**PHARMACISTS COUNCIL OF NIGERIA**

**REPOSITIONING OF PATENT AND PROPRIETARY MEDICINES VENDORS (PPMVS) FOR IMPROVED HEALTHCARE SERVICE DELIVERY**

Licensing and General Operational Provisions for the Three-Tier Accreditation Model

1. **Eligibility Criteria**

An applicant for the Patent and Proprietary Medicine Vendors Licence (PPMVL) shall satisfy the licensing authority (PCN), in respect of the eligibility for any of the three (3) tiers for the operation of the licence.

**1.1 Eligibility for Tier 1**

1. The applicant shall have attained the age of twenty-one (21) years;
2. The applicant is of good character and certified as such by two satisfactory referees; and
3. The applicant shall have the ability to read and write in English Language.

**1.2 Eligibility for Tier 2**

1. The applicant shall have attained the age of twenty-one (21) years;
2. The applicant is of good character and certified as such by two satisfactory referees; and
3. The applicant shall possess a PCN recognised qualification in health-related training.

**1.3 Eligibility for Tier 3**

1. The applicant shall have attained the age of twenty-one (21) years;
2. The applicant is of good character and certified as such by two satisfactory referees; and
3. The applicant shall possess a Pharmacy Technician Certificate from a PCN recognised institution.
4. **Requirements for an Application**
5. Handwritten application, indicating the exact location and address where the intended Patent Medicines Shop (PMS) 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.
6. 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 PMS.
7. Possession of certificate obtained from PCN entry point training programme in line with the appropriate tier.
8. The applicant shall attach copies of the relevant health-related certificate(s) to be verified by PCN (applicable to Tier 2).
9. The applicant shall attach copies of the Pharmacy Technician Certificate obtained from a PCN accredited institution and the current Annual Permit (applicable to Tier 3).
10. Letters of recommendations from two (2) reputable referees; one of whom shall be a registered and currently licensed Pharmacist.
11. Three (3) passport photographs, all of which shall be endorsed by one of the applicant’s referee, shall be attached to the application.
12. The applicant shall produce a current income tax clearance certificate.
13. Each application shall be accompanied with a non-refundable application fee as specified by the PCN.
14. **Procedures for the Issuance of the Licence**
15. Submission of a duly completed application form;
16. Interview of the applicant by the State PPMVL Committee;
17. Mandatory attendance of PCN entry point training programme in line with appropriate tier.
18. Payment of the prescribed inspection fee;
19. Inspection of the proposed shop by the State PPMVL Committee;
20. Forwarding of a satisfactory report to the PCN by the State PPMVL Committee;
21. Issuance of the licence by the PCN on payment of the prescribed registration fee;
22. The applicant shall be issued a booklet containing the list of medicines approved for sale by PCN.
23. **Conditions for the Renewal of the Licence**
24. All applications for the renewal of the licence must be submitted on or before the **31st of January of the year;**
25. The licence shall be renewed annually, subject to a satisfactory inspection report;
26. All licensed shops for the sale of patent and proprietary medicines shall be subject to the periodic monitoring by pharmaceutical inspectors appointed by PCN;
27. Evidence of attendance at a Continuing Education Programme (CEP) and any other workshop organised by PCN, at least once in every two years;
28. Payment of the prescribed fees.
29. **Entry Point Training and Continuing Education Programmes**

Every applicant for PPMVL shall be required to attend a training programme in line with the appropriate tier. Upon successful completion of the training programme and licensing, the holder shall be required to attend a Continuing Education Programme (CEP) and any other workshop, at least once in every two (2) years. Such programmes shall be organised at State level by PCN, in collaboration with the State PPMVL Committee and/or any other PCN approved organisation.

