Safe Drugs Save Lives

GUIDELINES FOR REGULATION OF LOCAL TRADITIONAL / HERBAL MEDICINES FOR HUMAN OR VETERINARY USE IN UGANDA

Please send any comments you may have to Miss Dora Namyalo, Officer, Quality Management (dnamyalo@nda.or.ug), with a copy to Mr. Peter Ssali (pssali@nda.or.ug) by **13th May 2021.** Please use our attached QMS Template for Comments for this purpose.

Our Draft documents for comments are placed on the NDA website (https://www.nda.or.ug/e-resources-database/) under the "Draft Documents for Comments" link

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Citation

These guidelines shall be cited as the *"Professional Guidelines for Regulation of Local Traditional/Herbal Medicines for Human and Veterinary Use in Uganda, Doc. No. DAR/GDL/033, Revision No. 0."*

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 for Regulation of Local Traditional / Herbal Medicines for Human and Veterinary** Doc. No. DAR/GDL/033 Revision No.: 0", made this day of 2021, that take effect on 1st March 2021

Signature

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Dr. Medard Bitekyerezo

CHAIRPERSON

National Drug Authority

Kampala, Uganda

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ACRONYMS

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

DEFINITION OF TERMS

***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 traditional herbal medicine combinations, to either prescribers, patients or both, of the existence of a traditional /herbal medicine or combination thereof.

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.

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.

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

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

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.

"Herbal medicine product" means a finished, labeled herbal medicine product that contain as active ingredients aerial or underground parts of plants, or other plant materials, or a combination of these, whether in the crude state or as plant preparations and which may contain conventional excipients in addition to the active ingredients and may also contain by tradition, natural organic or inorganic ingredients which are not of plant origin.

"Herbal preparations" are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

"Herbal substances" refers to all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen, animal, rocks or such natural components in an unprocessed, usually dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

"Herbal teas" consist exclusively of one or more herbal substance(s) intended for oral aqueous preparations by means of decoction, infusion or maceration. The preparation is prepared immediately before use. Herbal teas are usually supplied in bulk form or in sachets.

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

Supplement: Is any article written about traditional/herbal medicines or company that is intended to be published in newspapers or magazines.

"Traditional medicine" It is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. (http://www.who.int/medicines/areas/traditional/definitions/en/).

Traditional medicine as defined above will be synonymous with: Traditional healing, Folk medicine, Alternative medicine, Indigenous medicine, ethnomedicine.

NOTE:
The practice of witchcraft and occult practices for the purpose of the NDPA&A 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 5TH FLOOR, P.O.BOX 6848, KAMPALA.

CHAPTER ONE : INTRODUCTORY BACKGROUND

1.1 BACKGROUND / INTRODUCTION

National Drug Authority aims to ensure that only good quality, safe and efficacious human and veterinary medicines are available 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.

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.

The Vision of NDA: “A Uganda with safe, effective and quality medicines and health care products”.

The Mission of NDA: “Promoting and protecting public health through the effective regulation of human and animal medicines and health care products”.

These guidelines will mostly dwell on the manufacture, registration and sale of herbal medicines. The practice of traditional and complementary medicine will be handled under the auspices of the various (professional) organizations as will be stipulated in the Traditional & complementary medicine Act 2020

1.2 OBJECTIVES OF THESE GUIDELINES

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

a) To guide Local Herbal manufacturers and NDA Inspectors on acceptable minimum requirements for the manufacture of herbal medicinal products;

b) To guide applicants on how to meet minimum requirements for registration of local herbal medicinal products;

c) To offer guidance on Licensing of herbal medicine sales outlets.

d) To put in place a safety and monitoring mechanism;

e) To guide on advertising of herbal medicinal products.

f) 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.

1.3 POLICY

These guidelines are developed in accordance with the National Drug Policy and Authority Act Cap. 206;

a) Section 35(1)(a): *"the drug authority may scientifically examine any drug for the purposes of ascertaining efficacy, safety and quality of that drug".*

b) Section 2 (1) (g) (g) to intensify research in all types of drugs, including traditional Medicines

c) Section 5(g): *"The drug authority shall be charged with the implementation of the national drug policy and, in particular, but without derogation of the foregoing shall- encourage research and development of herbal medicines"*

d) Section 41(1): *The National Drug Authority shall encourage research by persons carrying on research and development in herbal and other medicines and where appropriate take such medicines into production as a component of the drug supply.*

e) The National Drug Policy and Authority (Control of Publication and Advertisement Relating to Drugs) Regulations, 2014. 33; *(Made under Sections 33 and 64 of the National Drug Policy and Authority Act, Cap 206)*.

