REGISTRATION, REGULATION AND DEVELOPMENT OF HERBAL MEDICINAL/ NATURAL FOOD PRODUCTS

"HIDDEN STRATEGIES TO MAKING IT WORK"

A PRESENTATION
BY

Dr. PAUL B. ORHII, JD, MD, PhD

DIRECTOR-GENERAL, NAFDAC

AT

HerbFEST 8ht October, 2013, RMRDC ABUJA

HerbFEST 2013, RMRDC ABUJA

Outline

- Introduction.
- Global Perspectives
- Current Status in Nigeria
- The role of NAFDAC
- Standardization and quality control of herbals /Natural products
- Hidden Strategies and the way forward
- Conclusion

Introduction

- **The use of natural medicinal products in modern medicine as complimentary and alternative therapy is on the increase globally, especially in developing and third world countries because many people cannot afford synthetic drugs.**

- **Many people also consume or use dietary supplements many of which are of herbal origin.**

- **A dietary supplement is intended to provide nutrients that may otherwise not be consumed in sufficient quantities, this include vitamins, minerals, fibre, fatty acids or amino acids etc. They are NOT intended to prevent or treat diseases**

Introduction Cont'd

- **Natural products include plant derived phytomedicines, food supplements/ neutriceuticals and cosmetics and are gaining popularity because the raw materials are abundantly available naturally, and also because access to essential drugs is lacking.**

- **FMoH/ NAFDAC has continued to encourage research and development, while at the same time applying regulation on commercial production and distribution of such products so as to protect public health.**

Global perspectives

- **In many parts of the world, traditional medicine is the preferred form of healthcare and remains the most available and affordable.**
- **In several developing and low income countries R&D is either limited in scope or non-existent due to cost.**
- In the pharmaceutical industry, medicinal plants have now become an integral component of research as they represent a source of molecular diversity for drug development. However, in spite of wide spread use, traditional medicine has not been integrated into the National healthcare systems of many countries (No National policies, no regulation etc.)

CURRENT STATUS IN NIGERIA

- Although Nigeria has a national policy on traditional medicine and NAFDAC regulations cover requirements for registration of natural products, with guidelines, getting manufacturers/ processors to comply is still a herculean task, as control is incorrectly perceived to be "discouragement/ bottlenecks"".
- However, we cannot continue to lament on the "burden" of regulatory compliance because it is a necessary tool for guaranteeing safety and quality.
- Knowledge of their potential adverse effects and efficacy is limited.Many acclaimed benefits are controversial.There is the worry expressed by many stakeholders on patenting rights, evidence of safety/ efficacy/quality.

CURRENT STATUS IN NIGERIA CONT'D

- **The irresponsible/ unapproved advertorials we continue to see and tolerate in the media is also a great dis-service to Nigerians.**

  In this sector, it will require not just regulations, which are very difficult to enforce but will need a total change of attitude by a few media houses, certain individuals unpatriotic companies so that they do not misinform and mislead the Nigerian consumer.

THE ROLE OF NAFDAC

- NAFDAC's major responsibility is to regulate and control importation, exportation, manufacture, distribution sale and use of regulated products including those of herbal origin.

- In general, all products, whether natural or synthetic should fulfil the basic requirements for safety and efficacy.

- Herbal Medicine and Related product (Registration) regulation 2005 stipulates that *''No herbal medicine and related product shall be manufactured, imported, advertised, sold or distributed unless it has been registered in accordance with provisions of the regulations''.*

- *We have only recently reclassified functional food/ health foods from the drug division to the Food safety and Applied Nutrition (FS&N) Directorate and retained only Herbal products and nuetriceutical in the DE& R*

THE ROLE OF NAFDAC CONT'D

- The registration process incorporates detailed and comprehensive documentation review and on-site assessment for Good Manufacturing/ Practices.

- The quality rules require that herbal /natural & allied products meet specifications for purity, strength and composition and manufactured, packaged, labelled and held under conditions to prevent adulteration.

- The NAFDAC guidelines also states that natural & allied products can not be promoted or claimed as a treatment, prevention or cure for diseases and must include on its label- a disclaimer.

