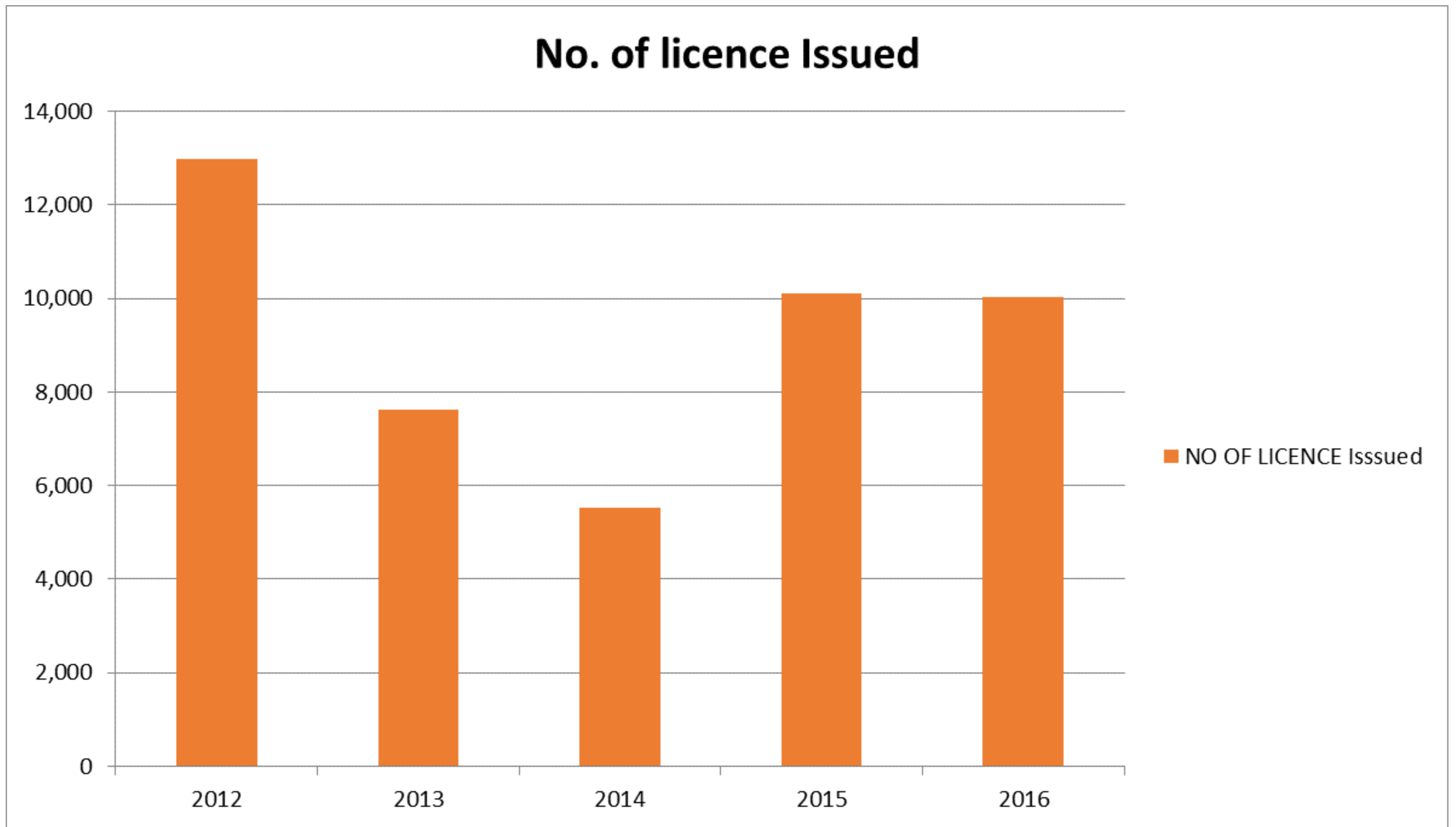

Fig 4. Number of Licensed issued 2012 to 2016

4.0 ACTUAL OPERATIONS OF PPMVs IN THE COMMUNITY (Survey Findings)

4.1 Distribution of PPMVs in Nigeria

Findings have shown thatabout 53% of PPMVs are situated and accessible in the remote and rural areas compared to urban areas. Few of the PPMVs have relationship with PCN while more than 82% of PPMVs are members of NAPPMED.

