Phytomedicines in Jamaica: regulatory issues

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Abstract

Jamaica is making its way towards a full regulation of herbal medicines and related products, namely food supplements. This has been pushed by the increasing imports of unregulated herbal products into the Island creating a need for protecting both our citizens and local producers alike. From a practical legal point of view the current legal framework was based mainly in the Food and Drug Act 1964, and the Food and Drug Regulations 1975, established by the Ministry of Health, but they did not refer to herbals and herbal medicines in its contents. From 1999, Jamaican governmental and private institutions are working on the amendment of these acts and participating actively in international workshops to regulate phytomedicines both within the country and the Caribbean/Centro American region. However the law will force growers to perform adequate laboratory tests that are often out of their economical reach, and the help of the administration has been proposed to solve this problem. Despite theses developments the answer to “what is the status on the Amendment?” is still in limbo.

Keywords: Jamaica, herbal medicines, regulatory affairs.

INTRODUCTION

Herbs are always difficult to characterise because of their complexity of active ingredients or compounds that are usually not known. History has shown that multiple choices exist for protecting human health. Since 1994 the revived interest of natural products as preventative and therapeutic agents accompanied by the high demand for natural remedies and herbs have drawn the attention of the Ministry of Health in Jamaica.

The Ministry has a responsibility to protect the health of citizens, and therefore has to set laws to govern the registration, importation, manufacture, storage, distribution, sale and use of herbal medicinal products. The Food and Drug Act 1964, and the Food and Drug Regulations 1975, established by the Ministry of Health did not refer to herbals and herbal medicines in its contents.
DEFINITIONS BY LEGISLATION SECTION 2-
JAMAICA FDA

**Food** - “any article used for food or drink by man, including chewing gum and any ingredient that may be mixed with food or drink for any purpose.”

**Drug** - “any substance or mixture of substance manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder, abnormal physical state or symptoms thereof in man or animal; restoring, correcting or modifying organic functions in man or animal; dis-infection in premises in which food is manufactured, prepared, preserved, packaged or stored for sale or sold for control of vermin or insects in such premises.”

The regulations pursue to address two important issues related with herbal medicines: Quality and Efficacy. **Quality** is an asset. The primary reason why standardization exists for herbal extracts is to achieve as much control in clinical double blind studies as possible. It is also to protect consumer interests specially relating to product claims and maintain requisite standards-batch to batch consistency. **Efficacy** is the ability to effect label claim-indication/action, identifying the pharmacological activity, the potency for effective doses and to justify the claims on the labels. **Safety** contributes to improve the quality of life. Safety is the fundamental principle and the critical component of quality management. There is the common misconception that all natural products or plants are safe! Safety eliminates/ control toxicity and drug interactions. Today good agricultural practices (GAP) are now in place so as to avoid growing where the soil is contaminated with heavy metals, as well as collection of the wrong species and adulteration with other herbs.

THE CURRENT STATE OF THE INDUSTRY

In 1994, the Ministry of Health (MOH) saw the necessity to intervene in the escalating importation of herbal materials and dietary supplements by treating these as “drugs”. The Wholistic Herbal Association (WHA), which was founded by this author among other stakeholders and consumers in the industry, took the M.O.H to task to prove if an “herb” is a drug or a “food”. The Association engaged the Ministry into a legal tangle along with media “war” with the medical practitioners during 1995-1999. The former Chairman Dr. Robertson and the former President Dr. Vance Lannaman NMD, along with the stakeholders in the industry lobbied with the M.O.H before the Houses of Parliament.

On March 22nd 1999, the Honourable Houses of Parliament took a decision that a special committee of members of the Association and “The Joint Select Committee on Human Resources and Social Development” (appointed by the Houses of Parliament and the Ministry of Health) met for one year preparing documentation to be submitted to Parliament to amend the FDA 1974 to include the following:

1. Herbal Remedies
2. Health Foods
3. Herbs
4. Finished Herbal Products
5. Herbal Materials
6. Dietary Supplements
7. “Over-The-Counter” OTC herbal products.

The document was prepared and submitted to the Permanent Secretary in the M.O.H for perusal and submission to the Chief Parliamentary Council. In 2000 the Ministry of Health appointing a representative of each complementary medicinal therapy, formed an Advisory Panel for Complementary Medicine. Dr. Sonia Davidson MD. was appointed by the M.O.H as the Chairman.

