###### Objective

This SOP is to ensure that a standardized procedure is followed by all inspectors when performing inspections of Pharmacies and Drug Shops and to ensure consistency in inspection reports between different inspectors. The SOP also describes the procedure for Licensing of Drug Shops and Pharmacies.

###### Scope

This SOP applies to conducting inspections for Drug Shops, Pharmacies and Local Drug Manufacturers in an objective, consistent and uniform manner to ensure that licensed drug outlets meet the stipulated requirements as per the licensing guidelines, NDA regulations and NDP/A Act Cap. 206.

###### Policy

* 1. The National Drug Policy and Authority Act Cap. 206, Section 14 (1) states that: “*if on application made in the prescribed form by any person and the authority is satisfied that; the applicant is fit to carry on a business of supplying restricted drugs by retail under immediate supervision of a pharmacist in a set of premises where the business is to be carried on and in case of a corporate body or a partnership one of the directors or partners is a Pharmacist resident in Uganda; may on payment of a prescribed fee, issue a license to the applicant to carry on the business required at the premises and on the conditions specified in the license”.*
	2. The National Drug Policy and Authority Act Cap. 206, Section 15 (1) states that: “*if on application made in the prescribed form by a person other than the pharmacist and the authority is satisfied that; the applicant is fit to carry on a business of supplying restricted drugs other than drugs of Class A and Class B in an area not sufficiently served by existing facilities for retail supply of drugs and the applicant is an authorized person; may be issued a license to the applicant to carry on the business required from the premises and on the conditions specified in the license”.*
	3. *The* National Drug Policy and Authority Act Cap. 206, Section 17 states that: “*if on application made in the prescribed form for a certificate in relation to any premises, the authority is satisfied that the accommodation, fixtures, equipment and other physical attributes of those premises render those premises suitable for the supply of restricted drugs or for the supply of restricted drugs other than drugs of classes A and B, it may issue in respect of those premises either a general or limited certificate”.*
	4. The National Drug Policy and Authority Act Cap. 206, Section 37 states that: “*if on application made in the prescribed form by any person and payment of a prescribed fee ,and the authority is satisfied that; the applicant is fit to carry on a business of supplying restricted drugs by whole sale under immediate supervision of a pharmacist in a set of premises where the business is to be carried on and in case of a corporate body or a partnership one of the directors or partners is a Pharmacist resident in Uganda; issue a license to the applicant to carry on the business required in separate premises apart from any other business”.*
	5. *The* National Drug Policy and Authority Act Cap. 206, Section 50 states gives an Inspector, Assistant Inspector of Drugs or any Police Officer not below the rank of Assistant Superintendent the power to enter any Drug outlet premises at any reasonable time to conduct an inspection.
	6. *The National Drug Policy and Authority regulations 2014 No. 35 for Licensing.*
	7. *The National Drug Policy and Authority regulations 2014 No. 36 for Certificate for Suitability of Premises.*
	8. *The National Drug policy and Authority Act Cap 206, Section 38 and section 39 provides restrictions on the manufacture of drugs and Section 50 promotes Local research and* production.

###### Definitions

* 1. Inspection: Inspection is to scrutinize or closely look at something or someone more keenly to find out if it conforms to set criteria, standards, and expected or required actions. Inspection does not only mean to identify problems and shortcomings. It also includes building mutual understanding between service providers and law enforcers and providing guidance on how to correct non-conformances and eventually provide quality drugs to the communities.
	2. **Routine Inspection:** This inspection is done to routinely determine if the pharmacy or drug shop business is being carried out in accordance with the licensing guidelines, NDA regulations and the NDP/A Act.
	3. **Follow-up inspection:** This inspection is done as a follow-up to the routine inspection in order to determine whether guidance provided during the previous inspections has been implemented. The inspection is for evaluation and confirmation of implementation of Corrective Action and Preventive Action (CAPA) after the previous inspection.
	4. **Investigative Inspection**: This inspection is conducted following surveillance reports or complaints on violation of licensing guidelines, NDA regulations and NDP/A Act by Pharmacies and Drug Shops.
	5. **Wholesale Pharmacy:** Premises where the business of wholesale supply of restricted drugs is carried on with authorization to carry on the business with a license granted under section 37 of the NDP/A Act.
	6. **Retail Pharmacy:** Premises where the business of mixing, compounding, preparing and supplying of restricted drugs on retail by a licensed person with a license granted under section 14 of the NDP/A Act.
	7. **Drug Shop:** Premises where the business of supplying by retail restricted drugs by licensed sellers, other than drugs of Class A or B in an area not sufficiently served by existing facilities for the retail supply of restricted drugs with a license granted under section 15 of the NDP/A Act.