1.4 SCOPE

These guidelines apply to regulation local traditional / herbal medicine products for Human and Veterinary Use in Uganda

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:

a) 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.

b) Its safety and efficacy should be justified by long period of use (At least for more than ten (10) years).

c) This category of medicines is not directly controlled by the national drug authority . **However, the traditional health practitioners should be certified by the recognition/registration of their practice** by the responsible body, community or any local Authority/Council.

d) It could be used freely by local people.

e) If the medicines in this category are introduced into the market (For commercial use), they must meet the regulatory requirements for the registration of traditional medicines specified under category 3.

1.5.2 Category 2: Galenicals

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

a) 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;

b) Its formulation is well known in a given locality and its preparation is according to established/traditional methods.

c) Its safety and efficacy should be justified by long period of use. At least more than ten (10) years.

d) However, if the medicines in this category are to go into the market (For commercial use), they have to meet the general requirements for registration of traditional medicines specified under category 3.

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:

a) It is developed by research based on ethno (common cultural tradition, indigenous) medical use.

b) The new formulation, dosage, dosage form and therapeutic use are based on research data.

c) It may be produced at semi-industrial scale

d) Its safety and efficacy are based on research data derived from standard scientific and clinical investigations.

e) This category of medicines may be used within the research establishment.

f) However, if it goes into the market (for commercial use), it has to meet the general minimum requirements for registration of traditional medicines.

1.5.3.2 Category 3B Researched – Industrial Traditional Medicines

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

a) It is developed by research based on ethno (common cultural tradition, indigenous) medical use.

b) The new formulation, dosage, dosage form and therapeutic use are based on research data.

c) It may be produced at Industrial scale

d) Its safety and efficacy are based on research data derived from standard scientific and clinical investigations.

e) 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

1.5.4 Category 4 Imported Traditional Medicines

These are imported traditional medicines each with the following characteristics:

a) It originates from a foreign country.

b) It should meet the definition of traditional medicines.

c) It should be registered in the originating country.

d) It should also meet the requirements for regulation of traditional medicines of National Drug Authority, Uganda.

Note: Guidelines for category 4 already exist in National Drug Authority (Guidelines On Registration Of Imported Herbal Medicine Products For Human Or Veterinary Use In Uganda) and this category is **not** included in the general minimum requirements

CHAPTER TWO : MANUFACTURE OF HERBAL MEDICINE PRODUCTS

2.1 GENERAL

Unlike conventional pharmaceutical products, which are usually prepared from synthetic materials through the application of reproducible manufacturing techniques and procedures, herbal medicine products are prepared from materials 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 medicine products.

2.2 CULTIVATION AND COLLECTION OF MEDICINE PLANTS

a) 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).

b) A lot of care should be taken during harvest on farms.

c) Mix up of herbal materials (i.e crude plant material) and adulteration should be avoided during harvesting.

d) The actual harvesting and transportation of raw materials should ensure that the quality is preserved since it will finally affect the final product.

e) The herbal material should be promptly unloaded and unpacked on arrival at the processing place.

f) During this operation, the herbal material should not be exposed to direct contact with soil.

g) Materials should not be exposed directly to the sun (except in cases where there is a specific need, e.g. sun-drying)

h) 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 and 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;

a) Water supply to manufacturing unit should be monitored, and, if necessary treated appropriately to ensure consistency of quality.

b) Care should be taken to choose appropriate methods for cleaning depending on the characteristics of herbal raw materials.

c) 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.

d) 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.

e) Animal & Toilet facilities should be located away from drying and manufacturing areas.

2.4 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.

a) They should have received adequate training regarding their hygiene control.

b) They should be without infectious diseases, or skin diseases.

c) Clear and illustrative Standard Operating Procedures (SOPs) listing the basic hygiene requirements should be made available.

d) Personnel must be protected from contact with toxic irritants and potentially allergenic plant materials by means of adequate protective clothing.

e) They should wear suitable and fitting garments such as: - gloves, caps, masks, work suits and shoes through the whole process from herbal material processing to product manufacturing.