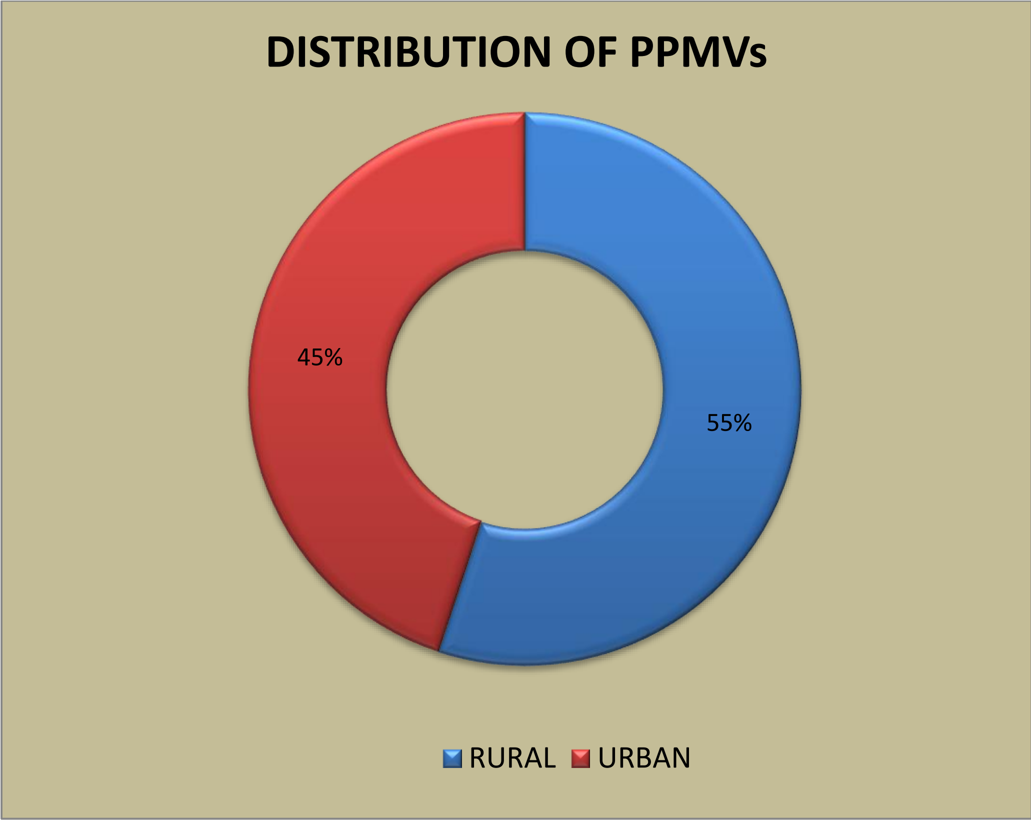

Fig.5: Distribution of PPMVs

4.2 PPMV *Education*

i. Level of Education of PPMVs in Nigeria

The guideline for the operation of PPMVs in Nigeria provides that a person willing to operate a PMS should be able to read and write in English language. Moreover, having Pharmacy Technician's Certificate obtained from a PCN accredited institution and current annual permit is an added advantage.

The survey of four hundred and sixty five (465) PPMVs operations in 6 states of Bauchi, Edo, Imo, Kaduna, Lagos and Niger across the geo-political zones shown that 5-25% of PPMVs had only primary school and 85-95% with post primary school level of education and up to 55% tertiary education. It has been shown that PPMVs with higher level of education were more likely to sell quality drugs. More than 50% of PPMVs have tertiary education in Bauchi.