THE ROLE OF NAFDAC CONT'D

- **The NAFDAC guidelines for the registration of Herbal products provide that the registration shall subsist for two (2) years before they shall be due for renewal.**

- Such products having been found to be processed/ manufactured according to Good Manufacturing Practice and pronounced fit for use by established laboratory evaluation shall be granted listing licensing status.

- The guidelines also provide that at the time of the second renewal of the products, the applicant shall submit a ***Periodic Safety Update Report*** (PSUR) on the use of the products by the consumer.

Standard and Quality of Herbal/ Natural products

- **The quality of Herbal/ natural products may be defined as the status of a product, which is determined either by identity, purity, content, and other chemical, physical or biological properties, or by the manufacturing process. Compared with synthetic drugs, the criteria and the approach for herbal /natural products are much more complex**.
- QA principle is the most effective way to guarantee that quality is built into a final product.
- GMP, a part of QA has several components including.
  - ✓ Facility layout
  - ✓ Materials and personnel
  - ✓ Product Focus
  - ✓ Utilities and equipment
  - ✓ Air control
  - ✓ Validation
  - ✓ Documentation etc

Standard and Quality of Herbal/ Natural products Cont'd

- The quality criteria for herbal / natural products is also based on a clear scientific definition of the raw material. Depending on the type of preparation, sensory properties, physical constants, moisture, ash content, solvent residues, and adulterations have to be checked to prove identity and purity.

- Microbiological contamination and foreign materials, such as heavy metals, pesticide residues, aflatoxins, and radioactivity, should also be tested for. To prove the constant composition of herbal preparations, appropriate analytical methods have to be developed and applied using different concepts in order to establish relevant criteria for uniformity.

Standard and Quality of Herbal/ Natural products Cont'd

- According to WHO (1996a and b, 1992), standardization and quality control of herbals is the process involved in the physicochemical evaluation of crude drug covering aspects, such as selection and handling of crude material, safety, efficacy and stability assessment of finished product, documentation of safety and risk based on experience, provision of product information to consumer and product promotion.

- **Attention is normally paid to such quality indices such as:**

Standard and Quality of Herbal/ Natural products Cont'd

1. **Macro and microscopic examination**: For Identification of right variety and search of adulterants.

2. **Foreign organic matter**: This involves removal of matter other than source plant to get the drug in pure form.

3. **Ash values**: These are criteria to judge the identity and purity of crude drug – Total ash, sulphated ash, water soluble ash and acid insoluble ash etc.

Standard and Quality of Herbal/ Natural products Cont'd

4. **Moisture content**: Checking moisture content helps reduce errors in the estimation of the actual weight of drug material. Low moisture suggests better stability against degradation of product.
5. **Extractive values**: These are indicative weights of the extractable chemical constituents of crude drug under different solvents environment.
6. **Crude fibre**: This helps to determine the woody material component, and it is a criterion for judging purity.

Standard and Quality of Herbal/ Natural products Cont'd

7. **Qualitative chemical evaluation**:

This covers identification and characterization of crude drug with respect to phytochemical constituent. It employs different analytical technique to detect and isolate the active constituents. Phytochemical screening techniques involve botanical identification, extraction with suitable solvents, purification, and characterization of the active constituents of pharmaceutical importance.

8. **Chromatographic examination**:

Include identification of crude drug based on the use of major chemical constituents as markers.

Standard and Quality of Herbal/ Natural products Cont'd

9. **Quantitative chemical evaluation**:

To estimate the amount of the major classes of constituents.

10. **Toxicological studies:**

This helps to determine the pesticide residues, potentially toxic elements, safety studies in animals like LD50 and Microbial assay to establish the absence or presence of potentially harmful microorganisms.

Standard and Quality of Herbal/ Natural products Cont'd

- **The storage of all raw materials and finished products must be such that they preclude the deleterious effect of harsh environmental effects of high humidity and heat of our tropical climate. Such packaging must be tamper-proof in order to discourage infestations by pests and vermins etc.**
- Factors such as the use of fresh plants, age and part of plant collected, period, time and method of collection, temperature of processing, exposure to light, availability of water, nutrients, drying, packing, transportation of raw material and storage, can greatly affect the quality, and hence the therapeutic value of herbal medicines.