2.5 PREMISES

2.5.1 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, production area and drying area for raw materials that do not need direct sunlight. In addition to the above;

a) 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.

b) Premises used for the manufacture of herbal medicine products should be suitably designed and constructed to facilitate good sanitation.

c) 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.

d) 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.

e) Premises should be designed and equipped so as to afford maximum protection against the entry of insects or other animals.

f) Premises should be as far as possible from animal houses

2.5.2 Auxiliary areas

a) Rest and refreshment rooms should be separate from other areas. These should have clean drinking water and smoking of cigarettes, tobacco and sniffing of other substances should not be done in these areas.

b) 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 be located away from production or storage areas. Toilets should have running water, soap and hand drying facilities.

c) 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.

d) Animal houses should be well isolated from other areas, with separate entrance (animal access) ..

2.5.3 Storage areas

a) 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.

b) 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.

c) 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.

d) 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.

e) 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.

f) Segregation should be provided for the storage of rejected, recalled, or returned materials or products.

g) 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.

h) 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.

2.5.4 Weighing areas (may belong to either storage or production areas)

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.

2.5.5 Production area

a) 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.

b) The production of certain other products, such as some antibiotics, hormones, cytotoxic substances, and non-pharmaceutical products, should not be conducted in the same facilities.

c) The manufacture of technical poisons, such as pesticides and herbicides, should not be allowed in premises used for the manufacture of herbal products.

d) The principle of campaign working in the same facilities can be accepted provided that specific precautions are taken and the necessary cleaning validations are made.

e) 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.

f) 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.

g) 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 of cracks and open joints; should not shed particulate matter, and should permit easy and effective cleaning and, if necessary, disinfection.

h) 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.

i) 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.

j) 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.

k) Premises for the packaging of herbal products should be specifically designed and laid out so as to avoid mix-ups or cross-contamination.

l) Production areas should be well lit, particularly where visual on-line controls are carried out.

2.5.6 Quality control area

a) 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.

b) 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.

c) The design of the laboratories should take into account the suitability of construction materials, prevention of fumes, and ventilation.

d) 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.

2.6 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.

2.7 MATERIALS

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

2.8 DOCUMENTATION

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

2.8.1 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. For some herbal materials detailed information may

be needed on aspects of their collection or agricultural production. i.e season of harvesting

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

a) The botanical name, with reference to the authors (This should be accompanied by a certificate of verification or a document from the National Herbarium (The Makerere University Herbarium)

b) 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.).

c) Part of the plant used.

d) The drying system.

e) A description of the plant material based on visual and/or microscopical/macroscopic inspection.

f) Suitable identification tests including, where appropriate, identification tests for known active ingredients or markers.

g) The assay, where appropriate, of constituents of known therapeutic activity or markers.

h) Methods for the determination of possible pesticide contamination and the acceptable limits for such contamination.

i) Test results for toxic metal and other contaminants, foreign materials, and adulterants.

j) Test results for microbial contamination and aflatoxins.

k) Method used to reduce fungal/microbial contamination or other infestation should be documented.

l) Specifications for starting materials (and also of primary or printed packaging materials) should include, if applicable, reference to a pharmacopoeia monograph.

m) 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.

2.8.2 Qualitative and quantitative requirements

These should be expressed in the following ways:

a) Herbal plant material:

i. The quantity of plant material must be stated; or

ii. 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

b) Plant preparation:

i. 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

ii. 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

2.8.3 Specifications for the finished herbal products

a) Microbiological contamination and tests for other toxins

b) 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.

c) Physical appearance such as colour, odour, form, shape, size and texture

d) Loss on drying or water content

e) Identity tests, qualitative determination of relevant substances of the plants (e.g. finger-print chromatograms)

f) Quantification of relevant active ingredients if they are identified and the adequate analytical methods are available

g) 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.

2.8.4 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.

2.8.5 Processing instructions

The processing instructions should list the different operations to be performed on the plant material, such as drying, crushing and sifting. They should 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.

2.9 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.

2.10 QUALIFICATION AND VALIDATION

For practical purposes validation has been left out intentionally in these guidelines. However where necessary the National Drug Policy and Authority (Guidelines on Good Manufacturing Practice For Medicinal Products Doc. No.: INS/GDL/001) should be consulted.