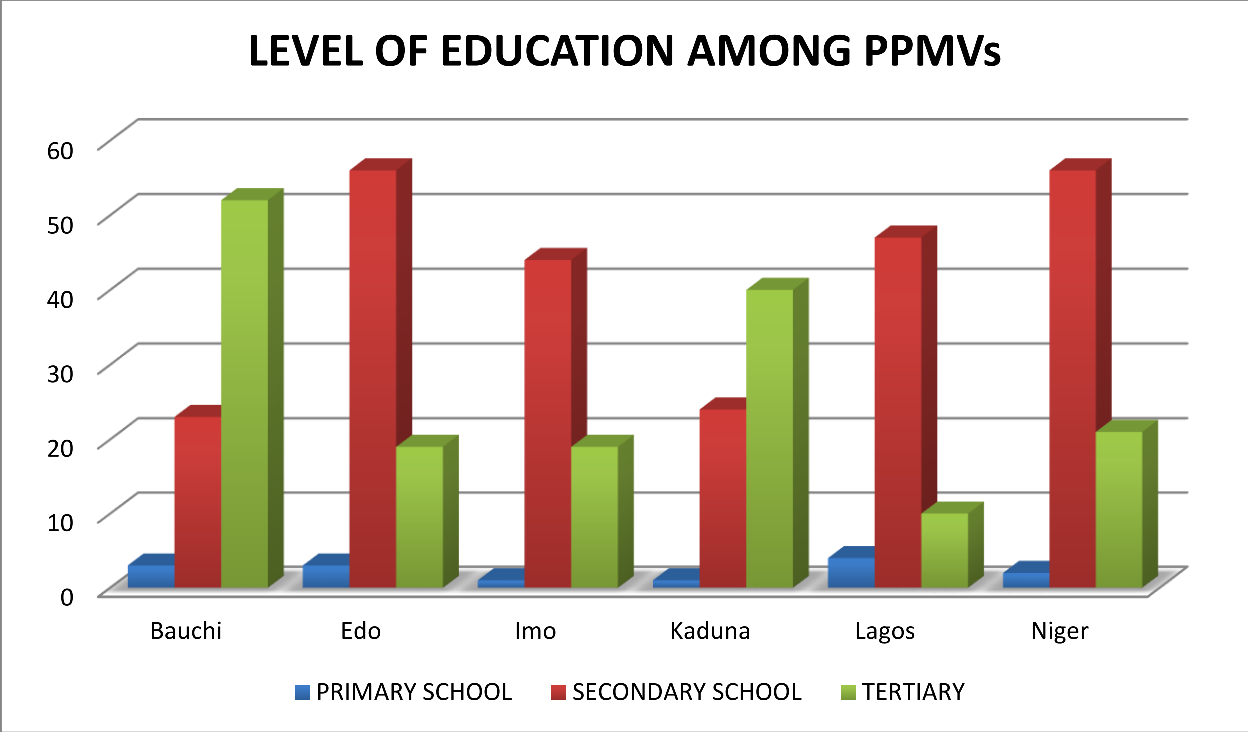

Fig.6. Level of education among PPMVs in Bauchi, Edo, Imo, Kaduna, Lagos and Niger

ii. Prior Formal Health Education

Findings have shown that apprenticeship remains the source of training for the majority of PPMVs. The analysis indicated that more than 63% of the PPMVs undergone apprenticeships and about 24% of the PPMVs are experienced health workers.

Some of the PPMVs were found to have undergone formal health education, more than 45% of them are Community Health Extension Worker (CHEW), 17% are Junior Community Health Extension Worker (JCHEW) and 38% are Nurse/Midwife,Pharmacists Technician and Pharmacists. It has been demonstrated that 36-64% of PPMVs with prior

formal training were more likely to be registered with PCN and stocked Antihypertensive, Anti diabetic, ORS, Zinc andInjectable.

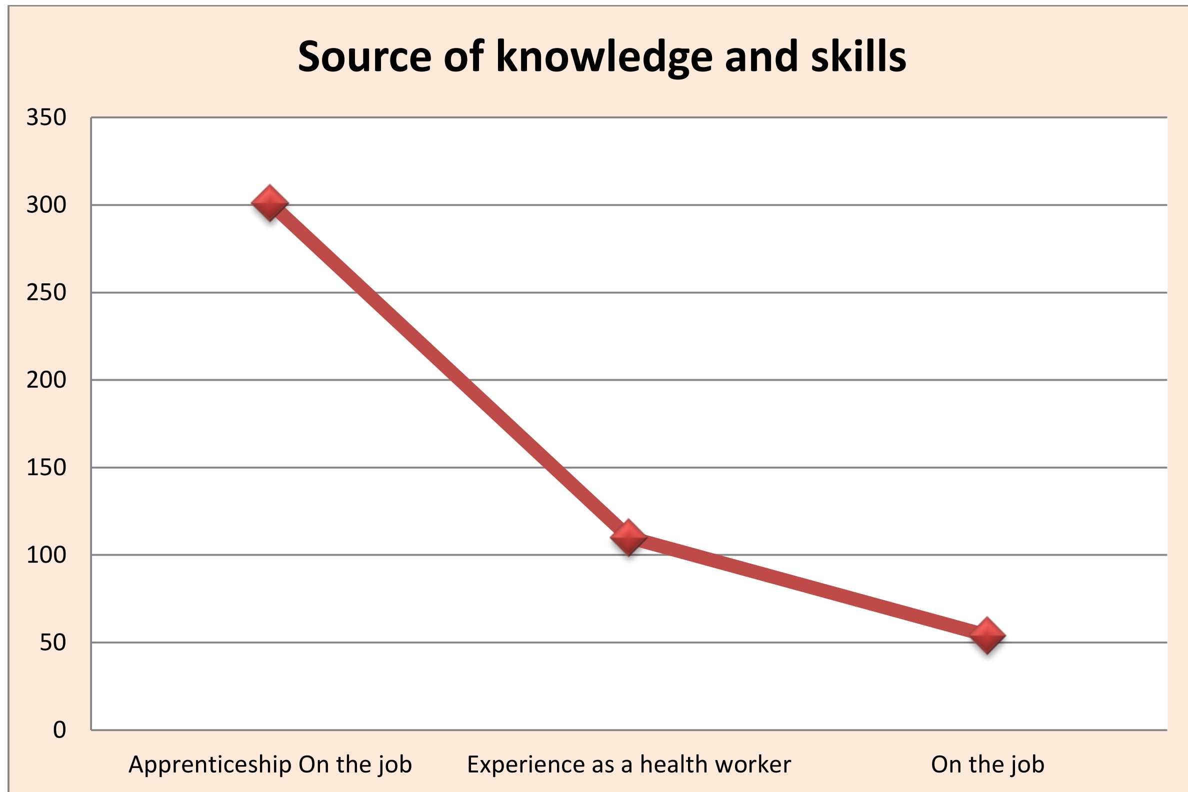

Fig. 7.Source of knowledge and skills of PPMVs.

iii. PPMV Knowledge about Disease Condition and Treatment

Findings have shown that majority of PPMVs had low knowledge of identification of disease condition and appropriate treatment, how medicines work, drug administration, drug-interaction, contraindications and adverse drug reaction. However, some of them are aware of causes, signs and management of childhood killer diseases;

diarrhea, pneumonia, and malaria. As well as high level of awareness of family planning method

4.3. PPMV Operation

i. Sources of medicines supply for PPMVs

Majority of PPMVs sourced their medicines from wholesalers, Drug Market, Retail pharmacies, Medical Reps and Informal markets (such as Idumota market in Lagos).

