



FINAL COPY

**GUIDELINES FOR REGULATION OF  
TRADITIONAL/HERBAL  
MEDICINES (LOCAL)**

**IN  
UGANDA**

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## ACRONYMS

NDA	:	National Drug Authority
ADR	:	Adverse Drug Reaction
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization
BMR	:	Batch Manufacturing Records
GACP	:	Good Agricultural and Collection Practices
SOP	:	Standard Operating Procedure
PM	:	Promotional Material

## **CHAPTER ONE : INTRODUCTORY BACKGROUND**

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National Drug Authority mission is to ensure that only good quality, safe and efficacious human and veterinary medicines are available and are correctly handled in Uganda; and to contribute towards their accessibility, cost effectiveness and appropriate use. It is against this background that these guidelines have been drawn to address the many issues of quality of herbal medicines that have arisen in the recent past.

These guidelines will mostly dwell on the manufacture, registration and sale of herbal medicines. The practice of herbal Medicine will be handled under the auspices of the various (professional) organizations that unite herbalists in the country. It is hoped that subsequent to putting in place guidelines for the regulation of herbal medicines the existing herbal associations in the country will unite under one umbrella body as is the case with other professionals. The National; Drug Authority will cooperate with MoH in formulating a policy on Traditional Medicine.

### **1.1. BACKGROUND**

A technical advisory select committee on herbal medicines wrote a report in September 1997, formulating policy regulations on local herbal medicines in Uganda. This has been translated into five (5) local languages, and is currently being used. This report has been used as a basis for sensitizing most of the districts in Uganda by the secretariat staff for the period 2005 -2008. Although relevant at that time it has been found lacking in many areas and hence the need to develop a comprehensive guideline.

National Drug Authority Secretariat, with funding from WHO, carried out more sensitization workshops in the country, focusing on regulatory requirements for local herbal medicinal products for the period 2005-2007. During these sensitization workshops, a lot of consultations were made with different stakeholders and the data collected has been used in developing these guidelines.

### **1.2. PROBLEMS/CHALLENGES;**

1. Owing to very low literacy levels in Uganda, many herbalists cannot read or write making it hard for them to compile and submit application documents to NDA.
2. There is a widespread misconception amongst herbalists that documentation requested for by NDA is intended to steal their indigenous knowledge and thus, there has been hesitation to submit applications.
3. Lack of funds to meet minimum requirements for NDA's approval.
4. Uncontrolled advertising all over the country.
5. Unethical practices not limited to but including sacrifices of human beings, adulteration of products with western medicines, peddling of products with no therapeutic benefits, making unsubstantiated medicinal claims.
6. Haphazard Manufacture and sale of herbal products
7. Lack of a single forum for local herbalists but rather many different associations with varying objectives. This has made it difficult for NDA to come to a unifying conclusion in many of the controversial areas.
8. Lack of a recognized body, to certify herbalists who would work in herbal manufacturing facilities and herbal outlets.
9. Building consensus among herbalists for the need to be regulated.
10. Limited capacity in both personnel and equipment to fully assess and analyze information submitted by applicants.
11. Advocacy by legislators has been limited due to lack of information among stake holders.

### 1.3. POLICY

The NDP/A Act chapter 206 of the Uganda Laws mandates NDA to regulate manufacture, registration and sale of herbal medicines. The regulation also includes control on promotion/advertisements pertaining to herbal medicines. National Drug Authority regulates only the product and information about it and not the practice.

### 1.4. OBJECTIVES.

These guidelines have been developed to guide applicants dealing in herbal medicinal products conform to regulatory requirements so as to foster proper monitoring of safety and efficacy issues involved. That is;-

- To guide Local manufacturers on acceptable minimum requirements for the manufacture of herbal medicinal products;
- To guide applicants on how to meet minimum requirements for registration of herbal medicinal products;
- To offer guidance on Licensing of herbal medicine sales outlets.
- To put in place a safety and monitoring mechanism;
- To guide on advertising of herbal medicinal products.
- To collaborate with other institutions to ensure that guidelines on good Agricultural practices are followed

Applicants are advised to study these guidelines carefully and understand the sections included herein before attempting to approach National Drug Authority in matters of regulation.

### 1.5 CLASSIFICATION OF TRADITIONAL MEDICINES

#### 1.5.1 Category 1: Home remedies

Medicines in this category are prepared by the traditional health practitioners or family members for treatment of individual patients and each has the following characteristics:

- (i) It is prepared in an extemporaneous (prepared there and then i.e. without previous planning but according to need) manner and according to traditional methods.
- (ii) Its safety and efficacy should be justified by long period of use (At least for more than ten (10) years).
- (iii) This category of medicines is not directly controlled by the national drug regulatory agency. **However, the traditional health practitioners should be certified by the recognition/registration of their practice** by the community or any local Authority/Council.
- (iv) It could be used freely by local people.
- (v) If the medicines in this category are introduced into the market (For commercial use), they must meet the minimum regulatory requirements for the registration of traditional medicines. \*\*

#### 1.5.2 Category 2: Galenicals.

Category 2 traditional medicines are popularly used in the community with commercial possibility and each possesses the following characteristics:

- (i) It is traditionally used in a locality and is well known by the local population, in terms of both its mode of use and treatment;

- (ii) Its formulation is well known in a given locality and its preparation is according to established/ traditional methods.
- (iii) Its safety and efficacy should be justified by long period of use. At least more than ten (10) years.
- (iv) However, if the medicines in this category are to go into the market (For commercial use), they have to meet the general minimum requirements for registration of traditional medicines.\*\*

### **1.5.3 Category 3 Traditional medicines**

#### **1.5.3.1 Category 3A Researched- Semi Industrial Traditional Medicines**

This category of medicines is developed based on scientific research and has the following characteristics:

- (i) It is developed by research based on ethno (common cultural tradition, indigenous) medical use.
- (ii) The new formulation, dosage, dosage form and therapeutic use are based on research data.
- (iii) It may be produced at semi-industrial scale
- (iv) Its safety and efficacy are based on research data derived from standard scientific and clinical investigations.
- (v) This category of medicines may be used within the research establishment.
- (vi) However, if it goes into the market (For commercial use), it has to meet the general minimum requirements for registration of traditional medicines.

