

2020

Module 7: Natural Health Products Advising



ACADEMY OF QUEST FOR HEALTH®

RX BALANCE Technology Inc.

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Module 7

Education with Excellence

7.0 Natural Health Products and the Law

Understanding natural health in terms of how the body works, the value of whole foods, nutritional supplements, and other remedies will be a valuable commodity in any natural health-related endeavor. In addition, understanding the legal implications in applying your knowledge becomes as important as the knowledge itself.

Awareness of regulations and legal restrictions related to selling natural health products is necessary for a health food store owner, manager, or employee, and for others in the natural health industry, including supplement manufacturers, distributors and salespeople, natural health-minded pharmacists, grocers, and large chain store staff.

Different countries, provinces, and states have their own specific regulations in regard to natural health products. In this module you will focus on the Canadian Food and Drugs Act. Once familiar with the regulations, you can apply them to retail sales and give natural health information with confidence. For information on provincial regulations, check each province's websites.

7.1 Regulation of Natural Health Products in Canada

According to Health Canada, 71 percent of Canadians take natural health products such as vitamins, minerals, herbal products, and homeopathic remedies. In Canada these products, traditionally regulated as either drugs or food, now fall under the Natural Health Products Regulations (effective January 1, 2004) of the Food and Drugs Act.

7.1.1 Defining natural health products

Natural health products (NHPs) are defined as:

- vitamins and minerals
- herbal remedies
- homeopathic medicines
- traditional medicines (like Traditional Chinese Medicines)
- probiotics
- other products such as amino acids and essential fatty acids

7.1.2 Labelling natural health products

The manufacturers of NHPs have a clear set of strictly enforced guidelines to follow under the NHP Regulations, including proper manufacturing, labelling, and identifying.

Under the NHP Regulations, the following is included in the information on NHP labels:

- brand name

- product number (issued with the product licence)
- dosage form
- the word "sterile" if the product is sterile; and
- net amount in the immediate container in terms of weight, measure or number
- name and address of the product licence holder
- name and address of the importer, when applicable
- common name of each medicinal ingredient
- proper name of each medicinal ingredient, if the proper name is not the chemical name
- quantity of each medicinal ingredient per dosage unit
- potency of each medicinal ingredient, if any
- recommended use or purpose
- recommended route of administration
- recommended dose
- recommended duration of use, if any
- risk information (cautions, warnings, known adverse reactions and contraindications)
- recommended storage conditions, if any
- lot number
- expiry date
- description of source material of each medicinal ingredient
- non-medicinal ingredients; and
- the quantity of mercury contained in the product if it contains mercury or its salts or derivatives as a non-medicinal ingredient

7.1.3 Safety of natural health products

Once an NHP is assessed by Health Canada, the product label will bear an eight-digit product licence number, preceded by the letters "NPN". The NPN on the label informs retailers and consumers that the product has been reviewed by Health Canada for safety, quality, and health claims. For homeopathics, the label will bear the designation "DIN-HM".

NHPs must be safe for consideration as over-the-counter products, available for self-care and self-selection, and sold without requiring a prescription. Products requiring a prescription continue to be regulated under the Food and Drugs Act.

7.1.4 Health claims

Before the new regulations, manufacturers who intended to sell their products in Canada were not allowed to state a health claim when labelling. But under the new regulations, if a health claim complies with Section 3 of the Food and Drugs Act, it may be stated on the NHP label.