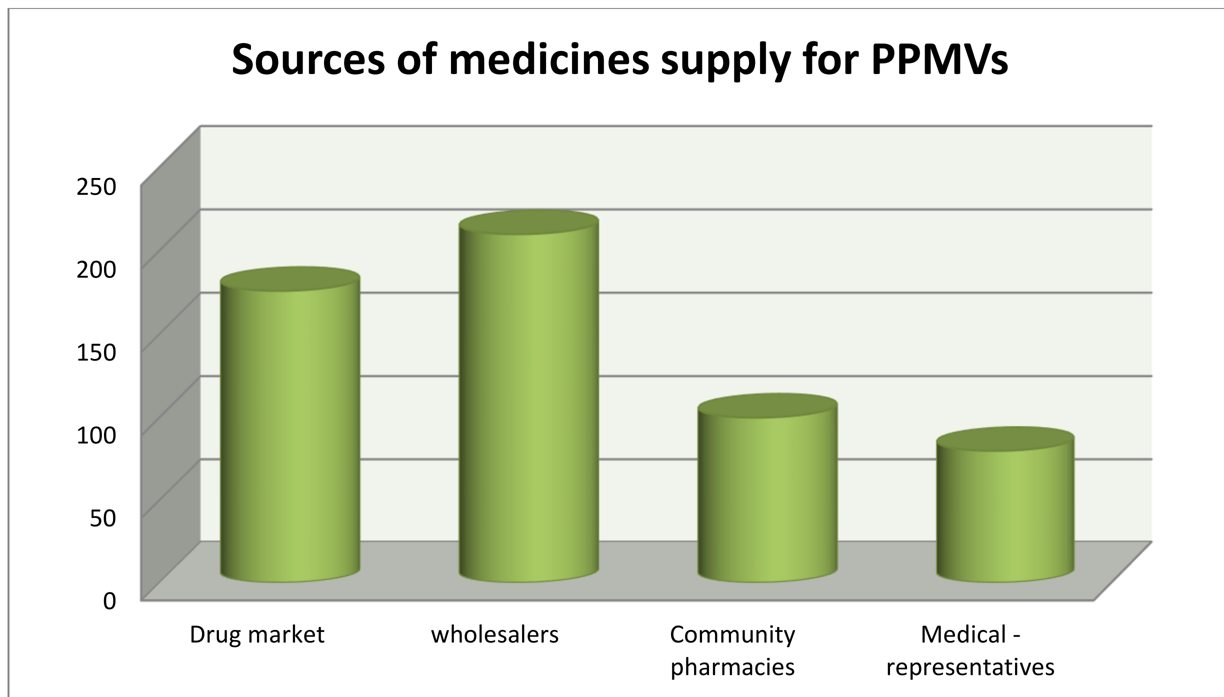

Fig. 8: Sources of medicines supply for PPMVs

ii. Commodities

Surveys have shown that many PPMVs stocked medicines such as antibiotics, injectable, sexual and reproductive health products etc. that are not in the APML. About 82% of even PCN registered PMV shops stocked medications that are not listed in the PCN's APML

iii. Arrangement of Drugs

Surveys have shown that 48-52% of the PPMVs have wall shelves, standing shelves and counter. Many of thePPMVs arranged the drugs pharmacological while some arranged the drugs in dosage form.

