

Mobilization and sensitization of THPs in Mbarara, Arua and Kabarole Districts

March 15th to April 25th 2017

Activity report



LC V Chairman Kabarole District with THPs of Rwenzori Region

Introduction

THETA exists to improve health of society and access to holistic health services through strengthening collaboration between the Biomedical Health practitioners and the Traditional health practitioners.

In collaboration with NDA, THETA has been undertaking mobilization and sensitization of THPs.

Three Regional workshops were conducted with THPs i.e. 15th March 2017 in Mbarara for South Western, 22nd March 2017 in Arua for West Nile region and April 25th 2017 for Rwenzori region. The key objective of the sensitization was to raise awareness on the minimum requirements for licensing and registration of herbal and traditional medicines in Uganda.

Specific topics addressed included:

- Phytochemical analysis and contaminants/adulterants in herbal products
- Minimum requirements for Manufacturing and sale of Herbal Medicines
- Requirements for Registration and notification of herbal products
- Advertisement and promotion of herbal products

Key elements of the Messages

a) Phytochemical analysis and adulteration of herbal products

Herbal medicines may either be adulterated with low quality plants (substitution of genuine plants with other closely related plants) or with pharmaceuticals. It was noted that Pharmaceuticals usually used as adulterants are steroids (Corticosteroids), slimming agents, antidiabetics (Glibenclamide and metformin), sexual enhancement agents.

- Drugs such as Sibutramine and fenfluramine are used to treat obesity and have been found in natural herbal products for weight loss.
- Sibutramine increases the risk of cardiovascular conditions like increased blood pressure and heart rate.
- Fenfluramine on the other hand is associated with severe lung and heart valve disease.
- Drugs such as sildenafil, tadalafil and vardenafil have been found in herbal products for sexual enhancement and these could cause heart attack, stroke among others
- Natural skin products have been found to contain corticosteroids; steroidal prescription drugs used to treat inflammatory conditions like arthritis, allergies and skin conditions like eczema.

- Corticosteroids have serious side effects like increased blood pressure, stomach ulcers and bone damage among others
- Of the samples tested in the year 2016, about 8 samples were adulterated with Metronidazole

Appealed to THPs to play significant role in Promoting Patient Safety. It is important to understand that National Drug Authority is interested in working with the herbalist community in Uganda to eliminate Adulteration of herbal medicine, realising that we share a common goal of achieving a healthy Uganda

b) Minimum requirements for Manufacturing and sale of Herbal Medicines

This focused on Good Manufacturing Practices.

Standards emphasized addressed requirements relating to Premises, Personnel, Documentation, Quality control, Sanitation and hygiene, Equipment and the Production

c) Requirements for Registration and notification of herbal products

The registration process is to ensure effective control over safety, efficacy and quality on the market. Requirements for notification and registration included:

- a) Application for registration.
- b) Form 6 - Application Form for Registration of Local Herbal Medicine
- c) Currently we have a notification form for local herbal medicines.
- d) . Registration -Notification exercise is taking place includes application
- e) Basic minimum requirements that involve
- f) Pharmaceutical Information
- g) Labeling requirements
- h) Safety and efficacy of the product
- i) Finished product

It was noted that a total of 300 Applications were received by NDA and only 7 products were duly notified.

c) Major Issues Noted During Assessment of Herbal Applications

1. Misinterpretation of the statements e.g. strength of the dosage form, active ingredient

- A) What is 'Strength' of a herbal medicine product?
- B) What is a dosage form
- C) What is active ingredient

2. The product labels are always missing this information:

- pack size,
- batch number,
- date of manufacture, date of expiry
- storage conditions and
- name/ common name/botanical name of the active ingredients

3. Literature at times does not support the claimed indications
4. Absence of package leaflet
5. Inclusion of the indications on the product label instead of being included on the package leaflet

Advertisement and promotion of herbal products

April 2014 Minister of health issued regulations to control promotion and advertisement in relation to all medicines (herbal and conventional).

