GUIDELINES ON COMPETENCE PROFILE OF SUPERVISING PHARMACISTS FOR A PHARMACEUTICAL MANUFACTURING FACILITY

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Adoption and approval of these professional guidelines

In EXERCISE of the powers conferred upon the Drug Authority by Section 5(i) of the National Drug Policy and Authority Act, Cap. 206 of the Laws of Uganda (2000 Edition), the Drug Authority hereby ADOPTS and ISSUES these **"Professional Guidelines on Competence Profile of Supervising Pharmacists for a Pharmaceutical Manufacturing Facility"** Doc. No. INS/GDL/048, Revision No. 0", made this 28th day of August 2023, that take effect on 6th September 2023.

Signature _____

Dr. Medard Bitekyerezo

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Abbreviations and Acronyms

DIE	Directorate of Inspectorate And Enforcement
GMP	Good Manufacturing Practices
NDA	National Drug Authority

1. INTRODUCTION

National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition). The Act established a National Drug Policy and National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

1.2 Objective of these guidelines

i) These guidelines are intended to provide guidance on the required competency for supervising pharmacists to work in a pharmaceutical manufacturing facility.

ii) To provide guidance on the roles of supervising pharmacists in a pharmaceutical manufacturing facility.

1.3 Policy

Sections 5 (a, e and f) and Section 38 (3) of The National Drug Policy and Authority Act, and Regulation 20 of The National Drug Policy and Authority (Licensing) Regulations, 2014 authorize NDA to establish measures to ensure quality of drugs, promotion and control of local production of essential medicines

These guidelines are developed in accordance with the National Drug Policy and Authority Act (Cap 206 of the laws of Uganda), Section 5 which states that *"the Drug Authority shall be charged with the implementation of the national drug policy and, in particular, but without derogation of the foregoing, shall –*

a) deal with the development and regulation of the pharmacies and drugs in the country"
b) Control the quality of drugs
c) promote and control local production of essential drugs; promote and control local production of essential drugs"

1.3.1 Section 38 (3) of the National Drug Policy and Authority Act states that *"No person shall manufacture any classified drug unless the processes of manufacture are carried out or supervised by a pharmacist."*

1.3.2 Section 64 (1) (j) states that *"the Minister may, on the advice of the drug authority, by statutory instrument, make regulations generally for better carrying into effect the provisions of this Act— the registration and operation of authorized persons"*

1.3.3 Section 1 of Regulation 20 of The National Drug Policy and Authority (Licensing) Regulations, 2014 states that *"the manufacturing process shall be carried out by a suitably qualified pharmacist."*

1.3.4 Section 2 of Regulation 20 of The National Drug Policy and Authority (Licensing) Regulations, 2014 states that *"the manufacturing process shall be supervised by the pharmacist whose registration is submitted with the application in regulation 18 (2)."*

1.3.5 Section 3 of Regulation 20 of The National Drug Policy and Authority (Licensing) Regulations, 2014 states that *"the process of quality control and quality assurance shall be under the supervision of a registered pharmacist and shall be conducted by a team of qualified pharmacists approved by the Authority."*

1.4 Scope

These guidelines shall apply to pharmacists supervising production, quality control and quality assurance activities in manufacturing facilities for drug products and drug substance in Uganda.

2. INTERPRETATION

2.1 **Batch:** A defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.

2.2 **Marketing Authorization/ Product registration:** A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeia or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labeling and shelf-life.

2.3 **Supervising Pharmacist;** Pharmacist supervising production, quality control or quality assurance activities.

3. QUALIFICATION, TRAINING AND PRACTICAL EXPERIENCE OF SUPERVISING PHARMACIST

3.1 A supervising pharmacist for activities of production, quality control or quality assurance shall be in possession of a valid certificate of registration from the Pharmacy Board of Uganda.

3.2 The supervising pharmacist shall have acquired practical experience of;

a) at least two years' experience in one or more undertakings which are licensed by NDA or authorized by stringent NMRAs to manufacture drug products and or drug substances; in production, quality control or quality assurance areas. or

b) at least two years' regulatory experience in quality control of drugs or GMP inspections of pharmaceutical manufacturers.