Section 3 states that, "No person shall sell any food, drug, cosmetic, or device that is represented by label, or that the person advertises to the general public as a treatment, preventative, or cure for any of the diseases, disorders, or abnormal physical states referred to in Schedule A." In other words, a manufacturer is not permitted to have a health claim on a supplement label if the health claim refers to any of the following Schedule A conditions:

- acute alcoholism (possible synonyms: alcohol intoxication; alcohol poisoning)
- acute anxiety state (possible synonym: panic attack/disorder; periods of intense anxiety or fear)
- acute infectious respiratory syndromes (possible synonyms: SARS; acute bronchitis; acute pneumonia)
- acute psychotic conditions (possible synonyms: schizophrenic episode)
- acute, inflammatory, and debilitating arthritis (possible synonyms: sudden onset of severe or sharp joint pain that impairs quality of life)
- addiction (except nicotine addiction) (possible synonyms: alcoholism; substance abuse; drug habit; drug fixation; psychological/physiological dependence)
- appendicitis
- arteriosclerosis (possible synonyms: coronary artery disease; cerebrovascular disease; arteriosclerotic ulcer, clogging or hardening of the arteries, atherosclerosis)
- asthma
- cancer (possible synonym: cancerous tumour; metastasis)
- congestive heart failure (possible synonym: heart failure)
- convulsions (possible synonyms: twitching and jerking of limbs; seizures; epilepsy)
- dementia (possible synonyms: Alzheimer's Disease; Pick's Disease; irreversible impairment of cognition)
- depression (possible synonyms: words describing depression such as suicidal ideation, prolonged marked mood changes, prolonged periods of sadness, etc.)
- diabetes
- gangrene
- glaucoma
- hematologic bleeding disorder (possible synonyms: hemophilia, Von Willebrand disease; abnormal hemostasis; clotting disorder; bleeding disorders; clotting factor VIII or IX deficiency; impairment of platelet adhesion/aggregation)
- hepatitis
- hypertension (possible synonym: high blood pressure)
- nausea and vomiting due to pregnancy (possible synonym: morning sickness)
- obesity (possible synonym: morbidly overweight)
- rheumatic fever
- septicaemia (possible synonyms: infection of the circulatory system; sepsis; blood poisoning; systemic inflammatory response syndrome)
- sexually transmitted diseases (STDs) (possible synonyms: sexually transmitted infections (STIs), AIDS (HIV infection); gonorrhea; syphilis; chancroid; genital and anorectal warts; genital herpes; chlamydia infections; trichomoniasis; amebiasis)
- strangulated hernia
- thrombotic and embolic disorders
- thyroid disease (possible synonyms: hyperthyroidism; hypothyroidism; thyroiditis; goiter; thyrotoxicosis)
- ulcer of the gastrointestinal tract (possible synonyms: peptic ulcer; ulcerative colitis; duodenal ulcer; inflammatory bowel disease; stomach ulcer; esophageal ulcer)

Please note that the above list is not all-encompassing. The list on the Health Canada guidance document will be updated from time to time.

7.2 Advising and Selling Within the Law

The professional practice of medicine is defined as diagnosing, treating, operating, or prescribing for any human disease, pain, injury, deformity, or physical condition. It is illegal for anyone except a qualified medical practitioner to diagnose or treat any form of disease or complaint. Therefore, a Natural Health Product Advisor who prescribes a supplement or remedy, offers recommendations about treating or preventing a specific disease or complaint, or offers a diagnosis, is practicing medicine without a licence, which is illegal.

Each province, territory, and state is responsible for the regulation of the practice of medicine in their respective jurisdiction. It is worthwhile for you to find out if there are any guidelines or regulations in your city that apply to you. In Ontario, for example, the Regulated Health Professions Act (RHPA), which came into effect in 1991, states that assessing and treating disease is no longer a privilege for medical doctors only. There are certain controlled acts that nonmedical people cannot do, such as administer a substance by injection or inhalation, but otherwise there is some room for addressing specific diseases. Check for the latest legislation as it applies to the RHPA by visiting www.ontario.ca/laws.

Natural Health Products Advisors or other nutritional consultants are not qualified health care providers. Titles referring to nutritionists and nutritional consultants are unregulated in Canada and in most US states. A qualified health care provider is a legally licenced medical professional, such as a doctor or nurse, or an institution that provides medical services, such as a hospital or laboratory.