###### Responsibility

The Authority Shall have the responsibility of issuing and revocation of Licenses under the NDP/A Act.

The following officers shall issue licenses on behalf of the authority.

* 1. **The Secretary to the Authority** is responsible approval and issuance of licenses to all approved Pharmacies, Drug Shops and Local Drug Manufacturers forwarded by Head Drug Inspectorate Services.
	2. **The Head, Drug Inspectorate Services** is responsible for review of inspection reports for new Pharmacies and forward to the Secretary to the Authority for approval.
	3. **The Senior Inspector of Drugs –LMS** is responsible for review of inspection reports for renewal of Pharmacies and forward to the Secretary to the Authority for approval. **The Senior Inspector of Drugs-GMP and GPRC** shall review GMP inspection reports for Local Drug Manufacturers and recommend for GMP compliance and Licensing.
	4. **The Regional Inspector of Drugs** is responsible for organizing, coordinating and leading inspections for Pharmacies and issue licenses for Drug Shops in their respective regions on behalf to the Authority.
	5. **The Inspector of Drugs/ Assistant Inspector of Drugs** is responsible for:
		1. Conducting an inspection for Pharmacies, Drug Shops Agreeing on the inspection’s scope;
		2. Discussion and resolving, where possible, any major problems which may occur during the inspection process;
		3. Making the recommendation on the licensing of the inspected premises;
		4. Preparing an inspection report;
		5. Conducting any follow-up measures; and
		6. Review of CAPA submitted by the Pharmacy or Drug Shop
	6. **The Administrative Assistant is responsible for:**
		1. Issuing and receiving fully filled application forms for licensing for Pharmacies and or Drug shops;
		2. Capturing and verification of information on the application for Pharmacies and enter into the NDAMIS database for licensing;
		3. Dispatching issued licenses to approved Pharmacies and Drug Shops;
		4. Providing the Inspectors with the necessary documentation and logistics for the inspection;
		5. Maintaining all records related to licensing of Pharmacies and Drug Shops;

###### Distribution

* 1. Controlled electronic copies to all employees at the head office on the shared folder on NDA head office server ([\\ndaserver\qms\sops](file:///%5C%5Cndaserver%5Cqms%5Cmanuals)).
	2. Controlled electronic copies to all employees at the NDA laboratory on the shared folder on NDA laboratory server ([\\ndqcl\qms\sops)](file:///%5C%5Cndqcl%5Cqms%5Cmanuals%29).
	3. Controlled hard copy to Secretary to the Authority
	4. Controlled hard copy to Head Drug Inspectorate Services Department
	5. Controlled hard copy to Senior Inspector of Drugs- LMS
	6. Controlled hard copy to Quality Officer- Drug Inspectorate Services Department
	7. Controlled hard copies as may be required/requested by an NDA staff

###### Safety Precautions

Inspectors of Drugs should have identification cards at all times during the inspection process.

###### Materials and equipment

* 1. Application forms for Certificate for Suitability of Premises and Licenses
	2. Inspection Template reports for Drug Shops, Retail and Wholesale Pharmacies
	3. NDA Licensing Guidelines, Regulations and NDA/P Act
	4. NDA Search Certificates
	5. Pens with indelible blue or black ink
	6. NDA Inspector’s Identity cards
	7. NDA business cards
	8. Measuring Tapes and GPS Machines

###### Procedure

* 1. **Application for Licensing**
		1. Applications for licensing for Pharmacies and Drug Shops should be submitted to the respective regional offices electronically or by hard copy an annual basis.
		2. Administration Assistants shall not receive incomplete applications. If applications are submitted electronically by the applicant; the Administration assistants shall verify the application in the NDA database under Pending Verification in the Premises Module of the NDAMIS data base (https://mis.nda.or.ug/). All applicants for a pharmacy license must submit the following before consideration for inspection:
			1. Duly filled application forms for the Certificate for suitability of premises
			2. Duly filled application forms for the license
			3. A certified copy of the Articles and Memorandum of Association or Partnership Deed showing the supervising Pharmacist as one of the Directors of Partnership of the firm, respectively. In addition the Certificate for Registration of the business and the URA TIN certificate shall be submitted.
			4. A sketch plan of the premises taking into consideration the minimum floor area for wholesale, retail and additional storage area.
			5. The certified copy of the certificate of registration for the supervising pharmacist issued by the registrar of pharmacy board, Ministry of Health
			6. A letter of commitment from the supervising pharmacist indicating time and duration he/she is expected to be physically present in each premise supervised and other places of work.
			7. A letter of commitment from the auxiliary pharmacy staff.
			8. Certified copy of Certificate of registration/enrollment and practicing license of the auxiliary pharmacy staff, issued by the respective professional councils.
			9. For auxiliary staff in Vet pharmacies, a Copy of academic certificate awarded by an institution recognized by Uganda veterinary board.
			10. For veterinary pharmacies commitment letter of the veterinary surgeon and a copy of certificate of the bachelors in Veterinary medicine.
			11. Proof of payment of the prescribed fees after approval of the application.