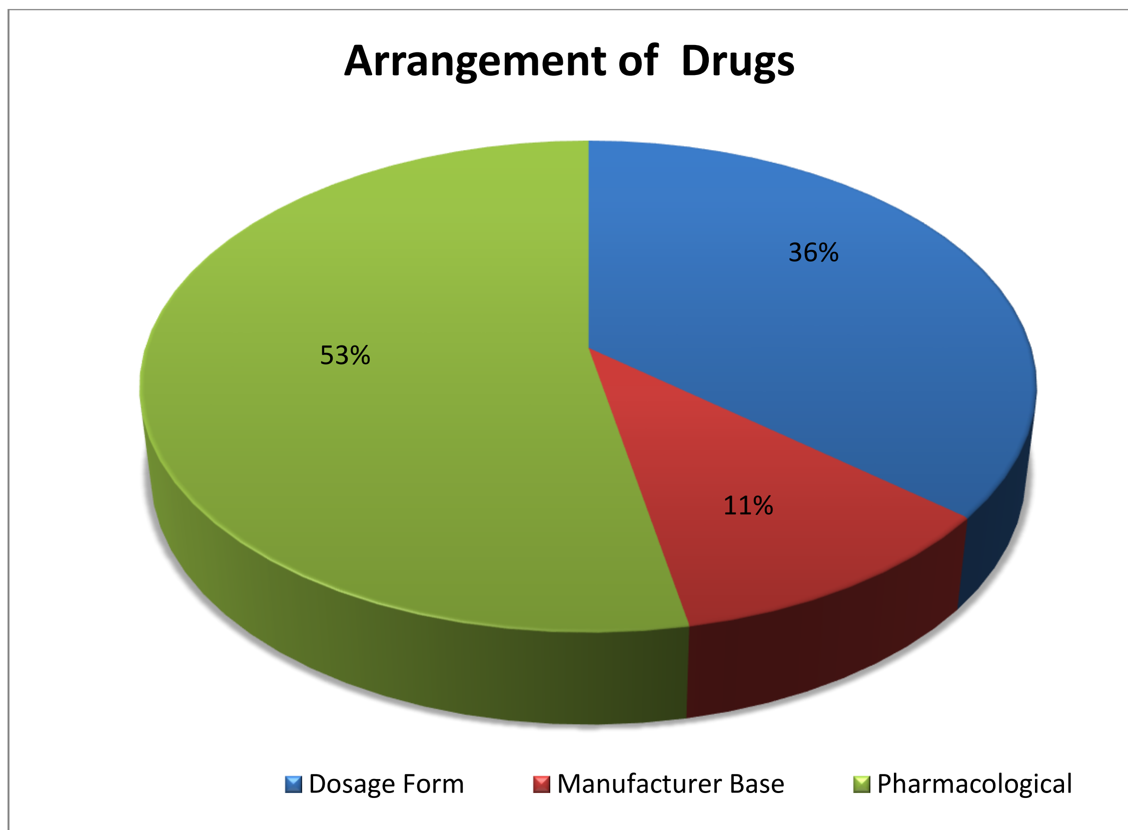

Fig. 9: Arrangement of Drugs at PMS

iv. Dispensing

Generally, all PPMVs are involved in dispensing medicines to their customers. And they do not follow good dispensing practice (incorrect dosage, regimen and inappropriate medications)

4.4 *Compliance with Legal Regulations*

i. Licensing

Information available has shown that many PPMVs operate without registration or license with PCN. In Edo, only 26% of PPMVs were registered with PCN, 34% in Kaduna and 41% in Bauchi state.