Guidance on drug promotion application

- Fill form 45 or write to the Executive Director NDA (Secretary to the Authority).
- Take this letter to Drug information Department of NDA together with a recorded advert on CD and script
- The application is screened and amount payable in respect of vetting fees is determined
- A **Fees advice slip** is given to the applicant.
- The advert and other promotional materials are retained by the officer who acknowledges in writing

A full application entails the following:

- Application letter or form 45 duly filled
- Receipt as evidence of payment
- Vetting fees advice slip that indicates the moneys to be paid
- Copy of notification letter in respect of the drug being promoted
- Ad advert script
- Recorded advert on CD

Other issues regarding sale and promotion of herbal medicine included:

- 1) NDA may need to first inspect the premises of sale of the herbal drugs before authorisation is issued
- 2) Sale of herbal drugs in market places is prohibited
- 3) Hygiene is paramount
- 4) NDA does not regulate traditional healers who use spiritualism and divination
- 5) . Scientific proof of claims is a Must
- 6)

Media Houses

- Broadcasting houses are supposed to receive only adverts with NDA approval
- No alteration of the approved advert is permissible.
- Approval for an advert is only for 1 year after which a fresh application is done

- NDA does not authorize live radio programs in relation to any herbal medicines

Key concerns of THPs

Arua

The workshop took place in Heritage Court Hotel and was opened by NDA regional Drug Inspector and closed by Representative of the Herbalists on NDA Board



A



B



C



D



E

A: A cross section of workshop participants been addressed by THETA TMD Manager

B: Some products of THPs on display

C: A meeting with selected District Focal persons for Maracha, Arua, Koboko, Yumbe and Adjumani

D: Dr Vincent Kayizi and NDA Regional Drug Inspector during Q&A session

E: Dr Ssekajja Yahaya, Herbalists Representative on NDA Board closing the workshop

Key concerns expressed by the THPs included:

1. Lack of capacity to meet the requirements specified by NDA
2. Long Distance to Kampala to NDA offices
3. Few sensitization opportunities for the THPs
4. Religious misunderstanding of Traditional medicine
5. Lack of promotion of notified traditional medicines by NDA to Ministry of Health and other Biomedical Health Practitioners
6. Lack of provision for integrative practice

Mbarara

The workshop took place on 22nd March 2017 at Rwizi Hotel. The Workshop attracted over 100 participants from Districts of South Western Uganda



A



B



C



D

- A- TMD Manager making a presentation to participants
- B- District Inspector of Drugs Mbarara closing the workshop
- C- Dr. Vincent Kayizzi of NDA using Malarid as a learning aid for the participants
- D- A cross section of workshop participants

Key concerns of Participants

1. Long duration of feedback on applications
2. NDA tends to promote foreign health products especially food supplements to the disadvantage of local products
3. Lack of model institutions for benchmarking standards required by NDA
4. Intellectual property protection. There is no guarantee in place to protect intellectual property of THPs
5. Lack of THPs at NDA. Participants were concerned that the structure of NDA does not have representation of THPs and therefore their products are entirely verified by professionals of different background

Kabarole

The workshop was opened by the LC V chairman of Kabarole District who emphasized on the need to correct the historical distortions that to date has led to the underdevelopment of the Traditional Medicine of Uganda and Africa at large.

The District Police Commander who also addressed the workshop pointed out key security issues with regard to Traditional Medicine Practice. He cautioned participants to be on the look out for THPs whose identities were not known in the area. He advised that THPs should have their local community structures, National ID and also report to the District Health Office and Police.



A



B



C

A: THETA TMD Manager addressing the participants

B: Group Photo with participants

C: LCV Chairman Kabarole District opening the workshop

Key concerns of Participants

1. Lack of Regulatory Council for Traditional Health Practitioners
2. Lack of Clinicians to help in clinical trials to validate Traditional Medicines of Practitioners
3. Inadequate sensitization of THPs. District level sensitization required
4. How does NDA protect intellectual property of THPs?
5. Concerns of who is available at District level to address issues regarding notification and registration of products of THPs?
6. Lack of essential equipments for manufacturing
7. Need to establish a school for Traditional Medicine

General

- It was noted that THETA was not strong in terms of structures and awareness among the THPs.
- Transport refund was not available and many participants were stranded at the end of the workshop with some who became violent putting lives and property at risk
- Participants were paid transport refund through mobile money about 5 days after the workshop. However there was a wide spread complain among participants that they did not receive the transport refund while other participants had no mobile phones

Key recommendations for THETA

1. Establish regional liaison offices for Technical assistance to THPs especially registration and notifications
2. Building capacity for phytochemical analysis especially procurement of the INFRARED SPECTROPHOTOMETER,
3. Strengthen capacity for value addition for herbal medicines
4. Strengthening District based structures for mobilization of THPs for THETA Programmes
5. Intellectual Property protection programme in liaison with URSB/NDA/NCRI
6. Advocacy for control of foreign food supplements in order to stimulate local market