#### **1.5.3.3 Category 3B Researched – Industrial Traditional Medicines**

This category of medicines is developed based on scientific research and has the following characteristics:

- (i). It is developed by research based on ethno (common cultural tradition, indigenous) medical use.
- (ii). The new formulation, dosage, dosage form and therapeutic use are based on research data.
- (iii) It may be produced at Industrial scale
- (iv) Its safety and efficacy are based on research data derived from standard scientific and clinical investigations.
- (v) This category of medicines may be used in the market (For commercial use) and has to meet the general minimum requirements for registration of traditional medicines

#### **1.5.3.4 CATEGORY 4 Imported Traditional Medicines**

These are imported traditional medicines each with the following characteristics:

- (i) It originates from a foreign country.
- (ii) It should meet the definition of traditional medicines.
- (iii) It should be registered in the originating country.
- (iv) It should also meet the requirements for regulation of traditional medicines of National Drug Authority, Uganda. Guidelines for category 4 already exist in National Drug Authority and this category is **not** included in the general minimum requirements.

## CHAPTER TWO : MANUFACTURE OF HERBAL MEDICINAL PRODUCTS

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### 2.1. GENERAL

Unlike conventional pharmaceutical products, which are usually prepared from synthetic materials through the application of reproducible manufacturing techniques and procedure, herbal medicinal products are prepared from material of plant origin which may be subject to contamination and deterioration, and may vary in composition and properties. The control of the starting materials, storage and processing assumes particular importance because of the often complex and variable nature of many herbal medicinal products.

### 2.2. CULTIVATION AND COLLECTION OF MEDICINAL PLANTS

- 1) It is desirable that cultivation and collection of medicinal plants, as the starting materials for herbal medicines should follow the guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. (In this respect WHO(GACP) will be followed )
- 2) A lot of care should be taken during harvest on large commercial farms.
- 3) Mix up of herbal materials and adulteration should be avoided during harvesting.
- 4) The actual harvesting and transportation of raw materials should ensure that the quality is preserved since it will finally affect the final product.
- 5) The herbal material should be promptly unloaded and unpacked on arrival at the processing facility.
- 6) During this operation, the herbal material should not be exposed to direct contact with soil.
- 7) Moreover, it should not be exposed directly to the sun (except in cases where there is a specific need, e.g. sun-drying)
- 8) It should be protected from rain and any form of contamination such as heavy metals

### 2.3. SANITATION AND HYGIENE.

In order to avoid damage alterations caused by microbial organisms and to reduce contamination in general, a high level of sanitation and hygiene during manufacture is necessary as indicated below;

- 1) Water supply to manufacturing unit should be monitored, and, if necessary treated appropriately to ensure consistency of quality.
- 2) Care should be taken to choose appropriate methods for cleaning depending on the characteristics of herbal raw materials.
- 3) **N.B.** Washing dried herbal raw materials with water, as a rule, is not appropriate. When their cleaning is necessary, air duster/air shower should be employed.
- 4) Waste from the manufacturing unit should be routinely disposed off in the most appropriate manner so as to maintain a high degree of hygiene in the manufacturing area. *Refer to Guide to the European market for Medicinal Plants and Extracts.*

#### Personal hygiene

Personnel entrusted with handling of herbal materials, herbal preparations and finished herbal products should be required to have a high degree of personal hygiene.

- 1) They should have received adequate training regarding their hygiene control.
- 2) They should be required to be without infectious diseases, or skin diseases.
- 3) Clear and illustrative Standard Operating Procedures (SOPs) listing the basic hygiene requirements should be made available.

- 4) Personnel must be protected from contact with toxic irritants and potentially allergenic plant materials by means of adequate protective clothing.
- 5) They should wear suitable and fitting garments such as: - gloves, caps, masks, work suits and shoes through the whole procedure from plant processing to product manufacturing.

## **2.4. PREMISES.**

### **2.4.1. Principle**

Premises must be located, designed, constructed, adapted, and maintained to suit the operations to be carried out. Their layout and design must aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of products. These guidelines may not limit on the size of the premises and number of rooms however the following sections should clearly be designated: Storage area, quarantine area and production and drying area for raw materials that do not need direct sunlight. In addition to the above;-

- 1) Premises should be situated in an environment that, when considered together with measures to protect the manufacturing process, presents minimum risk of causing any contamination of materials or products.
- 2) Premises used for the manufacture of drug products should be suitably designed and constructed to facilitate good sanitation.
- 3) Premises should be carefully maintained, and it should be ensured that repair and maintenance operations do not present any hazard to the quality of products. Premises should be cleaned and, where applicable, disinfected according to detailed written procedures.
- 4) Electrical supply, lighting, temperature, humidity, and ventilation should be appropriate and such that they do not adversely affect, directly or indirectly, either the herbal products during their manufacture and storage, or the accurate functioning of equipment.
- 5) Premises should be designed and equipped so as to afford maximum protection against the entry of insects or other animals.

### **2.4.2. Auxiliary areas**

- 1) Rest and refreshment rooms should be separate from other areas. These should have clean drinking water and smoking of cigars, cigarettes, tobacco and sniffing of other habit forming substances should not be done in these areas.
- 2) Facilities for changing and storing clothes and for washing and toilet purposes should be easily accessible and appropriate for the number of users. Toilets should not communicate directly with production or storage areas. Toilets should have running water, soap and hand drying facilities.
- 3) Maintenance workshops should be separated from production areas. Whenever parts and tools are stored in the production area, they should be kept in rooms or lockers reserved for that use.
- 4) Animal houses should be well isolated from other areas, with separate entrance (animal access) and air-handling facilities.

### **2.4.3. Storage areas.**

- 1) Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and products: starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned, or recalled products.