1. **Validity of the Licence**

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

1. **Premises Standards**

Every accredited PPMV premises, regardless of the tier, shall be required to meet the following minimum requirements:

1. The PMS shop shall be of a permanent nature;
2. The PMS shall have a design which includes;
3. Only one room of not more than 30sqm without any brick wall demarcation.
4. The PMS should be clean, well-lit and well ventilated.
5. Doors and windows which are well secured to prevent theft and unauthorised entry.
6. Handwashing facilities.
7. A designated cupboard to store some of the approved medicines.
8. Shelves made of laminated/polished wood which may be attached to the wall or stand alone; and the availability of a medium-sized glass counter.
9. Additional table and chair for the delivery of some primary health care services
10. The interior of the PMS shall be painted with washable white with tiled flooring that would enable washing with disinfectant.
11. The PMS shall be roofed and ceiled with leak-proof materials.
12. Location
    1. The PMS shall **not** be situated in a petrol station, marketplace or motor park.
    2. The PMS shall be located not less than 200m from the nearest PMS and 400m from the nearest Pharmacy.
13. The PMS shall be well protected from entry of rodents, birds and reptiles.
14. The PMS shall have access to portable water.
15. The PMS shall have access to adequate toilet facilities.
16. A sand bucket and/or fire extinguisher shall be present in the PMS at all times.
17. Medicines shall be arranged and displayed according to their dosage forms or therapeutic categories.
18. The original copy of the PPMV annual Licence and the approved PCN’s signage shall be displayed conspicuously in the PMS at all times.
19. The wordings “Patent Medicines Shop” shall appear as part of the name of the shop.
20. The PPMV shall wear the recommended overall at all times.
21. **Operational Tools**

The operational tool in every PMS shall include the following:

1. A documentation tool for services/interventions (see annexure 1)
2. Job aids for malaria, diarrhoea, pneumonia etc.
3. Referral forms (see annexure 2).
4. PCN Publications: PCN Approved Medicines List, PCN-PPMVL Guidelines, PCN Entry Point Training Manual.
5. Weighing scales and stadiometer (Height Metre Rule)
6. Counting tray and spatula
7. Pharmacovigilance adverse drug reaction reporting form (annexure 3).
8. Waste disposal boxes (in compliance with segregation)
9. Sales and purchase ledgers
10. Bin/tally cards
11. Refrigerators (where applicable)
12. **Primary Healthcare Services**

Every PPMV shall bear responsibility for the products and services provided under his/her care. The PPMV shall be required to provide the following primary healthcare services in line with the appropriate tier.

* 1. **Services to be rendered by TIER 1**

1. Stock and sell **ONLY** medicines in the PCN Approved Medicines List purchased from the approved drug distribution centres.
2. Conduct rapid diagnostic test (mRDT) for all suspected cases of malaria before treatment if trained to do so.
3. Undertake treatment of diarrhoea using ORS and zinc sulphate tablets but refer in the presence of danger signs.
4. Undertake pre-referral treatment of pneumonia in children under 5 using amoxicillin dispersible tablets.
5. Educate clients on the concept and methods of child spacing and family planning.
6. Stock and sell family planning commodities. These include condoms, spermicides, daily pills, oral emergency contraceptive pills and standard cycle beads.
7. Give advice on immunization for vaccine preventable diseases.
8. Make prompt referrals to appropriate centres based on danger signs using the approved referral forms.
9. Educate on preventive measures for HIV/AIDS.
10. Undertake case finding and referrals for suspected cases of tuberculosis.
11. Perform basic life-saving procedures where necessary.
12. Ensure appropriate disposal of expired and damaged medicines.

**9.2 Services to be rendered by TIER 2**

1. Stock and sell **ONLY** medicines in the PCN Approved Medicines List purchased from the approved drug distribution centres.
2. Conduct mRDT for all suspected cases of malaria before treatment.
3. Undertake treatment of diarrhoea using ORS and zinc sulphate tablets and refer in the presence of danger signs.
4. Undertake the pre-referral treatment of pneumonia in children under 5 using amoxicillin dispersible tablets.
5. Educate on the concept and methods of child spacing and family planning
6. Stock and sell family planning commodities including condoms, spermicides, daily pills and oral emergency contraceptive pills, standard cycle beads, implants and Depot-medroxy progesterone acetate (DMPA) injection.
7. Give immunization advice and refer patients to the appropriate centres.
8. Make prompt referrals to the appropriate centres based on danger signs using the approved referral forms.
9. Provide HIV and AIDS preventive services, testing and counselling if trained.
10. Undertake case finding and referrals for suspected cases of tuberculosis.
11. Perform basic life-saving procedures where necessary.
12. Ensure appropriate disposal of expired and damaged medicines.
13. Provide health promotion services on contemporary health issues: HIV/AIDS, Ebola, Lassa fever, Monkey pox, etc.