**For Pharmacies the invoice will be sent directly to the client through the NDAMIS database after approval of the application.**

* + - 1. Copy of the previous license for renewal
		1. Requirements for Drug shops applications;
			1. Two recent passport size photos of the qualified professional in charge.
			2. Commitment letter of the qualified professional in charge
			3. Dully filled application forms for the Certificate for suitability of premises
			4. Duly filled application forms for the license.
			5. Certificate of registration/enrollment and practicing license of the qualified professional in charge, issued by the respective professional councils.
			6. For Vet drug shops, a Copy of academic certificate for the qualified professional in charge awarded by an institution recognized by National Council for Higher Education and /or Uganda Veterinary Board.
			7. Proof of payment of the prescribed fees after approval following inspection.
			8. Copy of the previous license for renewal.
		2. A Record of received applications for Pharmacies and Bank Slips distributed to the districts shall be maintained by the Administrative Assistant. Applicants for Pharmacies shall sign in a book/form for received applications after submission for all requirements for suitability of premises and license. The District Drug Inspector shall maintain a record of applications and bank slips issued to Drug Shops.
		3. The Administrative Assistant or Applicant shall enter the data of applications for Pharmacies received in the **Premises Module** of the **NDAMIS data base** (**https://mis.nda.or.ug/**).
		4. The Administrative Assistant shall send a list of received applications for Pharmacies Regional Inspector of Drugs for scheduling for inspection electronically.
		5. The Regional Inspector of Drugs shall develop a pharmacy inspection schedule **under the Inspection Module of the NDAMIS data base (**[**https://mis.nda.or.ug/**](https://mis.nda.or.ug/)**) and** make requisitions for the required logistics and funds for the inspections to be conducted.
		6. The Administration Assistant shall prepare the required inspection tools for the inspectors.
		7. Inspections should be carried within 20 working days of receipt of applications and a response on the outcome of the inspection communicated to the applicant within 30 working days from the date of receipt of the application.
	1. **Preparation for the inspection**
		1. Before conducting any routine inspection, the inspectors shall prepare and/or have available the following;
1. The inspection visit timetable including a list of Drug outlets or Local Drug Manufacturers and the schedule for inspections,
2. Application forms for the outlets to be inspected,
3. Inspection report templates for conducting the inspections. For Drug shops and Pharmacies; Routine inspection reports to be filled in addition to the Inspection Checklist and addendum to the inspection report in the Annexes. For Whole sale Pharmacies an additional documents and guidelines for Good Distribution Practices for Pharmaceutical products INS/GDL/002 would be used.
	* 1. Inspectors are not obliged to notify premises that they want to carry out an inspection.
		2. All inspections for renewal of Drug Shop licenses shall be handled at Regional Offices and new drug shops shall be approved by SID LMS.
		3. All new pharmacies and those with major changes like location and management will be recommended for approval to SA by the Head, Drug inspectorate Services.
		4. **Renewal of pharmacies will be recommended for approval to SA by the SID-licensing and market surveillance.**
		5. **All drug shops applications will be handled using the MS access system and licensing applications and inspection reports for Pharmacies should be entered** in the **NDAMIS database** (https://mis.nda.or.ug/)
	1. **Inspection of Pharmacies ,Drug Shops**
		1. The inspection shall start with introductions and a brief on the inspection plan. The inspector shall explain the inspection process to the pharmacy staff or the pharmacist in charge. Inspectors must display their identity cards at all times during inspection.
		2. The inspector shall allow for pharmacy services to continue to be offered to members of the public unless the pharmacy is in critical contravention of the NDA/P act and/or other applicable legislation. The Inspector in this case shall take appropriate action.
		3. Record the persons present at the time of inspection and their role at the drug outlet in the relevant sections of the inspection report template.
		4. Conduct the inspection systematically according to the inspection plan with the aid of the **GPP Inspection Report for Retail Pharmacies** in Appendix I, **Accreditation Inspection Report for Drug Shops**  in Appendix II and **GDP Inspection tool for wholesale pharmacies** in Appendix III and In addition, the routine summary inspection reports; **Form 13- Inspection report for Whole sale Pharmacy**, **Form14- Inspection Report for Retail Pharmacy** and **Form 15 Inspection Report for Licensed Seller**; will be filled as appropriate depending on the premises inspected.

