THE AFRICAN HERBAL PHARMACOPOIEA: CURRENT SITUATION AND THE NEED FOR THE STANDARDISATION OF PHYTOMEDICINES

WASP 2019
WHO resolutions including WHA 31.33 of 1978 which requested WHO to coordinate efforts of member states to among other things;

Develop and apply scientific criteria and method of proof of safety and efficacy of medicinal plant products.

To establish international standards and specifications for identity, purity and strength.
To develop method for the safe and effective use of medicinal products including labelling that contains adequate direction for use or prescription by various levels of health workers.

Resolution WHA 41.199 of 1988 urged member states to examine the situation with regard to their indigenous medicinal plants and their conservative use by traditional medicinal practitioners.
Similarly, AFR/RC 50/R 5 of 1999 requested that WHO African regions and member states should be supported in carrying research in medicinal plants and promoting their use in health care delivery systems.

Presently, 25% of modern drugs are derived from plants that has been used by traditional medical practitioners including Catharanthus roseus (Madagascaran Periwinkle).
AFRICAN RICH BIODIVERSITY

- Africa contains 40 – 45,000 species of medicinal plants with potentials of activities.
- Only 5,000 species are medicinally used.
- Africa contributes nearly 25% of the world trade in biodiversity.
- Estimated 10% of the plant species are found in South Africa, only few are commercialised by reason of poor scientific information.
- African continent has only contributed 83 out of the 1,100 blockbuster drugs globally.
African potential bottlenecks

- Lack of sustainable technical specifications and quality control standards.
- Making it extremely difficulty for buyers local or foreign to compare batches
- Lack of trading standards including good agricultural and collecting practices
- Poor or NO Agricultural and collecting practices.
- Lack of good manufacturing practices contrary to other WHO regions as China and India
- Information about traditional use are rarely written but rather transmitted orally from one generation to another either by stories or traditional rulers.
Dependence on wide harvested plants which is very inimical to sustainable indigenous resources unlike the western world.

Plant extinction means also loss of accumulated traditional knowledge and invaluable wealth of information over years.

Established standards will not only help the potential buyer from Europe and America, but also the farmer and the seller from countries in WHO African regions and beyond (Ameenah et al, 2010)
New Frontiers In African Medicinal Plant Development

- Assurance of safety, quality and efficacy of medicinal plants and herbal products: the key issue in industrialized and developed countries
- Without well documented information on the safety, efficacy and phytochemical characteristics of different compounds, it is difficult to engage in billion dollar world business like India and China.
Advanced BLOOD PRESSURE Support

Natural Herbal Formula To Support Healthy Blood Pressure Levels*

Contains Garlic, Hibiscus, Forslean & Hawthorne Berry

SUGGESTED USE: As a dietary supplement, take 1 capsule twice daily.

Supplement Facts

Serving Size: 1 Capsule
Servings Per Container: 60

Amount Per Serving

- Vitamin C (ascorbic acid) 600 mg
- Niacin (nicotinamide) 2.5 mg
- Vitamin B-6 (pyridoxine hydrochloride) 5 mg
- Folic Acid 100 mg
- Vitamin B-12 (cyanocobalamin) 100 mcg
- Hawthorne Berry (1.5% extract) 150 mg
- Garlic (12% extract, unprocessed) 150 mg
- Hibiscus Flower Powder 100 mg
- Coleus Forskohlii (10% Forskolin) 75 mg
- Olive Leaf (15% extract) 75 mg
- Olive Leaf (powder) 75 mg
- Green Tea (80% decaffeinated) 25 mg
- Juniper Berry (powder) 25 mg
- Uva Ursi (15% extract) 15 mg
- Uva Ursi (powder) 15 mg

Other Ingredients: Gelatin, Magnesium Stearate, Silicon Dioxide.

Manufactured in the USA for: UltaLife
Palm Harbor, FL 34684
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For VIP Discounts & Coupons: www.UltaLife.com

Natural Dietary Supplement

*Not intended for infants or children.