**9.3 Services to be rendered by TIER 3**

1. Stock and sell **ONLY** medicines in the PCN Approved Medicines List purchased from the approved drug distribution centres.
2. Conduct mRDT for all suspected cases of malaria before treatment.
3. Undertake treatment of diarrhoea in using ORS and zinc sulphate tablets and refer in the presence of danger signs.
4. Undertake the pre-referral treatment of pneumonia in children under 5 using Amoxicillin dispersible tablets.
5. Educate on the concept and methods of child spacing and family planning
6. Stock and sell family planning commodities including condoms, spermicides, daily pills and oral emergency contraceptive pills, standard cycle beads, implants and DMPA injections.
7. Give immunization advice and refer patients to the appropriate centres.
8. Make prompt referrals to the appropriate centres based on danger signs using the approved referral forms.
9. Provide HIV and AIDS preventive services, testing and counselling if trained.
10. Undertake case finding and referrals for suspected cases of tuberculosis
11. Perform basic life-saving procedures where necessary.
12. Ensure appropriate disposal of expired and damaged medicines.
13. Provide health promotion services on contemporary health issues: HIV/AIDS, Ebola, Lassa fever, Monkey pox, etc.
14. **Monitoring and Inspection**

Licenced shops shall be subject to periodic monitoring and inspection by accredited pharmaceutical inspectors who shall submit their reports to the Pharmacists Council of Nigeria.

1. **Miscellaneous Provisions**
2. No holder of the PPMVL shall re-pack patent or proprietary medicines.
3. Any person who does anything likely to prevent or obstruct the effective implementation of the provisions of these *Guidelines* shall be guilty of an offence.
4. Any person aggrieved by the enforcement of the provisions of these *Guidelines* may appeal to the Registrar, Pharmacists Council of Nigeria.
5. The licensing authority shall not issue a licence to an applicant where any, but not limited to the following circumstances are shown to exist that the applicant is…
6. bankrupt or insolvent,
7. an ex-convict,
8. in disobedience of the Council’s directives, or
9. involved in practices inimical to the issuance of the licence.
10. The PCN shall exercise its powers generally and take such measures as are incidental to the effective implementation of the provisions of these *Guidelines.*
11. Any PPMV without a licence, or who contravenes any of the provisions of these *Guidelines* shall be guilty of an offence, and shall be liable, upon conviction, to a fine not exceeding N500,000.00, or to a term of imprisonment not exceeding two (2) years, or to both such fine and imprisonment.
12. The PCN or its representative shall have powers to seal the shops of erring PPMVL holders and where the seal is tampered with, the vendor shall pay the administrative fee charges.
13. Where the licensing authority is satisfied that a licence holder is in breach or in default of his/her responsibilities under these *Guidelines*, or laws in force, the licensing authority may, if it deems fit, revoke/withdraw any licence issued and/or strike off the name and shops from the register, but without prejudice to administrative charges that may be imposed on the defaulter.
14. The PCN is the first port of call for intending PPMVL holders.
15. Notwithstanding anything to the contrary in any enactment or law, the Federal High Court, the State High Court, and the Magistrate Court shall have jurisdiction to try offences under these Guidelines.

**ANNEXURE 1**

**SERVICES DOCUMENTATION TOOL**

**Name of Patent Medicine Vendor:** ........................................................................................................................

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S/No | DATE | NAME OF CLIENT | ADDRESS & PHONE NO | GENDER | AGE | SIGNS & SYMPTOMS | SUSPECTED ILLNESS | TESTS UNDERTAKEN | SERVICES RENDERED | DOSE | QUANTITY OF MEDICINES SOLD | REFERRAL IF APPLICABLE |
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**ANNEXURE 2**



**PHARMACISTS COUNCIL OF NIGERIA**

**MANAGEMENT OF CHILDHOOD ILLNESSES**

**PATENT AND PROPRIETARY MEDICINE VENDORS’ REFERRAL FORM**

**Serial Number: ……………..............………..**

# Information on Client and Referral Facility

**Name of Health Facility: ……………………………………………………**

**Date of Referral: ……………… Time of Referral………………………**

**Client’s Name: …………………………………………………………………**

**Residential Address: ………………………………………………………………**

**Age: …………………… Gender: …………………….......**

**Reason for Referral (Please tick as appropriate**)

**Vomiting Everything High Persistent Fever  Unable to drink or Eat  Convulsion/confusion Unconsciousness  Yellowness of the eyes  Pregnant woman  Extreme weakness  Chest in-drawing**