As a health food store staff member or industry professional, you don't need to be a medical doctor, naturopathic doctor, or other qualified health care provider to help people. Customers will still see you as an expert and seek your assistance. They may want to know which products are right for their particular health and nutritional needs, or they may ask your opinion about a symptom or course of treatment.

In the US the Food and Drug Administration inspects and enforces regulations. In Canada this responsibility is undertaken by the Health Product and Food Branch of Health Canada. Both authorities have been known to call or visit health stores to find out if employees or managers are infringing on regulations when selling products.

Remember, unless you are a qualified health care provider, it is illegal for you to diagnose, treat, suggest on, or help prevent any disease or complaint. The following information will expand on this important point. The examples, including accompanying explanations of each approach, will put the information into a practical context.

7.2.1 Do not diagnose

We cannot stress enough that any medical or health-related questions from a customer be directed toward qualified health care providers. Consider your job to be educational and service oriented.

Example: A woman comes in, complaining of intense cravings for sugar, bread, and alcohol as well as dizziness, fatigue, and recurrent yeast infection. You recognize these symptoms as possibly relating to candidiasis or dysbiosis. The customer says she read an article in *alive* magazine that makes her think she might have candida and asks your opinion.

Natural Health Products Advisors (NHPA): I am not trained or legally permitted to diagnose ailments (protecting yourself legally), but it certainly sounds as if you're uncomfortable (showing empathy and concern). Have you seen your doctor? (finding out more information so you know what to say next?)

CUSTOMER: Yes, but he said there is no such thing as candida, and he prescribed antibiotics. They helped for a while, but now it's worse than ever. I don't want to go back to him.

NHPA: Would you like me to give you the contact information for a local naturopathic doctor? If she recommends supplements or remedies, I'd be happy to help you find them in the store.

CUSTOMER: Yes, okay. Is there anything I can do in the meantime?

NHPA: If you would like to read more about candida, I can recommend a book that we have on our bookrack and I have some free pamphlets.

CUSTOMER: That's a good idea. Can you show me the book?

NHPA: Sure, no problem, follow me, and then I'll get you the contact information for a naturopath.

7.2.2 Do not treat or help to prevent disease or complaints

A study conducted by the Research Council for Complementary Medicine in London, England, concluded that health food stores can be a useful source of health information to customers. However, this source could also be harmful if inaccurate or inappropriate recommendations are made, delaying treatment of known benefit.

Only qualified health care providers can treat or prevent a disease or other specific complaint. An NHPA can help customers find supplements or information pertaining to balanced health, nutrition, and detoxification.

There are many ways to help a customer without mentioning a specific disease. Since disease is a sign of imbalance in the body, you can help the customer to choose supplements and remedies that help promote balance.

As a NHPA, you should neither give any indication of what a supplement or remedy will do or not do in relation to a disease nor make any health claims in relation to products sold. Leave that to the experts and manufacturers' labels. To relay any type of expectation is too close to treating or prescribing and is illegal.

Example: A man enters the store and says he has been diagnosed with arteriosclerosis. He'd like to use some natural remedies in addition to his drug and exercise therapy. He asks what you recommend.

NHPA: I am not legally permitted to prescribe remedies for disease (protecting yourself legally), but there is more and more scientific research being published about the many ways that natural approaches can help to prevent, treat, and reverse heart disease (giving him general information only and encouragement for seeking out alternative remedies). Has your doctor recommended a natural remedy? (finding out if he's come for or heard of something specific)

CUSTOMER: No, he just gave me a drug and exercise program, but I've read a lot about how garlic can help lower cholesterol and boost immunity and how hawthorn berries are helpful for the heart. Will these supplements bring down my cholesterol?

NHPA: Both of these herbs have been well researched and are remedies for many conditions. I can show you the different types we have. (No mention of his disease or promises about what the supplements will do. On the way to the herbal supplements shelf, you pick up a book about heart disease and hand it to the customer.) Perhaps you'd like to purchase this as well or have a look through it here in the store.