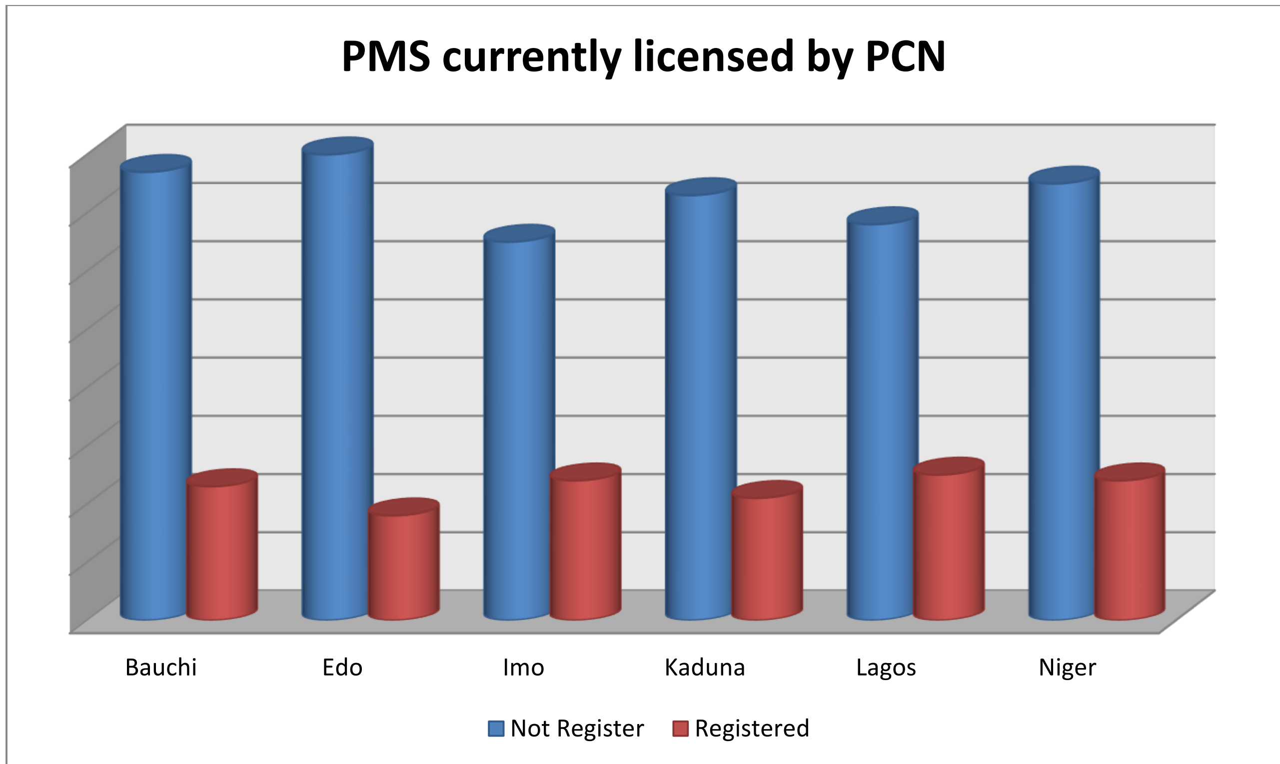

Fig. 10: PMS currently licensed by PCN

Moreover, it has been shown that PPMVs are more inclined to register with their membership association than with PCN. More than 87% of PPMVs were registered with NAPPMED, NAPPMV and LSMDA. The Chart below demonstrates the proportion of PPMV registration with regulatory and membership associations. In Bauchi more than 90% registerd with association, 93% Edo, 76% Imo,80% Kaduna, 78% Lagos and 82% Niger state.

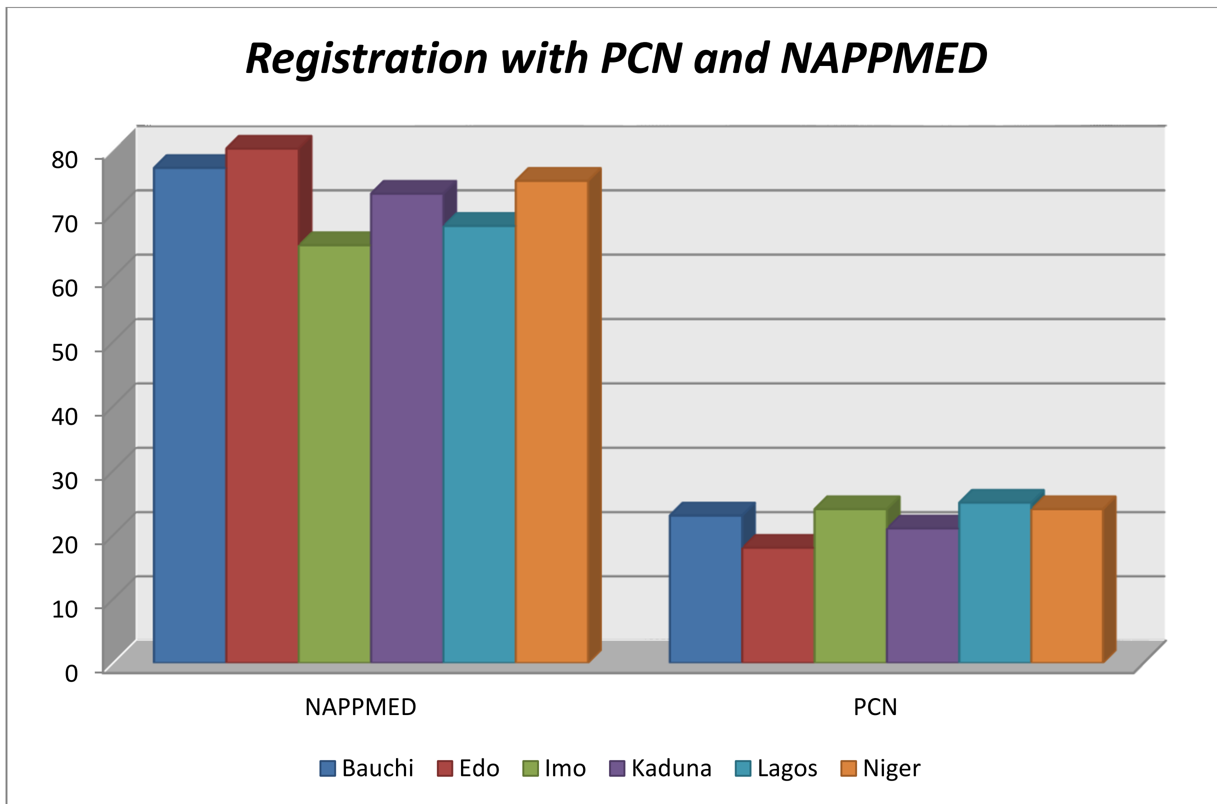

Fig. 11: Registration with PCN and NAPPMED

4.5. Referral

Information available has shown that more than 96% of PPMVs do not have source document to show the record of referrals (referral

form).But almost all of the PPMVs claimed referring clients to Hospital, Clinic, Community pharmacy and PHC

Services

Studies have found out that many PPMVs provided diagnostic and treatment services that are beyond their scope of operations. About 45% of PPMVs surveyed in each of the six states were found to be performing Pregnancy Test, Birth Delivery, Malaria Rapid Diagnostic Test and initiation of Family Planning Injectable and Pills.

