

**SPEECH BY THE EXECUTIVE SECRETARY NATIONAL DRUG AUTHORITY
AT THE OPENING OF THE CONSULTATIVE WORKSHOP ON LOCAL
TRADITIONAL/HERBAL MEDICINES REGULATORY REQUIREMENTS
GUIDELINES HELD AT FAIRWAY HOTEL ON – 21 ST MAY. 2009**

- ❖ The Residential District Commissioners (RDCs), Chairmen of Traditional Healers, the Media.
- ❖ Associations of Traditional Medicines/ Traditional Healers, Herbalists)
- ❖ Participants (From all sectors dealing in research, analysis, manufacturing and selling of Traditional/Herbal Medicines)
- ❖ Ladies and gentlemen

It gives me great pleasure to address you on the occasion of the official opening of the Consultative workshop on regulatory requirements guidelines for local Traditional/Herbal Medicines.

In an effort to fulfill our mandate in ensuring that only safe, efficacious and good quality drugs are available to the entire population of Uganda, and to encourage the sector of Traditional/Herbal Medicines, NDA has drafted a guideline that will help to put in place Quality Assurance and Regulatory measures and address the many issues of quality of herbal medicines that have arisen in the recent past

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. The guiding document was 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 across the country for the period 2005-2007, focusing on regulatory requirements for local herbal medicinal products.

During these sensitization workshops, a lot of consultations were made with different stakeholders and the information collected therein used in developing these guidelines.

1.2. PROBLEMS/CHALLENGES;

- Owing to very low literacy levels in Uganda, many handling Traditional/Herbal medicines cannot read or write making it hard for them to compile and submit application documents to NDA.
- 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.
- Lack of funds to meet minimum requirements for NDA's approval.
- Uncontrolled advertising all over the country.
- Unethical practices not limited to but including sacrifices of human beings, adulteration of products with western medicines, peddling of products with no therapeutic benefits, unsubstantiated medicinal claims.
- Haphazard Manufacture and sale of herbal products
- Lack of a single forum for local herbalists, but rather there exists 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.
- Lack of a recognized body, to certify herbalists who would work in herbal manufacturing facilities and herbal outlets.
- Building consensus among herbalists for the need to be regulated.
- Limited capacity in both personnel and equipment to fully assess and analyze information submitted by applicants.

- Advocacy of 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

Participants are advised to study and deliberate these guidelines carefully and contribute positively. I further thank you for the attendance and willingness to engage in furthering the regulation of local Traditional/Herbal medicines.

We these few words, let me declare the workshop officially open

Executive Secretary, NDA