- 2) Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required (e.g., temperature, humidity) these should be provided, checked, and monitored.
- 3) Receiving and dispatch bays should protect materials and products from the weather. Reception areas should be designed and equipped to allow containers of incoming materials to be cleaned if necessary before storage.
- 4) Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and their access restricted to authorized personnel. Any system replacing the physical quarantine should give equivalent security.
- 5) There should normally be a separate sampling area for starting materials. If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross-contamination.
- 6) Segregation should be provided for the storage of rejected, recalled, or returned materials or products.
- 7) Highly active materials, narcotics, other dangerous drugs, and substances presenting special risks of abuse, fire, or explosion should be stored in safe and secure areas.
- 8) Printed packaging materials are considered critical to the conformity of the herbal products to its labeling, and special attention should be paid to the safe and secure storage of these materials.

#### **2.4.4. Weighing areas (may belong to either storage or production areas) Dispensary.**

- The weighing of starting materials and the estimation of yield by weighing should usually be carried out in separate weighing areas designed for that use, for example with provisions for dust control.

#### **2.4.5. Production area.**

- 1) In order to minimize the risk of a serious medical hazard due to cross-contamination, dedicated and self-contained facilities must be available for the production of particular herbal products.
- 2) The production of certain other products, such as some antibiotics, hormones, cytotoxic substances, highly active pharmaceutical products, and non-pharmaceutical products, should not be conducted in the same facilities.
- 3) The manufacture of technical poisons, such as pesticides and herbicides, should not normally be allowed in premises used for the manufacture of herbal products.
- 4) In exceptional cases, the principle of campaign working in the same facilities can be accepted provided that specific precautions are taken and the necessary validations are made.
- 5) Premises should preferably be laid out in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels.
- 6) The adequacy of the working and in-process storage space should permit the orderly and logical positioning of equipment and materials so as to minimize the risk of confusion between different herbal products or their components, to avoid cross-contamination, and to minimize the risk of omission or wrong application of any of the manufacturing or control steps.
- 7) Where starting raw material, primary packaging materials and intermediate or bulk products are exposed to the environment, interior surfaces (walls, floors, and ceilings) should be smooth and free cracks and open joints, should not shed particulate matter, and should permit easy and effective cleaning and, if necessary, disinfection.
- 8) Pipe work, light fittings, ventilation points, and other services should be designed and sited to avoid the creation of recesses that are difficult to clean. As far as possible, for maintenance purposes, they should be accessible from outside the manufacturing areas.

- 9) Drains should be of adequate size and equipped to prevent back-flow. Open channels should be avoided where possible, but if they are necessary they should be shallow to facilitate cleaning and disinfection.
- 10) Production areas should be effectively ventilated, with air-control facilities (including control of temperature and, where necessary, humidity and filtration) appropriate to the products handled, to the operations undertaken, and to the external environment. These areas should be regularly monitored during production and non-production periods to ensure compliance with their design specifications.
- 11) Premises for the packaging of herbal products should be specifically designed and laid out so as to avoid mix-ups or cross-contamination.
- 12) Production areas should be well lit, particularly where visual on-line controls are carried out.

#### **2.4.6. Quality control area**

- 1) Quality control laboratories should be separated from production areas. Areas where biological, microbiological, or radioisotope test methods are employed should be separated from each other.
- 2) Control laboratories should be designed to suit the operations to be carried out in them. Sufficient space should be given to avoid mix-ups and cross-contamination. There should be adequate suitable storage space for samples, reference standards (if necessary, with cooling), and records.
- 3) The design of the laboratories should take into account the suitability of construction materials, prevention of fumes, and ventilation. Separate air-handling units and other provisions are needed for biological, microbiological, and radioisotope laboratories.
- 4) A separate room may be needed for instruments to protect them against electrical interference, vibration, contact with excessive moisture, and other external factors, or where it is necessary to isolate the instruments.

#### **2.5. EQUIPMENT.**

Since processing of herbal materials may generate dust or material which can be easily subject to pest-infestation or microbiological contamination and cross contamination, cleaning of equipment is particularly important.

Vacuum or wet cleaning methods are to be preferred. If wet cleaning is applied, the equipment should be dried immediately after cleaning in order to avoid the growth of microorganisms. Compressed air and brushes should be used with care and avoided if possible, as they increase the risk of product contamination.

Wooden equipment should not be used unless tradition demands the use of wooden material. Where it is necessary to use traditional equipment (such as wooden implements, clay pots, pallets, hoppers, e.t.c.), they should be restricted [dedicated] for that purpose. When such equipment is used, it is advised not to come into direct contact with chemicals and contaminated material. If it is unavoidable, special consideration must be given to their cleaning as wooden material may retain odour and colour and is easily contaminated.

#### **2.6. MATERIALS**

All incoming materials should be quarantined and stored under appropriate conditions taking into account the degradable character of herbal materials and herbal preparations.

## 2.7. DOCUMENTATION

This covers documents relating to specifications and processing instructions which should be kept at the manufacturing facility.

### 2.7.1. Specifications for starting materials, herbal preparations and finished herbal products

Specifications for starting herbal materials, for herbal preparations and finished herbal products are primarily intended to define the quality rather than to establish full characterization, and should focus on those characteristics found to be useful in ensuring the safety and efficacy. Consistent quality for herbal medicines (finished herbal products) can only be assured if the starting herbal materials are defined in a rigorous and detailed manner. In some cases more detailed information may be needed on aspects of their collection or agricultural production.

The specifications for medicinal plant materials should as far as possible include the following:

- 1) The botanical name, with reference to the authors (This should be accompanied by a certificate of verification or a document from the National Herbarium)
- 2) Details of the source of the plant (country or region of origin, and where applicable, method of cultivation, time of harvesting, collection procedures, possible pesticides used, etc.).
- 3) Part of the plant used.
- 4) The drying system.
- 5) A description of the plant material based on visual and/or microscopical/macrosopic inspection.
- 6) Suitable identification tests including, where appropriate, identification tests for known active ingredients or markers.
- 7) The assay, where appropriate, of constituents of known therapeutic activity or markers.
- 8) Methods for the determination of possible pesticide contamination and the acceptable limits for such contamination.
- 9) Test results for toxic metal and other contaminants, foreign materials, and adulterants.
- 10) Test results for microbial contamination and aflatoxins.
- 11) Method used to reduce fungal/microbial contamination or other infestation should be documented.
- 12) Specifications for starting materials (and also of primary or printed packaging materials) should include, if applicable, reference to a pharmacopoeia monograph.
- 13) If the herbal material for processing does not comply with its quality specifications, the rules that apply for its rejection, and storage and disposal of the rejected herbal material should be included.