7.2.3 Do not prescribe

Researchers from the Department of Internal Medicine, University of Mississippi Medical Center, studied 12 health food stores to determine what products employees were recommending for depression. The researchers concluded that, "Health food store employees offer health care advice regarding treatment of depression with dietary supplements without proper scientific and medical training. Their comments could cause significant harm to customers. In addition, the inconsistencies of dietary supplement content continue to raise concern for individuals who use these agents as medical treatment."

Another study, published in the *Canadian Journal of Gastroenterology* (2000), found that there was a great deal of inconsistency among health food store staff when it came to recommending supplements for the same chronic disease.

It is illegal for anyone but a doctor to prescribe supplements. As a product advisor you can help your customers choose their supplements by providing the information they need to make a decision, but you cannot tell them which ones to buy.

There may seem to be a fine line between prescribing and recommending, but they are quite different once you understand your role and the legal restrictions. Section 7.2.4 will outline what you can and cannot say in terms of recommending supplements. In short, however, any time you tell a person to take a supplement or recommend a supplement in specific reference to a disease or complaint, you are prescribing.

Example: A teenage girl comes to you and asks you what she should take for her premenstrual syndrome.

NHPA: I am not legally permitted to prescribe remedies for specific conditions (protecting yourself legally). Has your health care provider recommended you purchase a natural remedy?

CUSTOMER: No, but lots of my friends take natural stuff like evening primrose oil and it seems to help.

NHPA: I recommend seeing your health care provider for specific recommendations, but in the meantime, I can show you our selection of evening primrose oil. I also have some reading material that might be helpful. According to this book, for example, an imbalanced diet, especially a diet high in sugar and low in fibre, is a major factor in PMS (relaying information only).

CUSTOMER: That sounds good. Thank you. (The customer still leaves with what she came in for but without you prescribing it)

7.2.4 What can the NHPA talk about?

Your customers are looking for natural answers to health questions. Many are disillusioned with the state of orthodox medicine and health care. Though you may not diagnose or prescribe treatment, you have a fountain of natural health and nutrition information to pass along to your customer, who will greatly appreciate this knowledge.

There are many topics you are entitled and qualified to discuss with your customers. The more knowledgeable you are on these subjects and the more confidently you deliver the information, the more grateful and loyal your customers will be. Some of what you may discuss has been covered in this course and includes:

- digestion
- detoxification
- alternative diets
- nutritional supplementation
- elimination
- assimilation

7.3 Guidelines for the NHPA

The many choices, products, and methods can be overwhelming to the consumer. Effective product advisors must have, at the very least, a basic knowledge of what they are selling and how they can sell it within the parameters of the law to help customers safely and effectively. As mentioned earlier, it is helpful for you to think of yourself as providing educational information and service, not specific health recommendations.

If you follow these guidelines carefully, you can almost always find a way to help a customer without diagnosing treating, prescribing, making a health claim, or helping in disease prevention.

7.3.1 Listen carefully

Only by listening to customers can you find out what they require and provide them with educational information and helpful service.

Listening is one of the prime factors in a positive relationship. Conversation becomes a process of listening and discovering the customer's needs. With careful responses and replies, you can coax the information you need from the customer, allowing you to provide service that will both impress and win loyalty.

Pay attention to the detail of what someone is saying.

Truthful listening will inspire trust, allowing the conversation to progress. Not all people communicate clearly and concisely and sometimes you may need to read between the lines.

With practice and diligence, you can develop listening skills that will prove to be an invaluable tool in your role as a NHPA.

7.3.2 Identify the customer's need by asking questions

Listening carefully will help you ask the right questions and lead you to mutual trust where you can help the customer with educational information and service. Do not ask about symptoms. Instead, gear questions more toward what they are looking for in the store.

It may be necessary to use a series of questions. The most powerful question is “Why?” or “How come?” Asking your customer why he or she believes or wants a certain thing helps you discover what your service should be. Through this question-answer process of elimination, you can determine whether the customer is seeking self-medication for a possibly serious medical problem or just seeking information on natural healthy living. Then you can decide your course of action. With this method you also avoid diagnosing and prescribing treatment.