Consult a physician prior to use. This product is not intended to diagnose, treat, cure or prevent any disease. This product has not been evaluated by the Food and Drug Administration. This product is not intended to treat low blood pressure. If you are currently taking prescription medication including that for high blood pressure and have questions about the advisability of this product, consult a physician prior to use. This product is manufactured and packaged in a facility which processes milk, soy, wheat, egg, peanuts, fish and shellfish.
African herbal pharmacopoia

- Prepared by the Association of African Medicinal Plants standards (AAMPS)
- Contains monographs that provide information and technical data on some 50 medicinal plants.
- Aim is to have plant products that have met WHO standards to compete visibly in world market with emphasis on quality control, dosage, use, efficacy, pharmacology and safety of the plant products (Brendler et al, 2010)
Examples of plants in Pharmacopoeia

- Acacia Senegal
- Catharanthus roseus with anti-leukemia drugs
- Garcinia kola
- Moringa Oleifera
- Rauwolfia Vomitoria
- Vernonia Amygdalina
- Yew tree (Taxus sp.) with the active drugs Taxol, an anti-cancer drug
History of African Herbal Pharmacopoeia

- In 2000 a common wealth medicinal plants business forum was held in Cape Town, South Africa with delegates from across Africa to define policies of packaging African Medicinal Plants for National and International buyers based on safety and efficacy.

- In 2003, the EU ACP, a development cooperation between EU and African, carribean and pacific states (center for the development of the project of identifying the 50 most important African medicinal plants and to prepare a quality control standards/monograph for the chosen species.)
• In 2004, contract was awarded to Phytomedicine programme of the University of the pretoria for more scientific data from researchers across African region.
In 2005, following the centurion declarations a decision was taken to prepare the African Herbal Pharmacopoeia (AfrHP).

Following this decision, the African Association of medicinal plants standard (AAMPS) was constituted in Mauritius with a mandate enshrined in the centurion declaration to prepare an internationally acceptable pharmacopoeia.
Monographs of the plants were assembled including microscopical data of plant materials, HPLC, and TLC chromatograms of adulterants.

6 year work devoted to 31 experts in African medicinal plants.
The description of the monograph

Each plant was discussed under:

1. Scientific name with author
2. Synonyms, family, vernacular names, botanical description
3. Origin and distribution, ethnomedical uses
4. Phytochemical constituents
The description of the monograph contd.

- Quality control of active drugs, including Organolectic properties, macroscopic and microscopic characteristics, solubility.

- TLC & HPLC chromatograms, infrared spectroscopy for active drugs and adulterants
Pharmacological properties of the active drugs, preclinical safety drug testing including the sub-acute subchronic toxicity testing, carcinogenicity, teratogenicity.

Clinical studies with patients covering patients follow-up and key therapeutic information.

Data with biochemical parameters eg. Urea creatinine, FBC, Lipid profile, Serum protein, Bence jones protein.
Business / Trading Information

1. Definition of plant parts with highest demands
2. Seasonal differences in plant activity
3. Regional differences in plant activity
4. Propagative parts with highest yield
5. The nature of the plants herbitat for either wide or cultivated plants
6. Information on processing and storage
For a country to obtain self-reliance in her pharmaceutical industry, the following are considered necessary (Sofowora, 1979):

- The developing country must reduce unwarranted importation of drugs, only essential drugs (WHO, 1990) should be imported.
- Concerted attempt should be made to produce some pharmaceuticals locally.
STANDARDIZATION AND ECONOMIC DEVELOPMENT CTD.

- They should utilize locally available medicinal plants as substitute for other drugs.
- They should encourage large scale cultivation of medicinal plants such that any excess can be converted into drug product for exportation.
- They should direct research towards solving local problems in a collaborative manner.
LOCAL AND ECONOMIC IMPLICATIONS

- Lack of patronage of herbal medicine is due to lack of standardization and labeling of dosage form, and insufficient knowledge of herbal formulations.
- Developing countries like Nigeria therefore, should exploit their medicinal plants to their own advantage by using them in their health care system and producing drugs for export (Sofowora, 2012).
There is no or little information available in pharmacopoeia standards on raw materials and finished products.

information on standardization of herbal products in Nigeria are not documented.