2.11 COMPLAINTS

A manufacturing facility / premise 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.

a) 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.

b) 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.

c) Complaint records should be reviewed regularly to detect recurring problems requiring special attention and possible recall of marketed products

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.

2.12 PRODUCT RECALLS

The products recall procedure should be related to and depend very much on the NDA recall procedures. An SOP should be available and observed for storage of recalled herbal medicine products in a secure area, while their investigation is ongoing.

2.13 CONTRACT PRODUCTION AND ANALYSIS

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

2.14 SELF INSPECTION

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

2.15 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).

2.16 GOOD PRACTICES IN QUALITY CONTROL DURING PRODUCTION

2.16.1 General

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

2.16.2 Premises

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

2.16.3 Personnel

a) The department should preferably be under the authority of a person with appropriate qualifications and experience

b) He/she will be a person with a dispensing background, chemist or pharmacist.

c) For small scale manufacturers it may be a person of basic science knowledge i.e. Diploma in Botany, laboratory technology or pharmacy.

2.16.4 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 equipment. In the event when there is no capacity the services can be out sourced.

2.16.5 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;

a) Batch Manufacturing Records (BMR)
b) SOPs
c) Sampling and testing procedures for raw materials and finished products
d) 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

a) The identity and quality of herbal material, herbal preparations and of finished herbal products should be tested as described in the Quality control methods for herbal materials; ref: WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues; 2007.

b) Herbal material, herbal preparations (including extracts) and finished herbal products can be categorized as follows:

i. the active constituents are identified, and may be quantified as such;
ii. the main group of components that contribute to the activity (i.e. the constituents with known therapeutic activity) are known and can be quantified as a total (for example, essential oils) or calculated using a representative substance belonging to the group (for example, flavonoids);
iii. the former are not identified and/or are not quantifiable, but marker substances are;
iv. others, where quantification (i.e. specification for a certain quantity of a constituent) is not applicable or feasible.

c) Identification methods may be based on:

i. physical and, if applicable, macroscopic (organoleptic) and microscopic tests;

ii. chromatographic procedures (TLC, HPLC, HPTLC or gas–liquid chromatography (GLC)), spectrometric techniques (ultraviolet visible (UV-VIS), IR, nuclear magnetic resonance (NMR), MS); and/ or;

iii. chemical reactions.

d) The identification test methods should be specific for the herbal material, herbal preparation or finished herbal product and should ideally be capable of discriminating between the required herbal material and likely potential substitutes or adulterants.

e) Reference samples of herbal materials should be made available for use in comparative tests, for example, visual and microscopic examination and chromatography.

f) The development and execution of quality control methods for herbal materials, herbal preparations and the finished herbal products should be in line with subsection 2.8.3 (Specifications). Tests and quality requirements that are characteristic of the given analyte should be selected.

g) 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

2.17.3 Stability studies

a) If the expiry date for a herbal material or herbal preparation is given, some stability data to support the proposed shelf life under the specified storage conditions should be available.

b) Finished herbal products may contain several herbal materials or herbal preparations, and it may not be feasible to determine the stability of each active ingredient. Moreover, because the herbal material, in its entirety, is regarded as the active ingredient, a mere determination of the stability of the constituents with known therapeutic activity will not usually be sufficient. Chromatography allows tracing of changes that may occur during storage of a complex mixture of biologically active substances contained in herbal materials. It should be shown, as far as possible, for example, by comparisons of appropriate characteristic/fingerprint chromatograms, that the identified active ingredient (if any) and other substances present in the herbal material or finished herbal product are likewise stable and that their content as a proportion of the whole remains within the defined limits.

c) The methods used for the stability studies should be as similar as possible to those used for quality control purposes.

d) For identified active ingredients, constituents with known therapeutic activity and markers, widely used general methods of assay, and physical and sensory or other appropriate tests may be applied.

e) To determine the shelf life of finished herbal products, strong emphasis should also be placed on other tests mentioned in subsection 2.8.3 (Specifications), such as moisture content, microbial contamination and general dosage form control tests.

f) The stability of preservatives and stabilizers should be monitored. When these are not used, alternative tests should be done to ensure that the product is self-preserving throughout its shelf life.

g) Samples used for stability studies should be stored in the containers intended for marketing.

h) The first three commercial production batches should be included in the stability-monitoring programme to confirm the expiry date. However, where data from previous studies, including pilot batches, show that the product is expected to remain stable for at least two years, fewer than three batches can be used. The testing frequency depends on the characteristics of the herbal medicinal products and should be determined on a case-by-case basis.

i) The protocol for ongoing stability studies should be documented. This would normally involve one batch per year being included in a stability monitoring programme.

