



# NATIONAL DRUG AUTHORITY

## GUIDELINES FOR CLINICAL RESEARCH IN HERBAL MEDICINAL PRODUCTS

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# PRESENTATION OUTLINE

- Introduction
- Regulatory framework
- Objective of the guideline
- Critical areas of the protocol
- Supplementary Information to the protocol
- Post- authorization



# INTRODUCTION

- The guideline for clinical research in herbal medicinal products is in line with the following sections in the National Drug Authority/Policy Act NDA/P Act cap 206;
- **Section 3. Functions of the drug authority**
  - (g) Encourage research and development of herbal medicines;
- **Section 40. Clinical trials.**
  - (1) The authority may issue a certificate to any person for the purpose of carrying out clinical trials in respect of a drug that may be specified in the certificate.
  - (2) No person may carry out any clinical trial in respect of any drug unless he or she is in possession of a certificate issued under subsection (1)





# REGULATORY FRAMEWORK

- The National Drug Policy and Authority (NDP/A) Act.
  - Section 40
  - Section 3
  - Section 64
- The NDP/A (Conduct of Clinical Trials) regulations, 2014.
  - Regulation 7: Authorization of clinical trials
  - Regulation 3: Requirement for authorization of clinical trials
  - Regulation 4: Application for authorization to conduct a clinical trial



# OBJECTIVE OF THE GUIDELINE

- The guideline is aimed at stating the minimum standards that shall be complied with when any one is conducting a clinical trial on herbal medicinal products in Uganda.

The guideline also specifies;

1. The scope of herbal medicinal products
2. Rationale for regulating herbal medicinal product clinical trials
3. Non-clinical requirements
4. Process of the clinical trial applications to NDA
5. Submission, approval, amendments and the reporting procedures.



# SCOPE OF HERBAL MEDICINAL PRODUCT

Herbal medicinal products are;

Products from natural sources in their crude form, with medicinal claims when **formulated in a pharmaceutical dosage form** and are intended to be part of the list of medicines used for therapeutic or preventive or diagnostic interventions accessed by the public.



## SCOPE OF HERBAL MEDICINAL PRODUCT (2)

The guideline shall therefore not apply to products;

- in their unmodified or primary processed form i.e not formulated in pharmaceutical dosage form.
- which are not for commercial purpose or use by a third party
- where the composition of products is not indicated e.g. no information on plant names, active and non-active ingredients etc.
- where batch to batch consistency cannot be assured.
- whose quality to guarantee safety is not certain
- and any other as the authority may specify from time to time.





# APPLICATION REQUIREMENTS

Application- Must be in English, with a cover letter (Addressed to the Secretary to the Authority), on the institution headed paper.

The documents to be submitted along with the application should include, but are not limited to;

1. Signed and completed application form
2. Research protocol (including a soft copy.)
3. Ethical approval by REC and UNCST.
4. List of all investigators (CVs, designation and qualification)
5. Fees





# APPLICATION REQUIREMENTS (2)

6. Investigators brochure
7. Product manufacturer's approval letter permitting conduct of clinical trial
8. GMP certificate of manufacturer
9. Product dossier
10. Informed consent forms
11. Independent data management committee
12. Publications on the product
13. Other documents as may be requested for by the Authority



# THE PROTOCOL

Pertinent sections;

- Background
- Problem statement
- Justification
- Hypothesis/research questions
- Objectives
- Primary and secondary outcomes,
- Materials and methods (include description of products)
- Study procedures



## THE PROTOCOL (2)

- Study termination conditions
- Compensation of participants
- Sample size and data analysis plan
- Study time-frame
- Reporting plan
- Budget
- Ethical considerations
- Investigational product management



# PERTINENT ISSUES IN THE PROTOCOL

- Quality Specifications of Plant Materials and Products
- Non-Clinical Studies and Data for submission of the CTA
- General principles for non-clinical studies
  - Pharmacological methods
  - Toxicological methods
  - Systemic toxicity test
  - Specification of phase of the clinical trial





# POST AUTHORIZATION

- Annual renewal
- Amendments
- SAE reporting
- Interim reports
- GCP Inspections



# PROTOCOL AMENDMENTS

The applicant shall submit any new information regarding:

1. The product (e.g. change in manufacturer or formulation etc.)
2. Changes in the protocol (e.g. protocol amendments)

Approval of protocol amendment shall be required for the following;

- Extension of a product's shelf life
- Additional quantity of study medication;
- Additional trial site;
- Additional manufacturing site/re-packer;
- Change of PI/Sponsor.
- Extension of study period
- Change in sample size of participants
- Other changes considered significant by the Authority



# AUTHORIZATION OF CLINICAL TRIALS

## Considerations

- Relevance of the clinical trial
- Suitability of the principal investigator
- Quality of the facilities to be used for the clinical trial
- Informed consent process
- Terms of agreement between the sponsor and the principal investigator
- Protection of subjects





# THE END

Thank you for Listening

