Not All Herbs Are Remedies

In order to better educate patients, family physicians must familiarize themselves with regulatory categories for herbal products.

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As more patients explore the use of herbal products, it has become increasingly important for for health-care practitioners to be familiar with current regulatory categories for herbal products.

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Herbal/natural products can be grouped into the following four categories under the current Canadian Food and Drugs regulation:

1. Prescription products such as digoxin, morphine and penicillin where the active ingredient has been isolated from natural sources, purified and formulated into therapeutic products. Proof of efficacy for these herbal remedies is substantiated by scientific evaluation. They meet all the rigorous requirements for being a "drug" under the Canadian Food and Drugs Act and have drug identification numbers (DIN).[1,2] Their monographs can be found in the *Compendium of Pharmaceuticals and Specialties* (CPS).

2. Non-prescription products intended for the self-treatment of a self-diagnosed, self-limiting condition. For example, the use of:
   (i) Menthol as a decongestant: The active ingredient has been isolated from peppermint, purified and formulated into therapeutic products.
   (ii) Psyllium seed as a bulk forming laxative: The whole plant or part of the plant may be formulated into the dosage form.

   These products also meet all the requirements for a "drug" under the Canadian Food and Drugs Act and have a DIN.[1,2] Proof of efficacy is substantiated by scientific evaluation. Their monographs also can be found in the CPS.
3. Non-prescription, traditional herbal medicines (THM), intended for the self-treatment of a self-diagnosed, self-limiting condition (*i.e.*, the use of echinacea for the relief of sore throats due to colds).[3] The October 1995 *Health Canada Drugs Directorate Guideline: Traditional Herbal Medicines* requires the manufacturer of these herbal remedies to:
   - Follow good manufacturing practices (GMP);
   - Provide a complete quantitative listing of ingredients on the label;
   - Clearly indicate that it is a traditional herbal medicine; and
   - Supply a minimum of two traditional references to support the reputed pharmacological action for the part of the plant used.

A DIN is issued if the product is compliant. This ensures a clean, quality product. Proof of efficacy is based upon a minimum of two traditional references, however, to support the reputed pharmacological action for the part of the plant used. There is no evidence for efficacy substantiated by scientific evaluation. Efficacy of the product, therefore, remains in question.

Summary

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- The four categories under current Canadian Food and Drugs regulation are:
  - Prescription products where the active ingredient has been isolated from natural sources, purified and formulated into therapeutic products, which have been proven effective scientifically;
  - Non-prescription products intended for the self-treatment of a self-diagnosed, self-limiting condition;
  - Non-prescription, traditional herbal medicines (THM), intended for the self-treatment of a self-diagnosed, self-limiting condition; and
  - Herbal remedies sold as a food without a drug identification number (DIN).
- All herbal/natural remedies marketed as a food (category 4) are of concern to health professionals due to the lack of information provided and the numerous unsubstantiated off-label health claims being made.
- Most patients, and a large number of health professionals, are not aware of the regulations governing the sale of herbal products in Canada. It often is assumed Health Canada has approved a product for sale if it is packaged in an attractive form and available for sale in pharmacies and other retail establishments.

4. Herbal remedies sold as a food do not have a DIN. The consumer does not have any assurance of cleanliness, quality, efficacy or toxicity information. Data with respect to dosage, side effects, contraindications, warnings or duration of use are not provided. Furthermore, the contents may be adulterated, substituted or sophisticated. Neither the consumer nor the pharmacist is sure of the contents because full label disclosure is not required.

A herbal remedy can be categorized as 1, 2(i), 2(ii), 3 or 4, depending upon how it is marketed. Some herbal remedies may be marketed in more than one category (*i.e.*, aloe used as a non-prescription product for the relief of occasional constipation is marketed under category 2[ii]). Aloe also can be marketed as a traditional herbal medicine for the topical treatment of wounds, burns and abrasions under category 3. It also can be sold in category 4 as a food, providing blatant medical claims do not appear on the label. This is confusing for consumers and health professionals.

When marketed as a prescription or non-prescription product in category 1, 2(i) or 2(ii), there is scientific validation for the herbal product's therapeutic use, whereas this is not the case when marketed under categories 3 and 4. In category 3, the product with a DIN is the preferred choice because there is assurance of the identity and quantity of the stated product present.