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

3.1 PHARMACEUTICAL INFORMATION

The following pharmaceutical information should be made available at the time of registration/notification:

a) Product name;
b) Name of the active or main constituent/plant source of the active ingredient;
c) Indications;
d) Dosage forms e.g. Tablet, powder, ointment, capsule, syrup, powder, liquid;
e) Strength of dosage form, where applicable;
f) Excipients e.g. Starch, honey;
g) Major adverse effects/side effects;
h) Storage conditions;
i) Shelf life/expiry date;
j) Pack sizes or weight; and
k) Name and address of manufacturer and phone contact, email if available.

3.2 MONOGRAPH

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

a) 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.
b) The active or main constituents of the drug is known

3.3 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.

3.4 MINIMUM REQUIREMENTS FOR SAFETY AND EFFICACY

3.4.1 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 cannot 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.g. 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) Precautions: Measures that should be taken in case of pregnancy, lactation, renal and hepatic failure etc. during use of the product.

3.4.2 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, applicable to category 3.

iii. Experiences from traditional practitioners or

iv. Experiences from treated patients.

v. 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.

vi. Summary of Claims – Traditional Herbal medicine

b) General health maintenance: General health : Problems related to health conditions are those which, with time, could recover spontaneously, even without any medical intervention, e.g. loss of appetite.

c) Medium claims

i. reduction of risk of a disease / disorder

ii. relief of symptoms

iii. aids / assists in the management of a named symptom/ disease

iv. prevents/stops/ slows down the progress of a mild/ self-limiting

v. disease or medical condition

d) High claims

i. treats/ cures/manages any disease/disorder

ii. adjunct / to complement any treatment

e) Active ingredients (where applicable)

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.

f) 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: *NDA* ***Guideline for Clinical Research of herbal medicines.***

g) Traditional medicine labels shall include the following information

i. Name of product;

ii. 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;

iii. Dosage form;

iv. Therapeutic indications;

v. Dosage: the minimum and maximum as well as average dosage levels, must be stated (if appropriate, specified for children and the elderly);

vi. Over-dosage information;

vii. Contraindications, warning, precautions, and major drug interactions in as far as these incidences are available;

viii. Manufacturing date;

ix. Expiry date;

x. Lot/Batch number;

xi. Name of manufacturer or company with full address;

xii. Storage conditions; and

xiii. Main vehicle/base

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

3.5 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)

3.6 FINISHED PRODUCTS REGISTRATION

a) Qualitative and quantitative composition of the active components
b) Quantity and type of excipients
c) Quantification of the active ingredient
d) Description of the process of manufacture
e) Specifications of quality of the finished product
f) Methods of analysis
g) Stability studies
h) Licensing of manufacturing premises by National Drug Authority
i) Packaging

CHAPTER FOUR : LICENSING

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:

4.2.1 Facilities

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

a) Be constructed with materials of permanent nature;

b) Be of adequate size avoiding congestion of stocks (i.e. 8-10m^2);

c) Have shelves for display of herbal products and a sales counter;

d) Be properly constructed to facilitate cleaning, maintenance, and other operations;

e) Have adequate lighting, ventilation, and a proper ceiling;

f) 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;

g) Be maintained in a clean and orderly manner;

h) Be free from infestation by insects, rodents, birds, or vermin of any kind;

i) Have hand washing facilities and drying towel; and

j) 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.

4.2.2 Stores

a) Operators of herbal medicine sales outlets should have enough storage areas.

b) 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.

c) If no storage requirements are established for the herbal preparation, the medicine may be held at ambient temperature.

d) 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.

e) 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.

f) Products should be stored off the floor on pallets.