#### 2.7.1.1. Qualitative and quantitative requirements

These should be expressed in the following ways:

1. Medicinal plant material:
  - (a) The quantity of plant material must be stated; or
  - (b) The quantity of plant material may be given as a range, corresponding to a defined quantity of constituents of known therapeutic activity.

Example:

***Name of active ingredient Quantity***

Sennae folium (a) 900 mg or (b) 830–1000 mg, corresponding to 25 mg of hydroxyanthracene glycosides, calculated as sennoside B

2. Plant preparation:

- (a) The equivalent quantity or the ratio of plant material to plant preparation must be stated (this does not apply to fatty or essential oils); or
- (b) The quantity of the plant preparation may be given as a range, corresponding to a defined quantity of constituents with known therapeutic activity (see example).

The composition of any solvent or solvent mixture used and the physical state of the extract must be indicated.

If any other substance is added during the manufacture of the plant preparation to adjust the level of constituents of known therapeutic activity, or for any other purpose, the added substance(s) must be described as “other ingredients” and the genuine extract as the “active ingredient”.

Example:

***Name of active ingredient Quantity***

Sennae folium (a) 125 mg ethanolic extract (8: 1) or 125 mg ethanolic extract, equivalent to 1000 mg of Sennae folium or (b) 100–130 mg ethanolic extract (8 : 1), corresponding to 25 mg of hydroxyanthracene glycosides, calculated as sennoside B

***Other ingredient***

Dextrose 20–50 mg

**2.7.2. Specifications for the finished herbal products**

- 1) Microbiological contamination and tests for other toxins
- 2) Uniformity of weight (for tablets, single-dose powders, suppositories, herbal tea in sachets and capsules, e.t.c.), disintegration time (for tablets, capsules, suppositories and pills), hardness and friability (for example, uncoated tablets), viscosity (for internal and external fluids), consistency (semisolid preparations), and dissolution (tablets or capsules), if applicable.
- 3) Physical appearance such as colour, odour, form, shape, size and texture
- 4) Loss on drying or water content
- 5) Identity tests, qualitative determination of relevant substances of the plants (e.g. fingerprint chromatograms)
- 6) Quantification of relevant active ingredients if they are identified and the adequate analytical methods are available
- 7) Limit tests for residual solvents

The control tests for the finished product must be such as to allow the qualitative and quantitative determination of the active ingredients. If the therapeutic activity of constituents is known, this must be specified and determined quantitatively. When this is not feasible, specifications must be based on the determination of markers.

If either the final product or the preparation contains several plant materials and a quantitative determination of each active ingredient is not feasible, the combined content of several active ingredients may be determined. The need for such a procedure must be justified.

### **2.7.3. Specifications for Herbal preparations**

The specification of herbal preparations consists of relevant items of the specification of herbal materials of finished herbal products outlined above.

### **2.7.4. Processing instructions**

The processing instructions should list the different operations to be performed on the plant material, such as drying, crushing and sifting, and also include the temperatures required in the drying process, and the methods to be used to control fragments or particle size. Instructions on sieving or other methods of removing foreign materials should also be given. Details of any process, such as fumigation, used to reduce microbial contamination, together with methods of determining the extent of such contamination, should also be given.

For the production of plant preparations, the instructions should specify any vehicle or solvent that may be used, the times and temperatures to be observed during extraction, and any concentration methods that may be required.

## **2.8. PERSONNEL**

Production and release of herbal medicines should be under the authority of a person who has been trained in the specific features of the processing and quality control of herbal materials, herbal preparations and finished herbal products.

People with accrued knowledge in the production of herbal medicines should be allowed to practice as their knowledge is being assessed and documented.

## **2.9. QUALIFICATION AND VALIDATION**

For practical purposes validation has been left out intentionally in these guidelines. However where necessary the National Drug Policy and Authority (GMP Regulations-2008) should be consulted.

## **2.10. COMPLAINTS**

A manufacturing facility should have a system for handling market complaints. There are two basic types of complaints; product quality complaints and adverse reactions/events. Product quality complaints may be caused by problems such as faulty manufacture, product defects or deterioration as well as adulteration of the herbal material.

- 1) These complaints should be recorded in detail and the causes thoroughly investigated. There should be a written procedure to describe the action to be taken.
- 2) A register should be maintained where reports of Adverse Drug Reactions (ADR) are recorded. Investigations should be conducted to find if the ADR is due to poor quality problem and whether such a problem is already reported in the literature or it is a new observation.
- 3) National Drug Authority should be kept informed about any complaints leading to recall or restriction on supply and the records should be available for inspection.

## **2.11. PRODUCT RECALLS**

The product recall procedure should be related to and depends very much on the NDA recall procedures. An SOP should be included and observed for storage of recalled herbal medicinal products in a secure area, while their fate is being decided.

## **2.12. CONTRACT PRODUCTION AND ANALYSIS**

Where contract production is to take place the premises must be inspected and licensed by NDA. The details of the contract should be easily accessible

## **2.13. SELF INSPECTION**

At least one member of the self-inspection team should possess a thorough knowledge on herbal medicines.

## **2.14. TRAINING**

It is desirable that personnel involved in production and Quality Control should have appropriate training in relevant fields such as pharmaceutical technology, taxonomic botany, phytochemistry, pharmacognosy, hygiene, microbiology, and related expertise (such as traditional use of herbal medicines).

## **2.15. GOOD PRACTICES IN QUALITY CONTROL DURING PRODUCTION.**

### **2.15.1. General.**

There should be a quality control department independent of other department with the overall responsibility of ensuring that safe and good quality products are consistently manufactured.

### **2.15.2. Premises;**

There should be a separate room with adequate space designed for the laboratory with proper ventilation and running water.