** Difficulty in breathing  Fast breathing  Coughing longer than 14days  Blood in the stool  Sunken Eyes  Skin pinch goes back slowly Excessive thirst/drinks eagerly  Dry lips  Sunken Fontanel Passing little or no Urine Diarrhoea longer than 14days No improvement in 3days after administering drugs Others**

**Comments**: ……………………………………………………………………………...............................................

**Actions taken by PPMV: .................................................................................................................**

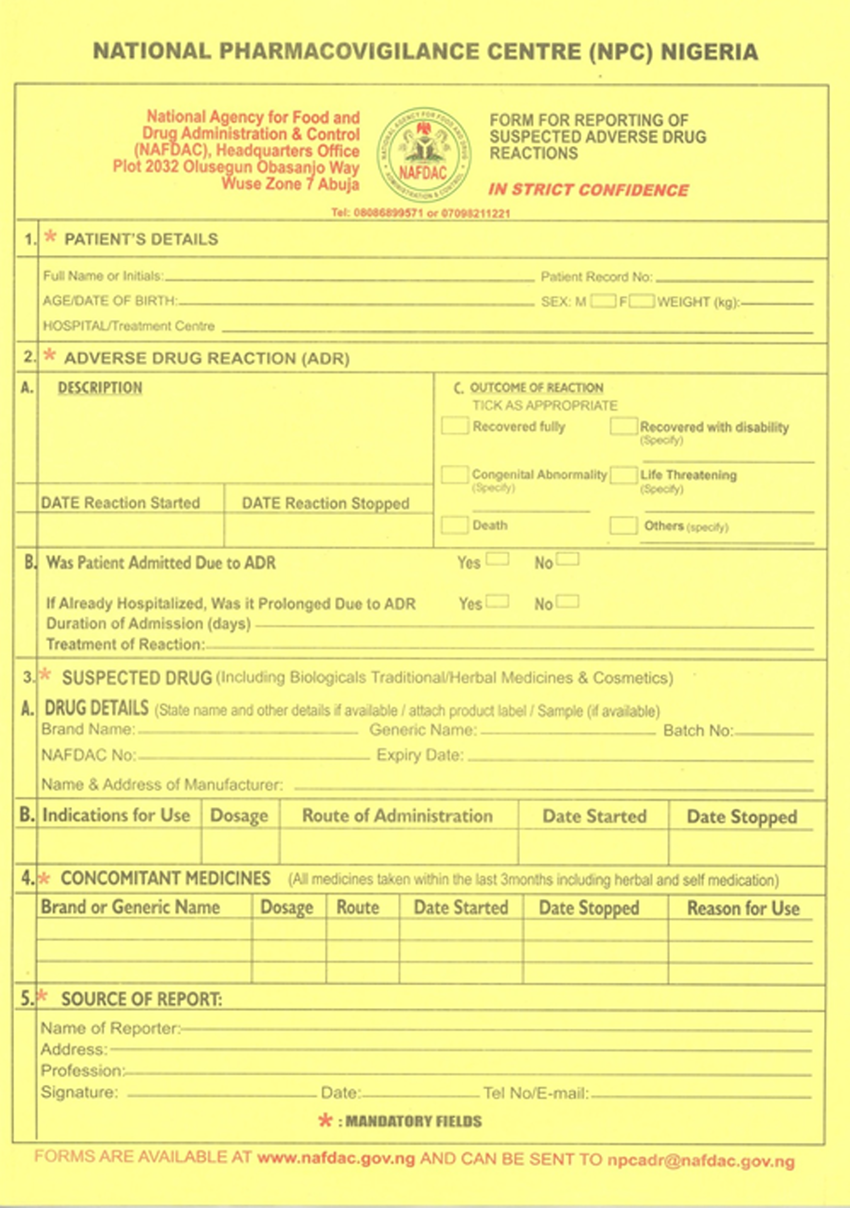
……………….........................................................................................................................................................................................…………………………………………...............................................................................