4.6 Documentation

There was a low rate of documentation by PPMVs. The study shows that only 1.5% of the PPMVs document the daily activities in their shops. 98% of the PPMVs do not have Bin/Stock card for Inventory Record, No Register for Treatment Record, No Individual Patient Record and 99% of the PPMVs don’t have computer system.

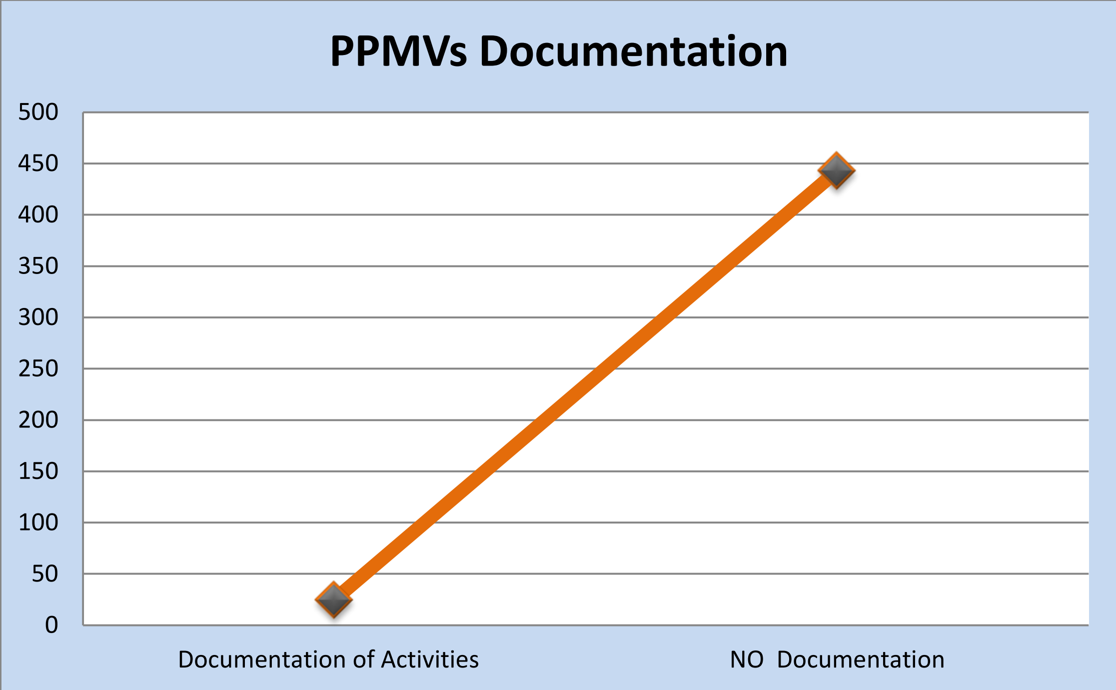

Fig. 12: PPMVs Documentation

4.7 Inspection and Enforcement Exercise of PPMVs

Findings have shown that PCNvisits PPMVs to conduct inspection and enforcement exercises in all registered PPMVs shops in Nigeria for the purpose of ensuring compliance with regulatory requirements at least once a year.

In addition, 52% of the PPMVs are not aware of the MoU between PCN and NAPPMED. 15% out of those that were aware do not know the purpose of the MoU and 5% do not agree with the MoU