### **2.15.3. Personnel**

- 1) The department should preferably be under the authority of a person with appropriate qualifications and experience
- 2) He /she will be a person with a dispensing background, chemist or pharmacist.
- 3) For small scale manufacturers it may be a person of basic science knowledge i.e. Diploma in Botany, laboratory technology or pharmacy.

### **2.15.4 Equipment.**

The laboratory should have capacity to carry out basic tests on the raw materials and the finished products. This requirement applies to manufacturers of syrups, solutions, and suspensions.

It is desirable for all manufacturers using powdered raw materials or producing powdered products to have the following-: moisture analyzer, oven, and analytical balance besides other basic equipments.

## **2.16. Documentation.**

In addition to quality control documents, Quality Control and Quality Assurance will review and approve all documents used in production. This includes but is not limited to;

- 1) Batch Manufacturing Records (BMR)
- 2) SOPs
- 3) Sampling and testing procedures for raw materials and finished products
- 4) Records of the results of inspection and testing of materials against specifications.

## **2.17. PROCESSES**

### **2.17.1. Sampling**

This shall be done in a manner that ensures that a representative sample is drawn for analysis.

Sufficient samples shall be retained to prompt future examination of products if necessary, and also aid monitoring of any changes in PH, color and smell over time.

### **2.17.2. TESTING /ANALYSIS.**

Where the facility does not have capacity to analyze its raw materials and products, it must have an agreement with at least one external quality control laboratory. In such a case a memorandum of understanding with the laboratory shall be submitted as a requirement for registration.

Copies of certificates of analysis from the contracted laboratory for raw materials and final products analysed shall be kept by Quality Control Department

## CHAPTER THREE: MINIMUM REGULATORY REQUIREMENTS FOR REGISTRATION OF HERBAL MEDICINAL PRODUCTS FOR INTRODUCTION INTO THE MARKET/ COMMERCIAL USE

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### 3.1.1 PHARMACEUTICAL INFORMATION

The following pharmaceutical information should be made available at the time of registration;

- 1) product name
- 2) name of the active or main constituent
- 3) indications
- 4) form of preparation, e.g. belladonna leaf, opium tincture, yeast tablets, convallaria tonic
- 5) dosage forms e.g. tablet, powder, ointment, capsule
- 6) strength of dosage form, where applicable
- 7) excipients e.g. starch, honey, "emmumbwa"
- 8) major adverse effects
- 9) storage conditions and shelf life/expiry date
- 10) pack sizes or weight
- 11) name and address of manufacturer

### 3.1.2 MONOGRAPH

A monograph will be required in the following cases and must be availed to NDA

- I. Where a drug is reputed to have adverse effects and/ or the history of the use of the drug is not well known in Uganda.
- II. The active or main constituents of the drug is known

### 3.1.3 LATIN BINOMIAL SYNONYM

The Genus and species, and, where applicable, variety be stated (Latin binomial synonym) for the plant or plants (being the source of herbal medicines) should be specified. . In case of failure to ascertain the botanical identity of the plant, the name in any of the local languages in Uganda should be supplied in addition to a herbarium specimen (Voucher number) verified by the National Herbarium should be provided.

### 3.1.4. MINIMUM REQUIREMENTS FOR SAFETY AND EFFICACY

#### I) SAFETY

##### a) *Botanical identification/authentication*

Name in Latin (genus and species) of the plant species, local names and family

##### b) *Ethno-medical Information (Literature search/database)*

- i. Information regarding the safety and efficacy of the product.
- ii. Documented proof of long period use should be taken into consideration when assessing safety. Detailed toxicological studies, documented experience of long term use without evidence of safety problems should form the basis of the risk assessment.

##### c) *Toxicity Studies:*

If the product has been traditionally used without demonstrated harm, no specific restrictive regulatory action will be undertaken unless new evidence demands a revised risk-benefit assessment.

- i. If a toxicological risk is known, it is mandatory to conduct standard toxicological studies and data derived from such studies should be appropriately documented and submitted to the regulatory authorities.
- ii. Toxicity data should be submitted if the long term traditional use can not be documented or if there are doubts on safety.
- iii. The absence of any reported or documented side-effects is not an absolute assurance of safety for traditional medicines; therefore some toxicological tests may be necessary.
- iv. Products that require acute toxicity studies should be submitted with a report.
- v. Tests include: (Can be availed according to guidelines by WHO) Acute toxicity, Immunotoxicity (e.g. tests for allergic reactions), genotoxicity, carcinogenicity and reproductive toxicity through long term use.

**d) Dosage (Posology) :** Therapeutic prescribed amount of the medicine to be administered to the patient. The measures and age group should be included.

**e) Dosage forms** in which the drug is presented, e.g. solution, liquid, suspension, emulsion, ointment, suppository, tablet, capsule, etc.

**f) Adverse reactions (Side effects):** an unwanted effect that was not intended but happens when product is taken e a subject suffers loose motion after taking an antimalarial product.

**g) Contraindications:** A condition which makes a particular treatment or procedure inadvisable or against should be mentioned.

**h) Warnings:** An intimation in case of any danger of effect after or during use of the product.

**i) Precautions:** Measures that should be taken in case of pregnancy, lactation, renal and hepatic failure etc. during use of the product.

## **II) EFFICACY**

For evaluation of traditional medical preparations, the following evidence shall be supplied

### **a) Assessment of efficacy**

Therapeutic activity refers to the successful prevention, diagnosis and treatment of physical and psychological illness; improvement of symptoms of illness; as well as beneficial alteration or regulation of the physical and mental status of the body and mind

- Requirements for proof of efficacy should depend on;
  - i. The kind of indications for use,
  - ii. individual experiences recorded in reports from physicians,
  - iii. experiences from traditional practitioners or
  - iv. Experiences from treated patients.

- Clinical evidence will be required in cases where traditional use has not been documented. Same applies to new formula consisting of traditionally used plants but with new appropriate indications.