**Name of Vendor/ Licence No: …………………………………...........................................…………………….......**

**Name and Address of PPMVL Shop: ……………………………………………………………………………….………........**

**Phone number of Vendor: ………………………...............................................…………………………………. Signature of Vendor: ………………………………………………………………...........................................**

**ANNEXURE 3**



**LOGOS**







**SUPERVISORY MODEL AS DEVELOPED BY THE CONSULTANTS Date……**

**1. Background**

The Patent and Proprietary Medicines Vendors License (PPMVL) was introduced through the Poison and Pharmacy Ordinance of 1936. Holders were (are) to provide medicines in an approved list in places with little or no presence of pharmacists. The proportions of pharmacists and other health professionals relative to the population have remained very low. Consequently, PPMVs are still relevant today particularly in pharmaceutically underserved parts of the country. To broaden the healthcare delivery capacity of the nation, PPMVs have been targeted for the delivery of certain primary healthcare services such as rapid diagnostic test for malaria, treatment of uncomplicated malaria, acute childhood diarrhoea, and pneumonia. Complaints that they operate far beyond the scope of their license have been raised severally. Indeed there is the thinking in some quarters that their operations often do more harm than any good that should have been expected. Such out-of-scope practices include the sale of medicines and commodities that are not in the approved list for their level of operation, treating diseases that they are incompetent to treat, and operating in premises that fall low in standard of cleanliness. There is no doubt that because of its peculiar nature, every healthcare system needs to be regulated. Over the years PCN has tried to regulate the activities of PPMVs in each State by use of PPMVL Committee but with yawning gaps and not much success. All these underscore the need for better supervision of PPMVs.

**2. The Hub and Spoke Model of Supervision**

Although there are different models of supervision, this model (Figure 1) has been adopted because it is simple, easy to implement and suits the order of manpower in the pharmaceutical service delivery that places the pharmacist at the topmost position. Like the hub of a bicycle wheel, the supervisor is at the centre and exercises supervisory role over an area akin to that of a bicycle wheel. The hub (supervisor) according to this model is a pharmacist and the supervisees are PPMVs within an area defined by PCN. The aim of the model is to enhance the quality of services rendered by PPMVs through adherence to the operational guidelines and all other regulatory instruments issued by PCN.

***2.1 Personnel and logistic requirements for the model***

The model shall be operated at each State and the Federal Capital Territory of Nigeria. It shall involve selected pharmacists (who shall serve as the hubs for supervision), and staff of PCN. The logistics required for operating the model shall be provided by PCN. The PCN shall incentivize the supervisors from time to time.

**PMS**

**PMS**

**PMS**

**PMS**

**PMS**

**Pharmacist**

**PMS**

**PMS**

**PMS**

**PMS**

**Figure 1:** The hub and spoke model for the supervision of PPMVs within a locality.

***2.2 Eligibility requirements for the supervising pharmacists (the Hubs)***

To be appointed a supervisor in the model, the supervisor shall be:

1. A registered pharmacist with no less than five (5) years post qualification experience.
2. A pharmacist knowledgeable about the standards and scope of operations of PPMVs.

***2.3 Operational guidelines for supervisors***

The supervising pharmacists shall operate using the following guidelines:

1. Use a PCN-approved form (Annexure I) to report their findings.
2. Visit the PMS within the area of operations at least once every quarter.
3. Discuss the observed lapses with the PPMV and suggest areas of improvements.
4. Forward a completed reporting form to the State officer of PCN.

***2.4 Ethical expectations***

It is expected that a supervising pharmacist in the model shall be ethically guided by putting the health of Nigerians first and above all other considerations. In addition, they shall observe the following:

1. They shall not in any way victimize any PPMV.
2. Where there is a clear conflict of interest, the supervising pharmacist shall promptly notify the appropriate PCN staff who may assign another supervisor to the PPMV.
3. They shall not conduct themselves in any way that may bring dishonour to the profession.
4. No supervisor shall accept gifts in cash or kind from the supervisee.
5. Interaction between supervisor and supervisee shall be formal and limited to issues of quality provision of services within the approved guidelines provided by PCN.
6. They should refrain from using derogatory language however appalling the quality of services by the PPMVs may be.
7. They must carry with them their identification cards during visits to the PMS.