On November 13-16 2000 the Ministry of health hosted a Regional Meeting on Herbal Medicine, which was held in Jamaica. Participants from Barbados, Brazil, Canada, Chile, Guatemala, Jamaica, Mexico, Panama, USA and representatives from PAHO /and World Health Organisation all attended. This meeting was an opportunity for drug regulators of various countries to come together to discuss the different issues surrounding the production, registration and use of herbal products and to develop a proposal on harmonized standards and regulations to assure safe safety and quality of products in share markets. It was also hoped that experiences of countries from other regions would serve as reference and guide for the discussion (Pan American Health Organization, 2002.).

The Advisory Panel completed a document on procedures to harmonise with Complementary Alternative Medicine, which included the operations of herbal practitioners and therapists to be regulated. To date the amendments for Phytomedicines and the Practitioners of Complementary Medicine have not been included in the FDA amendments, or submitted for approval by the Honourable Houses of Parliament.
PRESENT REGULATORY FRAMEWORK

After a period of four years the changes of the Regulatory framework have been completed, and submitted to the Chief Parliamentary Council for adjustments since late 2006, but still no amendments are in place. The Ministry of Health has made reference taken by competent authorities in Australia, Canada, Germany, England and the United States, references to WHO guidelines on the assessment of herbal products and definitions were also adapted for use (WHO. 1998, 2001, 2004a., 2004b).

There is not a Jamaican Pharmacopoeia in place. The British Pharmacopoeia is instead required to be in all Pharmacies in the island. In addition, References can be made from “The Complete German Commission E Monographs” (Blumenthal et al., 1999) published by the American Botanical Council which also includes some Canadian herbal references.

The Pharmacy Council in Jamaica has also made requests for their Laws to be amended to make it possible for herbas to be sold in “special shops” which would be regulated by the Pharmacy Council. This too has not yet been amended.

Since 2005 the Director of Standards and Regulation MOH and their officials along with representatives of Complementary Medicinal Practitioners met formerly on a monthly basis, but this has fell down tremendously.

Documentation Requirements for Registration of Herbal Remedies

It is interesting that the application form from the Pharmaceutical and Regulatory Affairs unit is still under the Registration of Herbal products, food and drugs Act of 1964.

This form has to answer pertinent questions such as a statement of content of the product, the posology, rationale for combinations, toxic/side effects, tests to conform quality and potency.

Attached to the form must be:

- A “Certificate of Free Sale” that must be endorsed by the Jamaican Consulate in the country of origin.
- A “Certificate of Analysis” indicating tests for quality and potency.
- Five samples of the product with the labels indicating manufacturer, expiry dates, and batch numbers.
- A fee of J$5000.00 (approx. U$71.00) applies.

Table 1. Herbs and by-products restricted by the M.O.H. for importation.

<table>
<thead>
<tr>
<th>Common name</th>
<th>Latin name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chaparral</td>
<td>Ceanothus spp.</td>
</tr>
<tr>
<td>Comfrey herb</td>
<td>Symphytum officinale</td>
</tr>
<tr>
<td>Germander</td>
<td>Teucrium chamaedrys</td>
</tr>
<tr>
<td>Willow Bark</td>
<td>Salix alba</td>
</tr>
<tr>
<td>Yohimbe</td>
<td>Corymanthe yohimbi</td>
</tr>
<tr>
<td>Lobelia</td>
<td>Lobelia inflata</td>
</tr>
<tr>
<td>Magnolia</td>
<td>Magnolia glauca</td>
</tr>
<tr>
<td>Ephedra, Ma Huang</td>
<td>Ephedra sinica</td>
</tr>
<tr>
<td>Kava Kava</td>
<td>Piper methysticus</td>
</tr>
</tbody>
</table>

The Requirements for Health Foods

Health food must comply with a simplified procedure to be registered in Jamaica:

- Evaluation and review of active ingredients and concentration.
- Verification of label claims, purity – certificate of Analysis.
- Five samples of products
- Proof of approval in country of origin.
- Scientific support claims may be requested.

All products are regulated except:

- Homeopathic preparations more dilute than 1-1000 fold dilution of a mother tincture.
- Herbal Teas except where there are claims.
- Products, which exist and function principally as food if they make no therapeutic claims e.g. garlic. (Allium sativa). Fees are required for passive assessment.

Several restrictions apply to this category. First of all injectable presentations are not allowed and they can only be registered as prescription drugs. Secondly, there is a list of herbs and by-products are restricted by the M.O.H. for importation. Restriction is based on “advisory reports” received from other international regulatory bodies (see Table1 for a list of restricted plant species).

OUR CHALLENGES

The need for an adequate laboratory support for testing our raw materials to acquire a Certificate of Analysis is most challenging for growers of raw materials. At present our Scientific Research Council is planning assistance in this area. This would assist the many applicants to provide requisite documentation for product approval.
The questions asked daily by stakeholders is “what is the status on the Amendment?” Its answer is still in limbo.

REFERENCES