**b) Active ingredients**

- i. The preparation of these medicines should be standardized to contain a defined amount of the active ingredients,
- ii. Where more than one active ingredient is contained in a product, one of the ingredients can be used as the reference. However all the active ingredients contained in the product should be mentioned.
- iii. In cases where it is not possible to identify the active ingredients, the whole traditional medicines may be considered as one active ingredient.

**c) Evaluation of documented evidence of efficacy**

*The following shall be considered while evaluating efficacy;*

- i. Scientific literature validated by clinical trials
- ii. pharmacopoeias and other relevant documents
- iii. Unpublished (Gray) literature and ethnographic reports

**Note: Guidelines for clinical study of traditional medicines in WHO African region are available.**

**Traditional medicine labels shall include the following information**

- 1) Name of product
- 2) Quantitative list of main active ingredients including the common English name of the relevant plants. If the product is from abroad, plant name should be mentioned along with Latin name
- 3) Dosage form
- 4) Therapeutic indications
- 5) Dosage: the minimum and maximum as well as average dosage levels, must be stated (if appropriate, specified for children and the elderly).
- 6) Over-dosage information
- 7) Contraindications, warning, precautions, and major drug interactions in as far as these incidences are available.
- 8) Manufacturing date
- 9) Expiry date
- 10) Lot/Batch number
- 11) Name of manufacturer or company with full address.
- 12) Storage conditions.
- 13) Main vehicle/base

As part of registration procedure the following information should also be submitted:-

### **3.2 INFORMATION REQUIRED ON RAW MATERIALS FOR PRODUCTION.**

#### ***a) Identification of Plant (s)***

- i. Definition: Latin name of the plant (Family, Genus, species, varieties).
- ii. Synonyms: legitimate Latin binomial synonyms for the plant.
- iii. Selected vernacular names: a selective list of vernacular names for the plant.
- iv. Geographical distribution: cultivated or wild natural distribution in the country or region, imported, etc.,
- v. Description: a brief description of the living plant, this may include photographs and/or drawings.

#### ***b) Plant part used and condition of the plant material***

- i. General appearance
- ii. Organoleptic properties
- iii. Microscopic characteristics
- iv. Powdered plant material

#### ***c) General identity tests***

- Relevant Chemical, biological or physical assays

#### ***d) Mandatory Purity tests***

- i. Microbiological( for E-coli, Aspergillus, Salmonella)
- ii. Chemical
- iii. Loss on drying
- iv. Swelling index ( where applicable)
- v. Pesticide residues( where applicable)
- vi. Heavy metals( Mercury and Lead)
- vii. Radioactive residues( where applicable)
- viii. Other purity tests( where applicable)

#### **3.2.2 Finished products**

- 1) Qualitative and quantitative composition of the active components
- 2) Quantity and type of excipients
- 3) Quantification of the active ingredient
- 4) Description of the process of manufacture
- 5) Specifications of quality of the finished product
- 6) Methods of analysis
- 7) Stability studies
- 8) Licensing of manufacturing premises by National Drug Authority
- 9) Packaging

## **CHAPTER FOUR : LICENSING.**

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### **4.1. LICENSING OF HERBAL MEDICINE MANUFACTURING FACILITIES.**

A license shall be issued to manufacturers that will conform to manufacturing guidelines of herbal medicines as laid down by NDA.

### **4.2. LICENSING OF HERBAL MEDICINE OUTLETS.**

Inspections of herbal medicine outlets shall be carried out using NDA Inspectorate guidelines and the applicants for licenses shall have to meet the following NDA requirements:

### **4.3. FACILITIES.**

All facilities at which herbal medicines and /or preparations are handled, offered, marketed, or displayed shall:

- 1) Be constructed with materials of permanent nature
- 2) Be of adequate size avoiding congestion of stocks (i.e. 8-10m<sup>2</sup>)
- 3) Have shelves for display of herbal products and a sales counter
- 4) Be properly constructed to facilitate cleaning, maintenance, and other operations
- 5) Have adequate lighting, ventilation, and a proper ceiling.
- 6) Have a quarantine area for storage of medicines that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or secondary containers have been opened.
- 7) Be maintained in a clean and orderly manner
- 8) Be free from infestation by insects, rodents, birds, or vermin of any kind.
- 9) Have hand washing facilities and drying towel
- 10) Premises shall not be used for other activities (e.g. occult practices, tailoring, accommodation)

**NOTE:** where a herbal medicinal outlet is compounding a separate dedicated room should be identified.

#### **4.3.1. Stores.**

- 1) Operators of herbal medicine sales outlets should have enough storage areas
- 2) All herbal medicines shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, on the labels of such medicines.
- 3) If no storage requirements are established for herbal preparation, the medicine may be held at ambient temperature.
- 4) In case of medicines that require controlled temperatures, as defined in an official compendium, in order to ensure that its identity, quality, and purity are not adversely affected, there must be facilities for cold storage.
- 5) The storage area should be well ventilated and be equipped in such a way as to give protection against the entry of insects or other animals especially rodents.
- 6) Products should be stored off the floor on pallets.

#### **4.3.2. Packaging Containers**

- a) Herbal medicine should be kept in suitable containers
- b) No reuse of primary containers (e.g used mineral water bottles are picked and used to package the medicines and then sold in the market)

#### **4.4. RECORD KEEPING**

Herbal medicines distributor shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or sale of medicines. These records shall include the following information:

a) Details of medicines procured. This should include

- The source of supply of the medicines, including the name and principal address of the seller or transferor
- Date of purchase
- The identity/ name and quantity of the medicines received
- Batch/Lot numbers and expiry dates
- The dates of receipt

b) For wholesalers and importers of herbal products, address of the supplier from which the medicines were shipped should be indicated.

c) In the case of medicines or preparations that are sold and distributed or disposed of to other outlets, the records shall show;

- Date of disposition
- Persons to whom medicines have been supplied
- The identity /name of medicines
- The quantity supplied
- Batch No.

#### **4.5. RESPONSIBLE PERSONS.**

Herbal medicine distributors or sellers shall indicate the person in charge of handling and selling of these medicines. Such people should be knowledgeable about the medicines and therefore be able to provide all the necessary technical and medical advice required by the clients or patients.