4.2.3 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)

4.3. RECORD KEEPING

Herbal medicine distributors 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:

i. The source of supply of the medicines, including the name and principal address of the seller or transferor;

ii. Date of purchase;

iii. The identity/ name and quantity of the medicines received;

iv. Batch/Lot numbers and expiry dates; and

v. 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:

i. Date of disposition;

ii. Persons to whom medicines have been supplied;

iii. The identity/name of medicines;

iv. The quantity supplied;

v. Batch No.

4.4. 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.

4.5. HERBAL MEDICINES

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

CHAPTER FIVE: PROMOTION / ADVERTISEMENT OF LOCAL HERBAL MEDICINES

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.

This chapter is intended for:

a) Herbal medicine Regulators;
b) All local herbalists and local herbalist organization / Associations;
c) All local herbal medicine manufacturers;
d) All media houses;
e) Importers and exporters of local herbal medicines;
f) Local Herbal medicine outlets i.e. the owners and directors;
g) Sales/marketing representatives of local herbal medicine products; and
h) Herbalists / Persons who may wish to make the public aware of their locations and /or of the premises.

The chapter targets all promotional material (PM) and activities, which may include but are not limited to:

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

This chapter shall apply to the following categories of items

a) Local Herbal medicines
b) Public health herbal and herbal cosmetics
c) Local Nutritional herbal supplements

Note: National Drug Authority shall vet traditional / Herbal medicine **i**nformation 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.

5.1. APPLICATION FOR ADVERTISING

5.1.1 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.

5.1.2 The application shall be addressed to;

The secretary to the Authority,

National Drug Authority,
Secretariat Office Kampala
P. O Box 23096, Kampala, Uganda
Plot 19 Lumumba Avenue (opposite TWED plaza)
Tel: +256 417 788 100/1 +256 417 788 124 / 041 788 129
Email: ndaug@nda.or.ug Website: www.nda.or.ug

REGIONAL OFFICES-.

Applicants in different regions can charnel their applications through the National Drug Authority Regional Offices.

Central regional offices Kampala
Plot 1-2 Jinja Road
Premier Complex Building Nakawa
P. O Box 40082 Kampala
Tel: 0393 261548
NAKAWA

South Western Region Office- Mbarara
House 29 Mbaguta Estates, Kamukuzi
P.O Box 1886 Mbarara, Uganda
Tel: 0414 671034
MBARARA

South Eastern Regional Office
Plot 16 Rippon Garden Road
P.O Box 1710 Jinja
Tel/Fax : 0434 122176
JINJA

Eastern Region Office Tororo
Plot No: 27 Kwapa Road
P.O Box 453, Tororo - Uganda
Tel/Fax: +256 454 445 195
TORORO

Western Region Office Hoima
Muganwa Center
Plot 30 Old Tooro Road
P.O Box 192 Hoima
Tel/Fax: 0465 440 688
HOIMA

Northern Region Office
Lira Erute Road
P.O Box 235 Lira
Tel/Fax: 0414 671032
LIRA

West Nile Region Office- Arua
P. O Box 1034, Arua Plot. 1mt
Wati Road at Anyafio
Tel: 0414 671033
ARUA

5.1.3 The application letter should clearly state the details of the advert to be vetted. 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 OR Evidence of submission of application for notification.

f) In case of renewals, the date of expiry and state if there are amendments to the advert. Letter of registration / notifications should be attached.

5.3. VETTING

The Applications shall go through a Vetting process by National Drug Authority and applicable fees will be as per The National drug policy and authority (fees) regulations 2014.

Type of materials	Examples
Written material	Calendars, diaries, booklets, supplements e.t.c.
Audio message with written scripts	CDs, tapes, VCDs
Visual aids	Posters/bill boards adverts on vehicles, wall branding
Miscellaneous items	T-shirts, caps, belts
Organizing a Launch / symposium	Coordinate presentations, invite others to exhibit
Participating in exhibitions	---
Miscellaneous	Road side shows
	Sponsorship of functions

5.4. SAMPLES

a) Two samples of the promotional materials are submitted at the time of application.

b) 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

a) The applicant shall submit along with the CD/DVD/tape, a written script in the language of interest.

b) If the advert is in a vernacular language, then a script in both the vernacular and English language must be submitted before vetting starts.

c) 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.

d) The audio message must not deviate from the approved script.

5.6. SUPPLEMENTS

a) Two copies of information to be published as a supplement shall be submitted.

b) The applicant shall move with the soft copy whenever queries are raised.

