Regulatory Issues for Phytomedicine & Nutraceuticals in Jamaica

DR. DIANE ROBERTSON (BH(M)), Honorary Doctorate, C.A.M, Pharmacist & International Herbal Consultant
Objectives

- Overview of MOH pending ‘Amendment of the Food & Drug Act 1964’ & ‘Food & Drug Regulations 1975 to include Herbs, Natural Products & Supplements in Jamaica’
- Update on status of ‘Regulatory framework for local & imported herbal products’
Introduction

- Existing proposal for the ‘Amendments to the Food & Drug Act & Regulations of 1964’ - since 1999
- Challenged by Wholistic Herbal Assn. (WHA) - from 1996
- Awaited changes for 9 years
HISTORY OF W.H.A STEAKHOLDERS. VERSUS M.O.H.

- Legal discussion to prove if a HERB is a DRUG or FOOD.
- Media war of words with the M.O.H. which led to the involvement of an appeal to the Houses
HISTORY OF W.H.A. STAKEHOLDERS VERSUS M.O.H.

- In 1995 the M.O.H saw it necessary to intervene as the imports of herbal materials, dietary supplements and supplements requirements were almost similar as drugs.
- The W.H.A engaged the M.O.H in a legal tangle, which forced dialogue with the Houses of Parliament.
HISTORY continued

- In March 1999 Parliament took a decision that a special Committee of members of W.H.A, and the JOINT SELECT COMMITTEE on “Human Resources and Social Development” appointed by Parliament and the Minister of Health met for one year preparing documentation to be submitted to Amend the antiquated Laws to include Herbs et.al.
HISTORY continued.

- After awaiting 5 years for the Amendments to be submitted to Parliament by the M.O.H, the WHA closed its offices 2004. Natural Products, Dietary supplements, herbal remedies imports continued as there was high demand for such products, even though a couple shipments were confiscated, returned or “fines” placed on importers.
Regulation

Current draft bill – ‘Food & Drugs Amendment Bill 2003’ - proposed to define OTC products & 5 new categories of products for human consumption:

- Herbs
- Herbal materials
- Herbal remedy
- Finished herbal products
- Health Foods
Regulation

This bill has been in draft for over 10 years.

“The Industry has evolved beyond Amendments!”
MOH Request Cabinet to Include NNI Industry

- MOH proposes this be done by amending Regulations to include this Division
- Legislation will address the establishment of a COUNCIL with the required officers to satisfy the Registrar of the required conditions
CURRENT STATE OF THE INDUSTRY.

- In 2014, The National Commission of Science and Technology (NCST) was mandated to develop a National Nutraceutical Industry (NNI) and Council committed to play a Regulatory Role within the Industry embracing Cultural Sciences, Traditional Knowledge and Technology involving healing PLANTS and SPA WATERS on the island.
LAUNCH OF THE N.N.I.

- This was officially launched by the Most Hon. Then Prime Minister Portia Simpson Miller March 5, 2015 at Hope Gardens. Prof Errol Morrison was appointed Dir. General earlier to form a Team to assist in moving the Nutraceutical Industry Forward.
Legislative Framework

Awaiting Amendments

- Food and Drugs Act & Regulations 1964
- Pharmacy Act & Regulations 1975
- Natural Products & Foods to be established by National Nutraceutical Industry (NNI)
Scope of Work

- Protect local existing & future nutraceutical products
- Certify spa waters, premises & HEALING waters.
- Establish a Council comprised of sector representatives & proven experts in the field of Natural Products.
Scope of Work (cont.)

- Monitor protection of indigenous species
- Strengthen communication & establish training for health professionals and certification
- Establish ethical marketing standards
- Work with institutions to protect Intellectual Property Rights (IPR) and ‘brand’ Jamaica
Herbs Defined

Include plant material e.g.
Leaves, flowers, seeds, fruit, stems, wood,
bark, roots, rhizomes or other plant parts,
which may be entire, fragmented or powdered
Herb Material Defined

In addition to herbs, these include:
- fresh juices:
- gums
- fixed oils
- essential oils
- resins
- dried herb powders
Herbal Remedy Defined

“Any botanical product consisting of a substance produced by subjecting a plant/plants to drying, crushing or any other process or mixture whose sole ingredients are two or more substances so produced. May have potential to be used for risk reduction, therapeutic or treatment purposes. Include traditionally used and new ones.”
Health Food Defined

“Any product other than tobacco taken by mouth that is intended to supplement the diet, such as, vitamin, mineral, amino acid, enzyme, nutraceutical, dietary substance or concentrate, metabolite, constituent, extract or combination of these ingredients”
Note

- All products regulated except:
  - homeopathic preparations more dilute than a one thousand fold dilution of a mother tincture.
  - herbal teas except where there are health claims.
  - products which exist & function principally as food if they make no therapeutic claims e.g. garlic

- Fees required for passive assessment

- All injectable formulations from herbs registered as prescription drugs
Current Requirements for Herbs & Health Foods

Review

- Concentration & ID of active ingredients
- Validate label claims
- Verification of purity, stability report - Certificate of Analysis
- 3-5 samples of each product.
- Proof of approval in country of origin i.e. Certificate of Free Sale, if imported.
- Scientific support claims may be requested.
The National Nutraceutical Industry Framework Operations

- Comprised of sector representatives & experts in the field of natural products approved by the Administrative Body
- No conflict of Interest.
- Minister selects the Board on advice of the Administrative Body
Challenges

- Public Perception remains unchanged.
- Regulatory intervention
- G.A.P in public education programmes
- Insufficient information for many herbs presents barrier to proper scientific review
- Inadequate laboratory support
- Requisite documentation often not supplied
The Way Forward

- MOH must support the growth of this INDUSTRY
- MOH must endeavor to:
  - continue to work with stakeholders/ producers
  - host an effective Advisory Panel and the
  - Amendments to F & D Act to be approved, and published / gazetted
The way forward contd.

- The M.O.H / N.N.I. and Parliament must recognise that there is a SHORTAGE of Technical Assistance, and must involve on their Team a Pharmacognosist, a Naturopath, a Food Scientist, Nutritionist, and a Caribbean Guideline on “Developing Consumer Info. On the proper use of Traditional, and Complementary and Alt. Medicine Editions.”
Expectations

- Maximum benefits to the consumer
- No double standards in quality
- Honest communication to the public
- Public health & safety not compromised.
Suggested Committees

- Research and Development
- Authentication and Validation
- Intellectual Property & Preservation
- Finance
- Information and documentation for local use of Jamaican Herbs
- Education (NNI Group)
FURTHER DEVELOPMENTS

- Educational materials are now required. I recommend 1ST Handbook for Healthcare Professionals on Potential Drug Interactions for commonly used Medicinal Plants and Foods in Jamaica. Contact Dr. Rupika Delgoda Exec. Director Natural Products Institute. U.W.I.
- Email thejani.delgoda@uwimona.edu.jm
- HERBALGRAM Journals. U.S.A see web/site
How Pharmacists Can Earn their True Potential?

- Utilizing your own Dispensary to develop O.T.C products. (Relate the Story of an Empire which began in a Pharmacist Lab in 1886. sold the exclusive rights for US$1.00, and the empire in 2014 partnered for US$ 2.15 billion with an option to increase by 25%.)
THANK YOU

Think of Energy Stamina and Wellness.