* + 1. Inspectors will gather and record evidence in a number of ways, including:
			1. Looking at written or documentary evidence,
			2. Observing interactions with patients,
			3. Questioning and posing scenarios to staff,
			4. By testing systems, processes and procedures.
		2. Inspection shall be carried out using the appropriate inspection tools mentioned in 9.3.7 in order to ensure that all inspections are fair and consistent across all drug outlets. All **Non-conformances** shall be recorded on the **Addendum to the Inspection report** (Appendix Iv) which will be filled in duplicate with the carbon copy left at the inspected outlet for corrective action. Use of diplomacy and other convincing tactics to enable collection of relevant information shall be employed Inspection activities will be conducted step by step as indicated in the inspection report templates. During questioning, ask questions one at a time and not all together to avoid confusion of the respondent.

At the end of the inspection, the Inspector will go through the non-conformances with the Responsible Pharmacist /Drug outlet staff, who will be asked to sign the Addendum to the Inspection report to confirm their agreement to the findings. For Pharmacies, Responsible Pharmacist shall have an opportunity to make any additional comments. This is important to show that the evidence recorded in the report is an accurate reflection of what the inspector observed / was shown on the day of the inspection. Fill out the report while conducting the inspection and it’s not advisable to fill the report after the visit has been completed.

* + 1. The inspector must submit the inspection results through the filling the inspection report in **the Inspection module of the NDAMIS data base** and/or report to the Senior Inspector of Drugs for LME or Regional Inspectors of Drugs for Drug Shops or Senior Inspector of Drugs for GMP/GPRC within 20 working days once any technical or inspection related challenges have been dealt with.
		2. Communications to the clients shall be made officially in writing by HDIS/ SA for Pharmacies, HDIS for and RID for Drug shops on the outcome of the inspection. Inspectors are not allowed to inform the clients the outcome of the inspection.
	1. **Rating of Drug Shops and Pharmacies**
		1. The inspector shall rate the pharmacy /drug shop according to the criteria of Poor, Satisfactory, Good or Excellent as defined below based on the inspection tool for Retail Pharmacies and drug shops.



* + 1. All Drug Outlets that are rated as ‘Excellent and or Good’ with Minor Non-Conformances shall be forwarded electronically to the HDIS/SID LME and thereafter SA for endorsement/approval and printing the certificate for suitability of premises and licenses using the **NDAMIS database**.
		2. All Drug Outlets that are rated as ‘Poor and or satisfactory’ and with Critical and Major Non-Conformances shall be required to submit an Action Plan with details of the Corrective and Preventive Actions for the communicated Non-compliances. Outlets in the Good category with minor issues shall also be required to submit CAPA but will not delay processing of their licenses.
		3. The Drug Outlet / shall be required to submit the Action plan for evaluation within two weeks from the date of the report and in any case not later than 31st January from the date of inspection and evaluated by the Inspector who conducted the inspection or as allocated by the RID/HDIS . The CAPA should be submitted not later than 31st January of the licensing year. If found satisfactory, the Inspector shall enter the inspection report into the **NDAMIS database**, the addendum to the report and the evaluated Action plan to the HDIS/RID for endorsement and proceed with processing of the certificate and license as in 9.4.2 and 9.4.3.
		4. All licenses and Certificates for Drug Shops shall be approved by the Regional Inspector of Drugs except as provided by the NDP/A Act and the Secretary to the Authority shall approve licenses and Certificates for Pharmacies. The Licenses and Certificates shall be issued on an annual basis for the Drug Outlets.
		5. All Licenses and Certificates shall be issued at the respective Regional Offices with a file of photocopies of the Licenses and Certificates issued maintained. The applicant shall sign for the documents before issuance after confirmation of the same.
		6. All unlicensed pharmacies should close shop effective 1st February of the licensing year.

**10.0 References**

* 1. National Drug Policy and Authority Act, Cap. 206
	2. Good Distribution Practices for Pharmaceutical Products INS/GDP/002
	3. Good inspection Guideline by the South African Pharmacy Council
	4. National Drug Authority Regulations SI 35 for Licensing of Pharmacies and Drug Shops
	5. National Drug Authority Regulations SI 36 for Certificate for Suitability of Premises for Pharmacies and Drug Shops.
	6. SOP for Preparation and Conducting GMP Inspections
1. **Appendices**
	1. GPP Inspection Report for Retail Pharmacies
	2. Accreditation Inspection Report for Drug Shops
	3. GDP Inspection tool for Wholesale Pharmacies
	4. Addendum to the Inspection Report
	5. Form13- Inspection Report for Wholesale Pharmacy
	6. Form 14- Inspection Report for Retail Pharmacy
	7. Form 15-Inspection Report for Licensed Seller (Class C Drug Shop)
2. **Document Revision History**

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