- The in-charge shall be a registered herbalist or person with qualifications in the medical or relevant field, who will have to prove their skills.

#### **4.6. HERBAL MEDICINES**

All such medicines should be either registered or notified with NDA.

## **CHAPTER FIVE: PROMOTION/ADVERTISEMENT OF LOCAL HERBAL MEDICINES**

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It's important to note that it is a requirement for all promotional materials regarding herbal medicine, to be submitted to NDA for vetting and subsequent approval prior to publication

5.1.1. This section is intended for;

- 1) Herbal medicine Regulators
- 2) All local herbalists and local herbalist organization/ Associations
- 3) All local herbal medicine manufacturers
- 4) All media houses
- 5) Importers and exporters of local herbal medicines
- 6) Local Herbal medicine outlets i.e. the owners and directors
- 7) Sales/marketing representatives of local herbal medicine products
- 8) Herbalists /Persons who may wish to make the public aware of their locations and /or of the premises.

5.1.2. Targets all promotional material (PM) and activities, which may include but is not limited to;

- 1) Any form of audio, visual and /or written material intended to be published in the media
- 2) Any written articles or supplements about herbal medicine companies.
- 3) Talk shows
- 4) Sponsoring of local herbal medicine, symposiums exhibitions
- 5) TV sponsorship of programs e.g. news, health talk/entertainment shows

5.1.3. This sections shall apply to the following categories of items.

- 1) Local Herbal medicines
- 2) Public health herbal and herbal cosmetics
- 3) Local Nutritional herbal supplements

**Note:** National Drug Authority shall vet traditional /Herbal medicine information and /or adverts including those originating from Ministry of Health. These guidelines shall not apply to practices e.g. reflexology, acupuncture, spiritualism, traditional practices .etc.

### **5.2. APPLICATION FOR ADVERTISING.**

- 1) All applications for local herbal medicine advertising shall be made in writing by the herbalists /directors in charge, or any person responsible for the local herbal medicine products' application.
- 2) The application shall be addressed to;

**The Executive Secretary /Registrar,**  
National Drug Authority,  
Plot No.46.48, Lumumba Avenue  
P.O. Box 23096  
KAMPALA.

### **REGIONAL OFFICES**

Applicants in different regions can channel their applications through the National Drug Authority Regional Offices or the office of the District health officer.

**NDA South Western Region**  
National Drug Authority,  
House 29 Mbaguta Estate, Kamukuzi  
P O. Box 1886  
Telephone 0485-21088  
**MBARARA-UGANDA**

**NDA Northern Region Office LIRA**  
Erute Road  
P.O. Box 235  
Telephone/Fax: 04734-20562  
**LIRA**

**NDA South Eastern Region**  
Plot 19 Stanley Road,  
P.O. Box 1710  
Telephone 0434-122176  
**JINJA.**

**NDA Eastern Region Office**  
South Bukedi Cooperative Building,  
Plot no 6 Busia Road,  
Tel: 0454445195  
**TORORO**

**NDA Central Region,**  
Plot no. 1-2 Jinja Road  
Premier Complex Building, Nakawa,  
P.O. Box 40082  
Telephone 0312-261548  
**KAMPALA.**

**NDA Western Region Office**  
Muganwa Centre,  
Plot no. 30 Old Tooro Road,  
P.O. Box 192  
Telephone 0465-40688  
**HOIMA**

**NDA West Nile Region**  
Plot 1, Mt. Wati Road, Anyafio,  
**ARUA.**

- 3) The application letter should state the details of the advert to be vetted clearly. i.e.
  - a) The name of the local herbal product
  - b) The brand name of the local product ; (where applicable)
  - c) The type of material carrying the advert information. i.e. scripts, posters, T-shirts, bags pens, etc
  - d) Audio CDs, tapes etc;
  - e) Copy of the letter of registration /notification with number of the product
  - f) In case of renewals, the date of expiry and state if there are amendments to the advert. Letter of registration /notifications be attached.

**5.3. VETTING**

The Applications shall go through a Vetting process by an appropriate committee of National Drug Authority.

Below are the vetting fees which shall be revised from time to time.

Type of materials	Examples	Amount annual
<ul style="list-style-type: none"> <li>Written material</li> </ul>	Calendars, daires, booklets, supplements etc	1.25 CP -per drug, per language
<ul style="list-style-type: none"> <li>Audio message</li> <li>with written scripts</li> </ul>	CDs, tapes, VCDs	1.75 CP -per drug, per language
<ul style="list-style-type: none"> <li>Visual aids</li> </ul>	Posters/bill boards adverts on vehicles, wall branding	2.5 CP- per language
<ul style="list-style-type: none"> <li>Miscellaneous items</li> </ul>	T-shirts, caps, belts	2.5 CP - per drug
<ul style="list-style-type: none"> <li>Organizing a</li> <li>Launch /symposium</li> </ul>	Coordinate presentations, invite others to exhibit	2.5 CP - per function
<ul style="list-style-type: none"> <li>Participating</li> <li>in exhibitions</li> </ul>		2.5 CP - annual fee
<ul style="list-style-type: none"> <li>Miscellaneous</li> </ul>	Road side shows	2.5 CP - per show
	Sponsorship of functions	Annual permit of 2.5 CP

1 CURRENCY POINT (CP) =20,000/- (TWENTY THOUSAND UGANDAN SHILLINGS)

**5.4. SAMPLES**

- Two samples of the promotional materials are submitted at the time of application
- All samples shall be in **ENGLISH** Language. For samples that are not in English, the applicants shall submit a correct translation of the advert in the English languages.

**5.5. AUDIO /VISUAL ADVERTS**

- The applicant shall submit along with the CD/DVD/tape, a written script in the language of interest.
- If the advert is in a vernacular language, then a script in both the vernacular and English language must be submitted before vetting starts.
- The applicant may initially submit the intended script for the advert. After vetting and approval of the submitted script, the applicant may then proceed to make an audio recording following the approved Script without deviating from approved information in the script. The resultant CD shall be submitted for vetting and final approval.
- The audio message must not deviate from the approved script.