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The term "standardized" on the label of a THM is misleading. Because the active ingredient is not known, the product is standardized to a marker. A marker is a secondary metabolite(s) known to be present in a particular botanical. For example, echinacosides serve as a marker for the authenticity of ingredients and quality in echinacea preparations. While the marker is present, the active ingredient(s) may or may not be. Without identification of an active ingredient(s) and knowledge of the quantity present, dosage cannot be established.

Health Canada defines the terms self-diagnosis, self-treatment and self-limiting conditions as follows:[3]

Self-diagnosis:

- The patient or guardian can accurately determine the condition and monitor the severity of the condition, and has some ability to differentiate whether professional help is required.

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Self-treatment:

- The patient or guardian can appropriately select and use a treatment and can monitor for positive and negative effects, as well as lack of effect of that treatment; and
- The patient or guardian can select appropriate prophylactic treatments in the absence of the condition or a definitive diagnosis.

Self-limiting condition:

- A condition that, if inappropriately treated or left untreated, generally would not lead to serious consequences;
- A condition that generally resolves within a limited time period, with or without treatment; and
- Does not include conditions for which prophylactic treatments are indicated (vitamin supple-

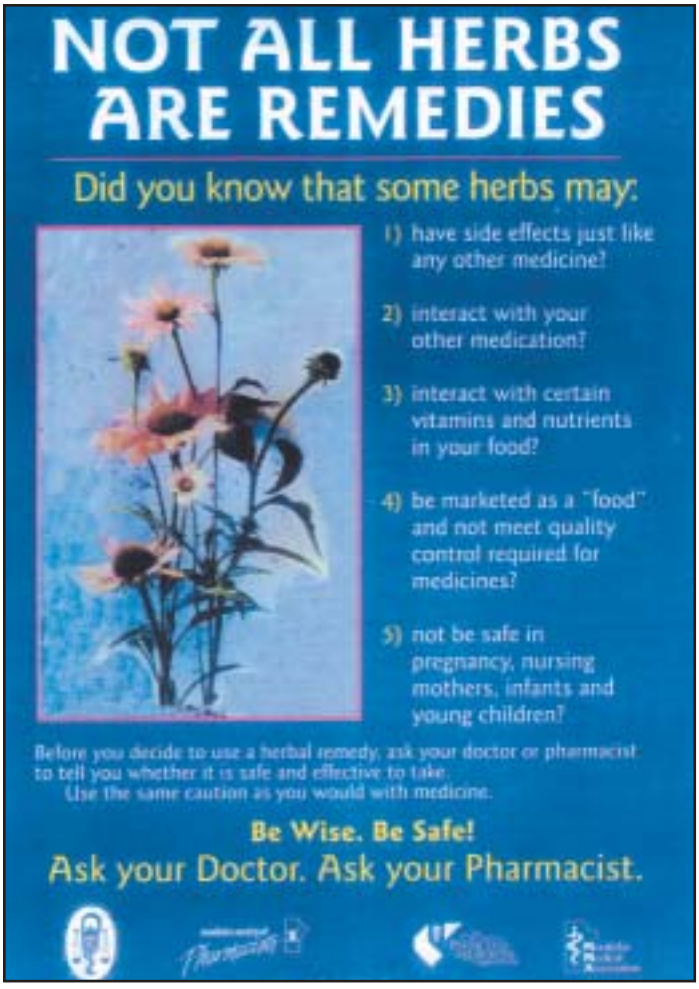

Figure 1. The poster "Not All Herbs Are Remedies" can be used to educate patients on the use of herbal remedies.

mentation, anti-caries fluoride).

Unfortunately, most patients, and a large number of health professionals, are not aware of the regulations governing the sale of herbal products in Canada. It often is assumed Health Canada has approved a product for sale if it is packaged in an attractive form and available for sale in pharmacies and other retail establishments. At the time of purchase, very few patients check to see whether the product has a DIN number on the label.

To confuse the issue further, the majority of patients rely on hearsay evidence, popular literature or the Internet for information that is often misleading or incorrect. While scientific literature is available, it takes time and effort to search reputable sources, such as the Medline, Cochrane Reviews or scientific journals (*i.e.*, *Journal of Medicinal Chemistry* or *Journal of Natural Products*).

Saw Palmetto

The following monograph for saw palmetto, a botanical being promoted for the treatment of benign prostatic hyperplasia (BPH), illustrates the information physicians and pharmacists require before they can make judicious therapeutic choices for their patientsf.

Saw Palmetto is a herbal remedy sometimes used to treat symptoms that may mask a more serious underlying disease, such as prostate cancer. The correct diagnosis, therefore, may be unnecessarily delayed.