***2.5 Roles and responsibilities of State Officers (PCN)***

The officer-in-charge (State Officer) of each State of the Federation and the Federal Capital Territory shall:

1. Support the supervising pharmacist with all the logistic requirements such as transportation and stationery items needed for his operations.
2. Share the report with the PPMVL Committee, Zonal Officer of PCN, and PCN Head Office in Abuja (Figure 2).
3. Coordinate and apply any commendation/sanction that may have been recommended for an erring PPMV.

***2.7 Roles and responsibilities of PCN***

The Pharmacists Council of Nigeria (PCN), shall:

1. Prepare a list of PPMVs assigned to a supervisor.
2. Inform the PPMVs of the supervisors assigned to them.
3. Inform each supervising pharmacist of the assigned PPMVs.
4. Prepare an identity card for each supervising pharmacist.
5. Provide supervisors with necessary documents such as the guidelines for operations of PPMVs, the approved medicines list and list of operational tools.
6. Approve and implement the commendations/sanctions recommended for the PPMV.

**Figure 2:** Flow and sharing of reports in the supervisory model.

**2.8 General Provisions for Supervision**

A supervisor shall not be assigned to more than 20 PMS in an urban area. In a rural area where pharmacists are few, a pharmacist may be assigned to an entire local government area. Such a pharmacist may have been working within the local government. In a situation where there is no pharmacist that meets the eligibility requirements for appointment as a supervisor, the State Officer of PCN may recommend a pharmacist from a contiguous local government area/town.

The supervisors may not inform the PPMV of their visit. The supervisor is meant to encourage the supervisee to do things properly. Observations are to be noted in the Reporting Form.

**ANNEXURE I**

**PHARMACISTS COUNCIL OF NIGERIA**

**REPORTING FORM FOR SUPERVISING PHARMACISTS (FORM MIII)**

1. **IDENTIFICATION**
2. Name of Patent Medicines Shop………………………………………………………………….
3. Address of Patent Medicines Shop……………………………………………………………..
4. Name of the owner (Vendor)………………………………………………………………………….
5. Registration number of Patent Medicines Shop……………………………………………
6. **THE SHOP**
7. Cleanliness of the PMS: Very clean [ ] Fairly clean [ ] Not clean [ ]
8. Disposal of wastes: Very good [ ] Good [ ] Fair [ ] Poor [ ]
9. Ventilation: Very good [ ] Good [ ] Fair [ ] Poor [ ]
10. Hand washing facility: Available [ ] Not available [ ]
11. Toilet facility: Available [ ] Not available [ ]
12. Functional refrigerator: Available [ ] Not available [ ]
13. Operational tools (List the ones available):…………………………………………........

…………………………………………........…………………………………………..................

1. **THE MEDICINES**
2. Arrangement of medicines: Very good [ ] Good [ ] Fair [ ] Poor [ ]
3. Presence of medicines outside the Approved Medicines List (List the medicines): ……………………………………………………………………………………………

……………………………………………………………………………………………………………...……………………………………………………………………………………………………….

1. Storage of some medicines: Appropriate [ ] Inappropriate [ ]
2. Presence of expired commodities: Present [ ] Not present [ ]
3. **THE VENDOR**
4. Present at time of visit: Yes [ ] No [ ]
5. Neatness: Very neat [ ] Fairly neat [ ] Not neat [ ]
6. Attitude: Very good [ ] Good [ ] Fair [ ] Poor [ ]
7. Attendance of training in current year: Attended [ ] Not attended [ ]
8. **THE SERVICES**

**\*list services expected\***

1. Rapid diagnostic tests: Available [ ] Not available [ ].

State type if available: …………………………………………………………………………….

1. Invasive family planning methods: Available [ ] Not available [ ].

State type if available: …………………………………………………………………………….

1. **COMMENTS BY SUPERVISING PHARMACIST**

………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………..

G. **SUPERVISOR**

1. Name (Capital letters with surname First ): …………………………………………….
2. Registration Number………………………………………………………………………………
3. Signature and Date of Visit: …………………………………………………………………..
4. Seal………………………………………………………………………………………………………