Moreso, the lack of quality standards has resulted in mild to serious adverse effect ranging from hepatotoxicity to death.
• Hence herbal ingredients require tools for determining identity, purity and quality control have to be technically sufficiently rapid and cost effective (Bele and Khale, 2011).
• Standardization and dosage were the major criticisms of herbal formulations.
Moreso, the ash values, extractive values, moisture content, chromatographic and spectroscopic evaluation, heavy metal determination, pesticide residue evaluation, microbial contamination, and radioactive contaminations are all evaluated and documented.

Moreso, the stability parameters for herbal formulations are evaluated and properly documented (Bele and Khale 2011). These include:
MORE STANDARDISATION CRITERIA

- Physical characteristics including the color, odor, appearance, clarity, viscosity, moisture content, pH, disintegration time, friability, hardness, flowability, flocculation, sedimentation, settling rate and the ash value are all documented of any herbal formulation.

- Chemical parameters includes the limit test, the chemical tests, and chemical assay etc. the chromatographic analysis of herbals can be done using TLC, HPLC, HPTLC, GC, UV, GC-MS, fluorimetry etc.
**OTHER PHYSICAL PARAMETERS**

- **Physical method of analysis:** The physical method includes: the refractive index of oils; foaming index for saponins; determination of total solid; determination of bitter activity for bitter principles.

- **various spectrophotometric methods** are applied to the quality for bitter principles to ensure standardization.
DOSAGE FORM

- **Standardization of final dosage of form:** Dosage form is necessary where plant extract is not to be used directly as such but are formulated into tablets, capsules, or other dosage forms.

- **Adjuvants added are stated and quality control test are required for formulations such as disintegration test etc.**
PERUVIAN
CHANCA PIEDRA
Stone Breaker
800 mg
Urinary System and Gallbladder Support
120 Tablets
Natural Dietary Supplement
WHO GUIDELINES AND AfrHP

- WHO guideline together with the African Pharmacopoeia are accepted as the standard for evaluation of medicinal plants.
- The standardization of dosage is not a mere specification of how much of herbal medicine has to be taken, but it is only when plant materials are collected at the correct time, contains a minimum quantity of active ingredients/constituents.
It is when plant is extracted by a specific method, that a specified dosage of final extract can be expected to produce a constant medicinal effect while allowing for individual variation in response.

African pharmacopoeia volume two described the methods to be used in analyses of African herbal medicine with modifications to suit African climates where necessary.
EVIDENCES OF EFFICACY

- Colorectal carcinoma
- CA prostate
- CA liver and cirrhosis
- Hepatic steatosis
- Diabetes
- CA cervix
- Renal pathology
- Chronic leg ulcers ETC
CASE 5
CANCER OF THE TONGUE
BEFORE TREATMENT
CANCER OF THE TONGUE AFTER TREATMENT
STRUCTURE OF EKENNA NATURES LIMITED
AUGUST VISITORS
PHARM. EKENNA
WITH THE RESEARCH TEAM FROM
UNIVERSITY OF NIGERIA NSUKKA (UNN)
CONFERMENT OF DOCTOR OF MEDICINE ON PHARM EKENNA AT THE WORLD CONGRESS.. 2018.

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(ALMA AT'A 1962)
affiliated with
The Open International University for Complementary Medicines
Based on the record of deeds dated September 1962 located at the Public Registry of Deeds of the Kazakhstan Socialist Soviet Republic No 115620 - 20 - 6 - 30
In Collaboration with Al-Farabi Kazakh National University

The Senate and the Board of Directors hereby confer on
ELIKEE EKENNA REGINALD
who has fulfilled the qualifying requirements, the degree of
Doctor of Medicine (Alternative Medicine)
with all the rights, honours and privileges pertaining to this degree,
In testimony where, we have hereto subscribed our names and caused the seals of the Open International University for Complementary Medicines and Medicina Alternativa to be herein affixed.