Scientific name. Serenoa repens Bartr., S, serrulata Mich., Sabal serrulate Mich.

Family. Arecaceae/Palmae. Common names: Sabal, Serenoa.

Part used: Berries. Category: 4 (food).

General description: Saw Palmetto is indigenous to the southeastern U.S. It is a 3 m to 4 m tall shrub, with 25 cm long palmate leaves, with white flowers and berries that become blue-black when ripe.

Uses. Traditional medicine: Historically used as a food source by indigenous people and as a survival food for European settlers. In Europe, powdered crude fruit, or ethanol extracts have been used to treat symptoms associated with prostate enlargement (difficulty in urination) without reducing enlargement.[4]

Chemical constituents. Carbohydrates (28.2%), consisting of mannitol and high-molecular-weight (MW 100,000) polysaccharides. Fixed oil (26.7%), composed of oleic, capric, caproic, caprylic, lauric, myristic, palmitic and stearic acids. Steroids: sitosterol and other unidentified compounds. Other constituents are flavonoids, pigment (carotene), resin and a volatile oil (1.5%).

Pharmacology. Clinical studies do not show saw palmetto to be any better than placebo for urinary symptoms, such as urgency, hesitancy and frequency associated with BPH. These data do not support the hypothesis that saw palmetto exerts its effect by inhibiting 5α-reductase activity.[5]

Studies focusing on urine flow rate and post-void residual (PVR) volumes did not show a statistically significant difference between the placebo and treated group.[6]

No mechanism of action has been elucidated. There are some concerns expressed with respect to the length of therapy (less than three months) being used to assess efficacy. Long-term, carefully controlled trials are needed to see whether saw palmetto is indeed effective in the treatment of BPH on prolonged use.[7]

The most common adverse effects are nausea and abdominal pain. Headache hypertension, urinary retention and back pain have been reported.[8] There are no known contraindications to saw palmetto.[9]

Pharmaceutical assessment. The proprietary product being quoted in the literature is not available in Canada. Health Canada has not approved saw palmetto as a therapeutic product and it is only available as a "food." Quality control, contents, concentrations and dosages, therefore, cannot be determined for the products currently available. Consequently, it is unwise for pharmacists to recommend saw palmetto for urinary problems. Such patients should be referred to a physician to determine the underlying cause(s).

Saw palmetto is not effective for treating urinary tract infections or prostate cancer. Patients who may be self-medicating with the herb could be delaying diagnosis of a more serious condition.

Given that standardized preparations are not available, the use of saw palmetto cannot be justified. Ultimately, the use of saw palmetto for the symptomatic treatment of urinary urgency, hesitancy and frequency associated with benign prostatic hyperplasia should be a decision made between the physician and the patient.

Guide to Patient Counseling

A herbal product should be treated like any other non-prescription product intended for symptomatic treatment of a self-limiting, non-life-threatening condition, such as the common cold. The product should be discontinued if side effects, such as headache, rash, nausea or anything unusual, are observed. If symptoms do not improve or the condition becomes worse, it should not go untreated.

For patients taking medication for diagnosed medical conditions, who insist on trying herbal remedies, the physician or pharmacist must:

- Provide whatever reliable information is available;
- Make the patient aware of any possible herb/drug or herb/food interactions, warnings, side effects and contraindications. If the remedy will not interfere with existing therapy, use the remedy for a short-term trial period (30 days);
- Ask the patient to inform his/her caregiver(s) of plans to use the herbal product;
- Follow up to determine whether the condition has improved, remained stable or worsened; and
- Suggest an appropriate course of action after the trial period is over.

This process allows the physician and patient to make an informed decision as to whether the product is suitable. It enables the physician to play an active, professional and responsible role in the patient's health care.

An information brochure or the poster shown in Figure 1 can be offered to patients to encourage them to ask their doctor or pharmacist for help in making appropriate and safe therapeutic choices. Additional copies of the poster can be obtained from the Manitoba Pharmaceutical Association or the College of Physicians and Surgeons in Manitoba.

Future Regulatory Developments

The 1999 report of the Canadian Standing Committee on Health recommended the Office of Natural Health Products (ONHP) be established to regulate herbal/natural products in a separate category from foods or drugs.

At the time this article went to press, however, the current Food and Drugs Act and Regulations and the Traditional Herbal Medicines Guidelines remain in effect.[1,2,3,10] CME

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