5.7. PRODUCTION OF PROMOTIONAL MATERIALS (PACKAGING MATERIAL)

The artwork of the Packaging Material (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:

a) Not be listed in schedule 1 of the NDP/A Act;

b) Be legally available in Uganda and registered with / notified to NDA;

c) The advert should not contravene Section 33 of the NDP/A Act.

5.8.2 The information on the advert should be:

a) Reliable; accurate; truthful; up-to-date, informative, educative and capable of substantiation;

b) Consistent with the dossier presented to NDA at the time of registration / notification;

c) Devoid of misleading information;

d) Advert should not be exaggerated and should be verifiable;

e) Should not be offensive to our cultural values.

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

a) Should contain full product information as defined by NDA;

b) The information supplied must be supported by acceptable evidence based on the dossier presented at the notification period;

c) 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:

a) Should be limited to those local herbal products manufactured by the advertising company/firm;

b) 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 (Common deficiencies) in the guideline include but not limited to:

a) 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. Reference to Section 33 (1) & (2) of the NDP/A & Fifth Schedule of NDP/A (Diseases as to which publication of descriptive matter is restricted or Prohibited)

b) Herbal products containing substances of class A category (**Class A drugs or narcotics)**

c) Herbal products not approved by National Drug Authority

6.0 REFERENCES

Guidelines On Registration Of Imported Herbal Medicine Products For Human Or or Veterinary Use In Uganda; Doc. No.: DAR/GDL/029

Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines - Annex 3 in WHO Expert Committee on specifications for pharmaceutical preparations. 40 Report, WHO, 2006 (WHO Technical Report Series, No. 937) (WHO 2006)

The National Drug Policy And Authority (Control Of Publication And Advertisement Relating To Drugs) Regulations, 2014; STATUTORY INSTRUMENTS 2014 No. 33

WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants. World Health Organization · 2003.

WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues; 2007

Appendix 1:

1. SUMMARY OF REQUIREMENTS FOR NOTIFICATION OF LOCAL HERBAL PRODUCTS

a) A filled application form;

b) A laboratory analytical report;

c) Phytochemical analysis;

d) Microbial Analysis [Ecoli ; TPC ; Yeast & mould] ref: WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues; 2007;

e) A minimum of two samples;

f) Payment of a fee of 50,000/= per product

g) Product must meet the basic requirements;

h) Provide a sample of the electronic artworks.

2. BASIC REQUIREMENTS FOR SUCCESSFUL APPROVAL OF LOCAL HERBAL APPLICATIONS

a) **Labelling**:

A label must have:

i. Name of product;

ii. Name of medicinal plant(s), (either In English or botanical);

iii. Direction on use e.g. " Adult: take 2 teaspoons three times daily";

iv. Indications/diseases that the product treats;

v. Quantity (In grams, mls, ltrs etc.);

vi. Dosage form-e.g. syrup, powder, solution, mouthwash etc.;

vii. Name and address of manufacturer;

viii. Storage conditions .e.g. store at room temperature, protect from light and moisture;

ix. Manufacturing date;

x. Expiry date (shelf life, max is 12 months for local herbal products);

xi. Batch number;

xii. Precautions / side effects

xiii. Evidence of efficacy or claims –In other words, there should be evidence that the product treats the disease.

xiv. Avoid names that are misleading-e.g. **SUPERNATURAL HEALING TONIC, BABY GENIUS, LIFE RESTORATION TONIC**.etc.

xv. Avoid labels with pictures of body organs.

3. Centres / instututions that conduct analysis

a) DGAL- Government analytical laboratory; Location: Plot 2 Lourdel Road, Nakasero Wandegeya ; Tel:0414250218

b) NCRI- National chemotherapeutic research institute; Plot 2A, Lourdel Rd, Nakasero ; http://ncri.ug/ Telephone +256-414-250488

c) GULU – Gulu University

d) Mbarara – Mbarara University of Science & Technology

e) UIRI – Uganda Industrial research institute ,Plot 424 Makubuya Road Nakawa Industrial Area .www.uiri.org , Telephone +256414286124 , +256414286245 , +256414286695

f) Department of Pharmacy, College of Health Sciences, Makerere University, Tel: Gen. +256—312213113

g) National Drug Quality Control Laboratory

4. Research and Ethics committee (RECs) responsible for approving research

a) Theta , Uganda Plot 724/725 / P.O. Box 21175 Mawanda Rd, Kampala ; Tel: +25641 4530619; https://www.uncst.go.ug/research-ethics-committee-accreditation/