**5.6. SUPPLEMENTS**

- Two copies of information to be published as a supplement shall be submitted.
- The applicant shall move along with the soft copy when ever queries are raised.

**5.7. PRODUCTION OF PROMOTIONAL MATERIALS (PM).**

- The artwork of the PM should be vetted and approved before bulk printing. This applies to developing promotional materials for publication and/or distribution.

**5.8. EXHIBITIONS/SYMPOSIA/LAUNCHES.**

These should notify NDA of their intention to exhibit, and shall declare all activities that would be done during exhibition.

The organizer of the function shall submit the following;

- a) List of presenters and their presentations
- b) Stall attendants if any
- c) PM samples
- d) Tentative program
- e) Copies of speeches and list of Invitees.

All promotional activities to be carried out in the Launch/ exhibitions / symposium should be stated and declared.

**5.8.1. The herbal medicine being advertised should:**

- 1) Not be listed in schedule 1 of the NDP/A Act
- 2) Be legally available in Uganda and registered/ notified with NDA.
- 3) The advert should not contravene section 33 of the NDP/A Act.

**5.8.2. The information on the advert should be;**

- 1) Reliable; accurate; truthful; up-to-date, informative, educative and capable of substantiation
- 2) Consistent with the dossier presented to NDA at the time of registration /notification ;
- 3) Devoid of misleading information
- 4) Advert should not be exaggerated and should be verifiable
- 5) Should not be offensive to our cultural values

**5.8.3 Herbal Medicine Promotional material/Advert targeted to prescribers /health related professionals:**

- 1) Should contain full product information as defined by NDA
- 2) The information supplied must be supported by acceptable evidence based on the dossier presented at the notification period
- 3) Free samples of the products can be provided to the above categories of health workers on request but in modest quantities.

**5.8.4 Promotional material targeted to the general public:**

- 1) should be limited to those local herbal products manufactured by the advertising company/firm
- 2) Should not be targeted at children and the PM should not contain pictures of children.

**5.8.5 Approval of the local herbal adverts.**

- Any advert with critical errors shall not be approved unless amendments have been made  
*The critical errors in the guideline include but not limited to:*
  - *Descriptive matter on/claims to treat the following prohibited diseases: Amenorrhoea, arteriosclerosis, bladder stones, blindness, brigts" disease, cancer, cataract, deafness, diabetes, diphtheria, dropsy, epilepsy, erysipelas, gallstones, glaucoma goiter, heart disease hernia,, kidney stones, leprosy , locomotorataxy, lupus, nephritis, paralysis, pleurisy, pneumonia, poliomyelitis, scarlet fever, schistosomiasis, septicaemia, smallpox, tetanus or lockjaw, trachoma tuberculosis..*
  - *Herbal Products containing medicinal substances of class A category*
  - *A herbal product not notified to/approved by National Drug Authority*

Reference to Section 33 (1) & (2) of the NDP/A & Fifth Schedule of NDP/A

## GLOSSARY

1. **Advertising:** In this guideline, advertising shall mean availing to the public useful, properly detailed unbiased information intended to create awareness of either traditional /herbal medicine or tradition herbal medicine combinations, to either prescribers, patients or both, of the existence of a traditional /herbal medicine or combination thereof.
2. **Supplement:** Is any article written about traditional /herbal medicines or company that is intended to be published in newspapers or magazines
3. **Traditional Medicine**  
The sum total of all knowledge and practice whether they can be rationally explained or not, used in the diagnosis, prevention, elimination of physical, psychological and social imbalances and relying exclusively on practical experiences and observations handed down from generation to generation, either verbally or in writing.

Traditional medicine as defined above will be synonymous with:

Traditional healing, Folk medicine, Alternative medicine, Indigenous medicine, ethnomedicine.

4. **Herbal medicine**

Herbal medicines consist of finished, labelled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant materials, or combinations thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils and any other substances of this nature. Herbal medicines may contain excipients in addition to the active ingredients.

***Medicines containing plant material combined with chemically defined active substances, including chemically defined, isolated constituents of plants, are not considered to be herbal medicines.***

For the purpose of the NDA Act and in the Uganda context, herbal medicines may also contain natural organic or inorganic active ingredients (e.g. lime, clay, and crude salt) which are not of plant origin.

5. **Crude plant material**

Any part of a plant (e.g. roots, bark, leaves, floral parts, seeds, fruits, wood, bulbs), or plant exudates, or juice that has been harvested for use as a medicament

6. **Crude plant preparation**

Any part of a plant or plants or mixtures thereof that has been made into a dosage form without undergoing any extraction or purification processes.

7. **Finished Herbal product**

Any preparation of crude herbal extracts, active principles have not been separated into chemical entities.

8. **Herbal Promotion:**

In this guideline, herbal promotion means a marketing method of creating awareness to the public about herbal medicine products by means of advertising in the media, be it radio, TV or newspaper, billboard or on vehicles, use of medical representatives, giving of free herbal product samples, sponsorship of symposia and other scientific

meetings, carrying out post marketing studies and surveillance and dissemination of information obtained from such studies.

**9. Herbal based drugs**

Any preparation whose active ingredient has been isolated from a plant, and characterised chemically. They are not included in the categories mentioned and are regulated differently.

**10. Food/Dietary Supplement**

Food/Dietary Supplement is a product taken by mouth that contains a dietary ingredient intended to supplement the diet.

**NOTE:**

*The practice of witchcraft and occult practices for the purpose of the NDA Act is not included under traditional medicines.*

**NOTE:**

*Applicants who wish to have legal protection of their Intellectual Property Right (IPR) in order to acquire exclusive use to their patents, brand names, logos, labeling of their products etc, are advised to have the same registered with the Intellectual Property Registry located at the following address:*

**UGANDA REGISTRATION SERVICES BUREAU,  
REGISTRA GENERAL.S OFFICE,  
PLOT 5, GEORGE STREET,  
AMAMU HOUSE 5<sup>TH</sup> FLOOR,  
P.O.BOX 6848, KAMPALA.  
TEL: NO. 0414-233218/9,  
DIRECT LINE: TEL. NO. 0414-235915**