- Apart from these criteria, factors such as the method of extraction microbial load, heavy metals, and pesticides can alter the quality, safety, and efficacy of herbal / natural products and therefore should be effectively controlled.

Hidden Strategies and way forward

- **NAFDAC is therefore seeking to enlighten the public while at the same time urging R&D institutions and the industry to work with the Agency and come up with acceptable standards for QC of herbal medicines beginning with anti malarials and other commonly needed medicines.**

- Standadization and Quality control: Nigeria and indeed African medicinal plants needs to be standadized. There is therefore a need for deliberate policy on medicinal plants **standardization**, including the **procedures and methods for sourcing, collecting, drying, processing, packaging** etc. of RM (from the field to the bottle, covering planting, manuring, tendering to harvest and storage of raw materials RM we must have QC and standardise extraction procedures and preparation of biomass to dosage form.

Hidden Strategies and way forward cont'd

- Because herbal medicine is multi component, you cannot isolate each plant therefore a wholesome standardization is required, which is what the Indians adopted for their Ayuvedic medicine and China for their TCM.

- The R&D institutions and the pharmaceutical industries should embark on indigenous phytomedicines standardization and have a local agenda for such R&D as was done by India and China Both had policies which they implemented to the letter carefully throughout.

- A close and synergistic relationship between the academic and industry is critical to ensuring a robust national Pharmaceutical research capacity for the development of medicinal products

Hidden Strategies and way forward cont'd

- **Another hidden strategy is a strong Government support to Research Institutions and Manufacturing/ Technology industry to meet the Health needs of the African populace which is already given, but expect to see the synergy between stakeholders which should translate into a robust industry.**

- Application of modern science and technology resources to stimulate local raw materials production-collaborative e.g. verification committee recently setup

- **There should be a deliberate Government policy to develop herbal/natural products to pilot stage for local entrepreneurs/manufacturers.**

Hidden Strategies and way forward cont'd

we propose that producers of Herbal /natural products be guided by experts in botanical, pharmacognostic and forestry research institutes located in the various regions of Nigeria, on identification of particular species of plant they intend to utilize in their production process. These tertiary centres can also to provide information on the characterization of the active constituents as well as the possible quantification of such in order to give approximate determination of their expected value.

Hidden Strategies and way forward cont'd

- The NAFDAC regulation stipulates packaging for natural products which should be of pharmaceutical or food grade.

Hidden Strategies and way forward cont'd

- Quality control and the standardization of herbal medicines involve several steps like source and quality of raw materials, GAP and GMP. We can also apply HACCP as a risk management alternative.

- Applying these practices play a pivotal role in guaranteeing the quality and stability of herbal preparations.

- The quality of a plant product is determined by the prevailing conditions during growth, and Good Agricultural Practices can control this. These include seed selection, growth conditions, fertilizer application, harvesting, drying and storage.

CONCLUSION

- Nigeria may be able to enhance access to cost-effective medicines and reduce household financial burden of diseases considerably by supporting infrastructure development and investing in local R&D of medicinal plants. Currently it is estimated that projects in Nigeria cost 30-50% more than elsewhere because of inadequate infrastructure.

- The relationship between the academia and the Pharmaceutical companies is complementary and naturally lends itself to the formation of joint research enterprises. Academia brings strong insight into the fundamental mechanisms of disease along with expertise in patient care and clinical practice.

CONCLUSION CONT'D

- The Pharmaceutical industry possesses the knowledge and tools to translate basic research discoveries into practical applications in patients. Collaboration between the academic and industrial sectors will indicate a synergistic relationship between academic research and commercial activity.

- As the translational gap between discovery and clinical development has become increasingly difficult to bridge, strategies that will ensure core capacity building, market creation, product development, industry promotion, financial burden reduction and disease eradication will lip frog development of the medicinal plants sector in Africa.

Thank you

Acknowledgments

- WHO Technical report series
- NAFDAC Regulations and Guidelines
- Blumenthal et al., 2007
- (EMEA, 2002; Blumenthal et al., 1998; Roberts and Tyler, 1997).