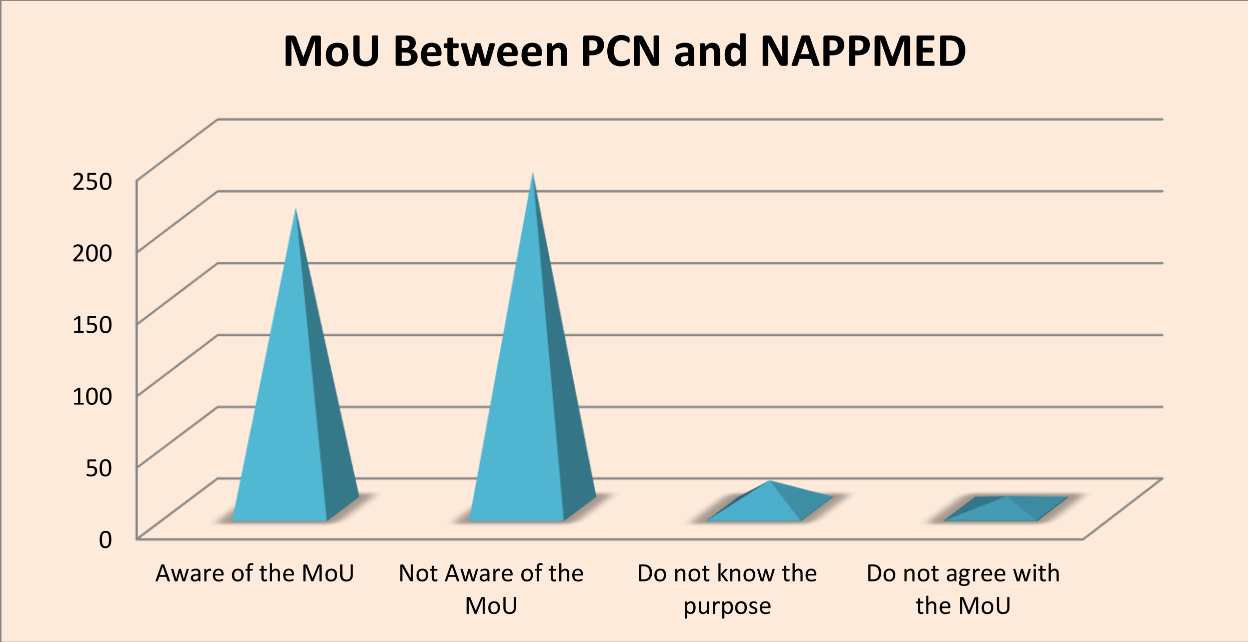

Fig.13: MOU between PCN and NAPPMED

4.9 Reports from NAFDAC/PSN/NAPPMED

Findings have shown that NAPPMED, NAFDAC, NDLEA and NGOsregularly organized sensitizationworkshop for the PPMVs on awareness of fake drugs, drug arrangement, and expired/unregistered drugs for both registered, unregistered PPMVs in the rural and urban areas. At least 74% of the PPMVs have attended one or two workshop form year 2015 till date.

4.10 PPMVs Interventions by Development/Implementing Partners

Great numbers of the interventions by development/implementing partners were focused on workshops and training activities for PPMVs which has led to

improvement in knowledge of the PPMVs (especially management of childhood illness) and they always create awareness on management of expired drugs and eradication of fake drugs.

4.11 The Orientation and Continuing Education Programmes

Information available has shown that less than 43% of the PPMVs have attended Orientation and Continuing Education Programs which are capacity-building instruments developed out of the obvious need to educate the PPMVs with global best practices, prevailing healthcare needs, which in turn will improve the service delivery capacity of the Vendors while giving recourse to regulatory issues and code of conduct.

More than 50% of the PPMVs are yet to attend any Orientation and Continuing Education Programs both in the rural and urban due to lack of information and license issue.

5 Assessment Survey

5.1 Methodology

The assessment spotlight six (6) states chosen across the six geopolitical zone of the country – Bauchi (North East), Edo (South South), Imo (South East), Niger (North Central), Lagos (South West) and Kaduna (North West). In each state, an urban and a rural LGA were visited for the survey.

5.2 Tools

Questionnaires were developed to elicit as much information as possible from the respondents. The assessment drew on both quantitative and qualitative data. Data was gathered through interviews with participants; primarily PMS owners were targeted as respondents. (An average of 80 respondents per state was targeted).

5.3 Limitations

This assessment faced a number of minor limitations: In some cases the data that the assessment was able to acquire was not always complete; Additionally, due to time and resource constraints, the assessment team was only able to interview a limited number of respondents; Finally, as with any assessment, there is a possibility that respondents were bias based on their interest in seeing the pilot declared a success or a failure.

6.0 FINDINGS

- PPMVs are more distributed in the rural areas than urban areas
- More PPMVs undergone apprenticeship in acquiring skills
- Most PPMVs attended secondary school (except Bauchi, where tertiary education is the bulk?)
- Most PPMVs have little or no knowledge of disease condition and treatment. However, most engage in all manners of interventions
- Majority of PPMVs source their stock from Drug market and Wholesalers
- Most PPMVs stock above the APML
- All PPMVs visited are dispensing
- Very few PPMVs registered with PCN, but most are registered with their association (NAPPMED)
- About half of the PPMVs are aware of the MOU between PCN and NAPPMED. However, most do not understand the content of the MOU and even less agreed with the spirit of the MOU
- Most PPMVs don't engage in referrals
- Majority of PPMVs don't keep documentations
- NAFDAC, NDLEA, NGOs, IPs and others tend to collaborate more with PPMVs than PCN. These organizations provide sensitization workshops and build capacity of PPMVs

- Less than 50% of PPMVs has attended the Orientation and Continuing Education Programmes of PCN

7.0 RECOMMENDATIONS

The identified gaps above clearly create opportunities for PCN to better understand the workings of the PPMVs and to know how best to engage them through capacity building and reorientation. PCN needs a better engagement model with the PPMVs. Since PPMVs has a great regard for their association (NAPPMED), PCN should build on a better collaboration and partnering with the leadership of NAPPMED to get all the members compliant with PCN directives (MOU already in place).

Finally, the adoption and implementation of the ADDO initiative by PCN to reposition the PPMVs in Nigeria is a laudable one that if well implemented will raise the benefit of PPMVs to the teeming populace yearning for good services from this group of stakeholder who are widely spread across the nooks and crannies of the country as a stop gap to the inadequate supply of pharmacists.

Acknowledgements

Appreciations goes to MSH for the collaboration with PCN, BMGF for funding the projects and interviewers that were involved in the collection of data during the pilot field survey.