5. Botanical identification (Plant identification)

Department of Plant Sciences, Microbiology and Biotechnology, College of Natural Sciences (CoNAS), Makerere University. P.O BOX 7062, Kampala, Uganda ; Tel: +256 414 540765

6. Animal studies

COVAB – Makerere University

College of Veterinary Medicine, Animal Resources and Bio-Security (COVAB), Makerere University P.O. Box 7062 Kampala

Appendix 2: FORM 6 - APPLICATION FORM FOR REGISTRATION OF LOCAL HERBAL MEDICINE PRODUCT

Regulation 19(2)

1(a)	Particulars of applicant i.e. name and contact address: (Email address inclusive), telephone number	
(b)	Age (where applicable)	d) Gender (Where applicable)
(c)	Marital status(where applicable)	e) Educational background(if applicable)
2.	Reference of Local Council (with signature and stamp) or certificate of incorporation	
3.	Name of product (As it appears on the pack):	
4.	Dosage form and pack size:	
5.	Mode of administration (Topical, Oral)	
6.	Common name(s)/ source plant(s) that's active (botanical name(s)	
7.	Herbarium specimen number). (Got from the National Herbarium). (Evidence of authenticity of the plants used.)	
8.	Community and name by which its known by the community /if applicable	
9.	Part of the plant or method of preparation used (e.g. leaf, root, oil, extract etc.)	
10.	Strength/quantities per dosage form (where applicable to a prepared dose such as tablet, mixture etc.)	
11.	Indication for use as given on the pack/literature/manufacturer's instructions)	
12.	Major side/adverse effects, if any:	
13.	Storage conditions	
14.	Shelf life	
15.	Address of the manufacturer	
16.	Period during which the herbal medicine product has been in use	
17	Any written literature to support use of the product	
18.	Method/outlet used for sale and address of location	
19.	Signature	
	Date	

Appendix 3: APPLICATION FORM FOR NOTIFICATION OF LOCAL TRADITIONAL / HERBAL MEDICINES IN UGANDA

One copy of this form should be completed for each Traditional/Herbal medicine product

1	Particulars of applicant i.e. *(Name and Contact address, telephone number)*			
2	Name of product (As it appears on the pack)			
3	Dosage form and Pack Size: *i.e liquid, powder ,chewable tablet ,teabag, capsule ,granule ,gel ,cream ,ointment*			
4	Name of the main or active Ingredient (Botanical Name)			
5	Part of the plant or preparation (eg. leaf, root, oil, extract etc)			
6	Strength of dosage form (where applicable to a prepared dose such as tablet, mixture etc)			
7	Active Ingredient (Botanical Name)	Local name	Part of the plant or preparation (eg. leaf, root, oil, extract etc)	Method of extraction
	e.g. Eucalyptus		*leaf*	*Distillation, Boil, powder*
	Inactives used			
	i.e flavouring, preservative			
8	Indication for use as given on the pack/literature/Manufacturer's instructions) *i.e. helps, supports*			
9	Instructions of use / administration.(*Please state how the product should be taken by the consumer . State the quantity of the product that can be used)* *i.e Take two 5 ml spoons daily* *Please indicate different dosages for adults & children.*			
10	Major side/Adverse effects			
11	Storage conditions i.e *(store in a cool dry place , protect from light*)			

12	Shelf life *(Maximum time for which the product remains stable)*	
13	Address of the Manufacturer ; (*Manufacturer's name , Manufacturer's address , telephone number*)	
14	How long has this medicine been in use? (*Attach supporting literature)*	
15	Signature	
	Date	

a) Provide a minimum of two samples of each package type and size.

b) Provide a copy of the label artworks. (Note labelling should comply to labelling requirements)

c) Provide a copy of phytochemical and microbial analysis report.

d) Indicate the source of raw materials. (N.B Raw materials should be sourced from places of assured Quality)

Note: NDA does not regulate the practice of witchcraft, occult practices and the practice of traditional and complementary medicine.

DOCUMENT REVISION HISTORY

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision
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