4. ROLES OF A SUPERVISING PHARAMCIST IN CHARGE OF QUALITY ASSURANCE

4.1 A supervising pharmacist in charge of quality assurance, without prejudice to his relationship with the holder of a certificate of registration[1], is responsible, for ensuring:

a) in the case of manufacture of pharmaceutical products or drug substances, that each batch of pharmaceutical products or drug substance has been manufactured and checked in compliance with the requirements of the registration;

b) that each production batch has undergone a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of pharmaceutical products is in accordance with the requirements of the registration;

c) that the manufacturer of the pharmaceutical product applies standards of good manufacturing practice at all times during the production process of each batch of pharmaceutical product and or drug substance.

d) that prior to the release for sale, placing on the market, or export a certification is made in a register or equivalent document provided for that purpose, that each batch of pharmaceutical product or drug substance has been manufactured and checked in compliance with the National Drug Authority and policy act and in accordance with the requirements of the registration.

e) that the principal manufacturing and testing processes of the pharmaceutical products and drug substance have been successfully validated in accordance with stipulated qualification and validation requirements.

f) that any deviations or planned changes in the production and quality control of the pharmaceutical products have been authorized by the persons responsible as per the defined system.

g) that any changes requiring variation to the registration or manufacturing authorization have been notified and authorized by the relevant authority.

[1] Pursuant to the Uganda National Drug Policy and Authority Act, Market Authorization Holders are referred to as Holders of Certificates of registration and the process of marketing authorization is referred to as registration.

h) All necessary production and quality control documentation has been completed and endorsed by the authorized staff and is in compliance to the requirements of market authorization.

5. ROLES OF A SUPERVISING PHARMACIST IN CHARGE OF PRODUCTION

5.1 A supervising pharmacist in charge of production, without prejudice to his relationship with the holder of the manufacturing authorization, is responsible for:

a) approving instructions relating to production operations and to ensure their strict implementation;

b) ensuring that products are produced and stored according to the appropriate documentation so as to obtain the required quality;

c) ensuring that the production records are evaluated and signed by pharmacist in charge of quality assurance;

d) ensuring that production department, premises and equipment are qualified and maintained;

e) ensuring that the appropriate validations are done;

f) ensuring that the required initial and continuing training of department personnel is carried out and adapted according to need.

6. ROLES OF A SUPERVISING PHARAMCIST IN CHARGE OF QUALITY CONTROL

6.1 A supervising pharmacist in charge of quality, without prejudice to his relationship with the holder of the manufacturing authorization, is responsible for:

a) approval or rejection, as he/she sees fit, starting materials, packaging materials, intermediate, bulk and finished products;

b) ensuring that all necessary testing is carried out and the associated records evaluated;

c) that specifications, sampling instructions, test methods and other Quality Control procedures are approved;

d) approving and monitoring any contract analysts;

e) ensuring the qualification and maintenance of his/her department, premises and equipment;

f) ensuring that the appropriate validations are done;

g) ensuring that the required initial and continuing training of his/her department personnel is carried out and adapted according to need.

7. DELEGATION OF DUTIES OF A SUPERVISING PHARMACIST

7.1 The responsibilities of Supervising pharmacists in charge of quality assurance may be delegated to any other supervising pharmacists in the quality unit who have demonstrable experience and qualification as the appointed supervising

pharmacist in charge of quality assurance.

7.2 The responsibilities of Supervising pharmacists in charge of quality control may be delegated to other supervising pharmacists in the quality control unit who have demonstrable experience and qualification as the appointed supervising pharmacist in charge of quality control unit.

7.3 The responsibilities of Supervising pharmacists in charge of production may be delegated to other supervising pharmacists in the quality production department who have demonstrable experience and qualification as the appointed supervising pharmacist in charge of production.

7.4 In delegation of the roles and responsibilities of a supervising pharmacist, the manufacturer or holder of a certificate of registration must ensure that the supervising pharmacists in charge of production and the supervising pharmacists in charge of quality control are independent of each other at all times.

8. REFERENCES

EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Part 1, Volume 4.

NDA Guidelines on Good Manufacturing Practices for Medicinal Products Document Number INS/GDL/001 part 1, Revision No. 3.

The National Drug Policy and Authority Act. Cap 206.

DOCUMENT HISTORY

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