Given
November 2018

Chancellor
Registrar
Chairman
Secretary - General

The above-named is hereby authorized to use the suffix M.D. (A.M.) after candidate's name.
CONFERMENT OF DOCTOR OF MEDICINE ON PHARM EKENNA AT THE WORLD CONGRESS.. 2018.
CONFERMENT OF DOCTOR OF MEDICINE ON PHARM EKENNA AT THE WORLD CONGRESS.. 2018.
CONFERMENT OF DOCTOR OF MEDICINE ON PHARM EKENNA AT THE WORLD CONGRESS.. 2018.

56th World Congress of Integrative Medicines

23th, 24th, 25th November 2018 - Colombo - Sri Lanka
PATENT RIGHT CERTIFICATE FOR DISCOVERY AND INVENTION OF NATURAL DRUGS, NATURAL FORMULAR AND METHODOLOGY FOR CURE AND PREVENTION OF CHRONIC DISEASES ETC.

FEDERAL REPUBLIC OF NIGERIA
Certificate of Registration of Patent
(Patents and Designs Act, CAP 344 Laws of the Federation of Nigeria 1990)
R.P: NG/PT/NC/2018/0224
Date of Patent: 10/10/2018
Date of Sealing: 27/11/2018

CERT. No. 011336

President of the Federal Republic of Nigeria and Commander-in-chief of the Armed Forces
MUHAMMADU BUHARI, GCFR.

Whereas a request for the grant of a patent has been made by: EKENNA NATURES LTD OF SI REHAB ROAD EMENE ENUGU, ENUGU STATE, C/O MRS CHINYERE EKENNA OF SI REHAB ROAD, EMENE ENUGU, ENUGU STATE, NIGERIA.

For the sole use and advantage of an invention for: "INNOVATION-FOR-LIFE NATURAL FORMULAR FOR PREVENTION AND TREATMENT OF CANCERS, KIDNEY FAILURE, TUMOURS, DIABETES, FATTY LIVER AND LEG ULCER"

AND WHEREAS the Federal Government being willing to encourage all invention which may be for public good, is pleased to accede to the request:

KNOW YE THEREFORE, that I do by this Instrument give and grant unto the person(s) above named and any successor(s), executor(s), administrator(s) and assignee(s) (each and any of whom are hereinafter referred to as the patentee) by special licence, full power, sole privilege and authority, that the patentee or any agent or licensee of the patentee may subject to the conditions and provisions prescribed by any statute or order for the time being in force at all times hereafter during the term of years herein mentioned, make, use, exercise and vend the said invention throughout the Federal Republic of Nigeria, and that the patentee shall have and enjoy the whole profit and advantage from time to time accruing by reason of the said invention during the term of twenty years from the date first above written on this Instrument: AND to the end that the patentee may have and enjoy the sole use and exercise of the full benefit of the said invention, I do by this Instrument strictly command all citizens of the Federal Republic of Nigeria that they do not at any time during the continuance of the said term either directly or indirectly make use of or put in practice the said invention, nor in anywise imitate the same, without the written consent, licence or agreement of the patentee, on pain of incurring such penalties as may be justly inflicted on such offenders, and of being answerable to the patentee according to law for damages thereby occasioned:

PROVIDED ALWAYS that this patent shall be revocable on any of the grounds from time to time by law prescribed as grounds for revoking patents granted by me, and the same may be revoked and made void accordingly:

PROVIDED ALSO that nothing herein contained shall prevent the granting of licences in such manner and for such considerations as they may by law be granted.

MADE this: 27th Day of NOVEMBER, 2018.

STELLA OZO EZENDUKA
Registrar
PATENT RIGHT CERTIFICATE FOR DISCOVERY AND INVENTION OF NATURAL DRUGS, NATURAL FORMULAR AND METHODOLOGY FOR CURE AND PREVENTION OF CHRONIC DISEASES ETC.
THANKS