7.3.3 Educate and provide service

A Cancer Research Center of Hawaii study, published in the Archives of Family Medicine (2000), concluded that retailers supplying supplements to people with breast and other cancers can play an important role in the network of authorities by providing information about products.

The best-case scenarios are when customers know what they want. Then it's your job to show them what you have and give educational information about each product such as the strength, dosage directions on the label, ingredients, and how one is different from the other. Be sure to offer information without advising how to prevent or treat a specific disease as that is considered prescribing.

If customers are looking for a diagnosis or specific information that you cannot provide, direct them to their professional health care provider.

7.3.4 Give them a choice

You don't always have to reveal everything that you know. When you educate customers about their choices and let them make a final decision, you are not prescribing to them and are therefore not accountable for their decision.

7.3.5 Speak carefully

It is of the utmost importance that you think before you speak. Choosing your words carefully can mean the difference between prescribing and educating. An understanding of what to say and what not to say will be an invaluable tool for helping customers without breaking the law. The NHPA must find the balance between saying too much and possibly breaking the law, or saying too little and not being helpful to the customer. In some cases you may choose to use neutral expressions such as, “Uh huh,” “Hmmm,” or “I see,” in response to your customer, and then transition the conversation to something within your boundaries.

Example:

You can say: This supplement may help to build good health.

You cannot say: This supplement may help to treat/cure/reverse your disease.

You can say: What brought you in today? What are you looking for? Have you seen your health care provider?

You cannot say: What are your symptoms? What disease do you have? What is your problem?

You can say: I am not a doctor so I cannot diagnose you.

You cannot say: You seem to have...You may have...What you need is...

You can say: This product may help you achieve nutritional balance.

You cannot say: This product will cure you/lower cholesterol/treat your symptoms.

You can say: I can offer advice about food and nutrition.

You cannot say: I can offer advice about treating disease naturally.

You can say: This book/chart/pamphlet shows the types of supplements that may improve nutritional balance.

You cannot say: This book/chart/pamphlet shows you how to eliminate your symptoms.

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Module 7: Natural Health Products Advising

quiz

1. According to Health Canada, 71 percent of Canadian take natural health products such as:
 - a. homeopathic remedies
 - b. vitamins and minerals
 - c. organic foods
 - d. all of the above
 - e. a and b only

2. In Canada, Natural Health Products (NHPs) are defined as:
 - a. vitamins and minerals
 - b. herbal remedies, traditional medicines, and homeopathic medicines
 - c. probiotics, amino acids, and essential fatty acids
 - d. all of the above
 - e. a and c only

3. Canadian NHP regulations include strict guidelines for the following:
 - a. retail sales
 - b. labelling and identification
 - c. manufacturing
 - d. all of the above
 - e. b and c only

4. In Canada, NHPs must be:
 - a. safe for consideration as over-the counter products

- b. sold by prescription only
 - c. properly labelled
 - d. all of the above
 - e. a and c only
5. Which of the following condition cannot be referred to in relation to a health claim, as per Schedule A, Section 3 of the Canada Food and Drugs Act:
- a. asthma and arthritis
 - b. depression and cancer
 - c. obesity and acute alcoholism
 - d. all of the above
 - e. a and b only
6. As an NHP understanding the legal implications in applying your knowledge is as important as the knowledge itself. True or false?
7. In Canada, if health claim complies with Section 3 of the food and Drugs Act, it is allowed to appear on the NHP label. True or false?
8. An eight-digit product number and the initials "NPN" on the label of a Canadian NHP informs retailers and consumers that the product has been reviewed by Health Canada for safety, quality and health claim. True or false?
9. It is legal for an NHPA to prescribe supplements to customers. True or false?
10. The professional practice of medicine is defined as diagnosing, treating, operating, or prescribing for any human disease, pain, injury, deformity, or physical condition. True or false?