

Regulation of Natural Health Products in Canada

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I. INTRODUCTION

Since the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA),¹ many U.S. manufacturers, importers, and distributors of natural health products, dietary supplements, functional foods, and analogous products (referred to here collectively as “natural health products”) have wondered how to move their products onto the Canadian market. Interest is high because Canada constitutes a largely English-speaking market of 30 million people with buying habits for natural health products similar to Americans.

This article examines the current regulatory framework in Canada for natural health products, the nature and extent of enforcement of the current regulations, and the government’s plans for future regulations. This article also addresses the legislation and regulations currently in force, the approach of Canadian regulators to the current regime, exceptions made to enforcement, the development of a new regulatory regime, and speculation on the implementation of that new regime.

II. THE CURRENT FOOD AND DRUGS ACT AND FOOD AND DRUG REGULATIONS

Responsibility for drug approvals (although not health matters generally) lies with the federal government in Canada. The statute governing the regulation of drugs, medical devices, food, cosmetics, and most natural health products in Canada is the Federal Food and Drugs Act² originally enacted in 1953 and periodically amended since.³ Detailed regulations for those working in the field are provided by the *Food and Drug Regulations*,⁴ which are regulations made under the Food and Drugs Act.⁵

The government agency primarily concerned with the administration of the Food and Drugs Act and the *Food and Drug Regulations* is the Therapeutic Products Directorate (TPD) of the Health Protection Branch of Health Canada. Another agency, the Canadian Food Inspection Agency (CFIA), deals with many of the food-related issues arising from the Food and Drugs Act and the *Food and Drug Regulations*. These agencies issue a number of subregulatory documents providing guidance for those dealing in regulated products. Such documents are variously referred to as Guidelines, Directives, Information Letters, and Policies.

The Food and Drugs Act can be amended only by Parliament, requiring the government of the day to introduce a bill amending the Act and to secure its passage through the House of Commons and Senate. The *Food and Drug Regulations*, however, can be

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¹ Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. § 301 note (1994)).

² Food and Drugs Act, R.S.C. ch. F-27 (1985) as amended (Can.).

³ Based in part on the United Kingdom’s Sale of Food and Drugs Act of 1875, although influenced by U.S. legislation.

⁴ Food and Drug Regulations, C.R.C. ch. 870 (1978) as amended (Can.).

⁵ Medical devices are covered by the separate Medical Device Regulations, SOR/98-282, also made under the Food and Drugs Act.

amended by the Governor-General-in-Council (effectively, the Federal Cabinet), which is an easier and speedier process.

The Food and Drugs Act provides the definitions of “drug,” “food,” “cosmetic,” and “medical device.”⁶ No definition of dietary supplement, functional food, or natural health product currently is provided; such a category of products was not contemplated at the time of the Food and Drugs Act’s passage. Many of the difficulties surrounding natural health product regulation in Canada flow from the absence of a definition of the term in the Food and Drugs Act or any other law. The Food and Drugs Act defines “drug” as including:

- . . . any substance or mixture of substances manufactured, sold or represented for use in
- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals,
 - (b) restoring, correcting or modifying organic functions in human beings or animals, or
 - (c) disinfection in premises in which food is manufactured, prepared or kept;

Because the definition is based on what a product is “sold or represented for use in,” which products constitute “drugs” in Canada is determined by what claims are made for them. The effect of this definition is that, where a product makes a health claim, directly or indirectly, that product is a drug. This can be taken to extremes. For example, if one places a sticker on an orange stating that the orange “Prevents Scurvy,” a health claim has been made and that food has, in theory at least, been converted into a drug for regulatory purposes. This means that, under the current rules, even an ordinary food that is sufficiently fortified to make health claims is considered a drug in Canada. By regulation and policy, the TPD also has stated that certain other substances, regardless of the presence or absence of health claims, will be considered drugs.⁷

Under this definition, most natural health products are drugs under Canadian law. It is worth noting that, under the current regime, there is no exemption for structure/function claims as opposed to other health claims. Such claims are treated the same as any other health claim, in contrast to the United States, which has treated them more leniently under DSHEA.⁸ Another important aspect of the Food and Drugs Act, from the natural health product perspective, is that annexed to it is a list of diseases, disorders, or abnormal physical states known as “Schedule A.” It is forbidden to make any claims to the general public that treat illnesses or conditions listed on Schedule A.⁹ The intention of Schedule A was to prohibit the promotion to the public of any drug to treat serious diseases, with the attendant risk that the public might fail to seek competent medical advice. Among the many diseases, disorders, or abnormal physical states listed on Schedule A are arthritis, cancer, heart disease, nausea and vomiting of pregnancy, and sexual impotence. No drug can be advertised to the general public to treat these conditions, even if it can be shown that it in fact does so (i.e., that it is efficacious).

⁶ See Food and Drugs Act, *supra* note 2, at s. 2.

⁷ Therapeutic Products Directorate, Listing of Drugs Currently Regulated as New Drugs (Apr. 1999) available at (last visited Feb. 25, 2002) www.hcsc.gc.ca/hpb/dgps/therapeut/htmleng/guidmain.html#new.

⁸ Food and Drugs Act, *supra* note 2.

⁹ *Id.* s. 3(1).

III. TODAY'S REGULATORY ENVIRONMENT

Due to the fact that natural health products are drugs in Canada, they must be approved by Health Canada's TPD prior to sale.¹⁰ This requires a new drug submission (NDS), where the manufacturer must show that the product is safe and efficacious for the claims made, or a submission for a Drug Identification Number (DIN) directly, if reference can be made to a monograph.¹¹ If the manufacturer successfully shows the product is safe and effective by either route, a DIN is issued, and the product may then be sold.¹² Similar to a new drug application in the United States, a very high level of proof is required for a NDS, and many natural health product manufacturers are unable, or unwilling, to meet this burden of proof. Often, expensive procedures such as double-blind clinical trials are necessary to show the efficacy and safety of long-known and well-established herbal remedies.

As noted, for common or previously-marketed drugs, a DIN can be obtained by showing that a product conforms to a monograph. There are no monographs for common natural health products at this time. There are, however, monographs for conventional vitamin and mineral supplements, which provide that as long as vitamin and mineral sources are acceptable and daily dosages fall within an acceptable range, a DIN may be obtained by reference to such monographs.¹³

The NDS process is usually an insurmountable barrier for a natural health product manufacturer. There is, however, considerable desire among Canadian consumers for natural health products. They are exposed to U.S. advertising in magazines and on television, and expect to find these same products freely available in Canada. Further, as in the United States, many consumers are suspicious of the mainstream medical and pharmaceutical establishment and wish to take more responsibility for their own health.

Attempts to rigorously enforce the provisions of the Food and Drugs Act that require natural health products to be government-approved prior to sale and to have a DIN, as well as to meet other requirements of the Food and Drugs Act, such as establishment licensing, have met with criticism from the public and the press.¹⁴ As a result, Health Canada bowed to such pressure, and eased up on full enforcement of the laws. In an attempt to regularize this, the government introduced on January 1, 1998, a policy entitled the "Interim DIN Enforcement Directive."¹⁵

IV. ENFORCEMENT TODAY

A. *Exceptions to Enforcement*

The Interim DIN Enforcement Directive,¹⁶ which remains in effect as of this writing,

¹⁰ Food and Drug Regulations, *supra* note 4, pt. C Div. 8.

¹¹ *Id.* C.01.014.

¹² *Id.*

¹³ Category IV Monographs for "Dietary Mineral Supplements" and "Dietary Vitamin Supplements" can be found on the TPD's website at www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidnpd.html#NpcatIV.

¹⁴ Submission of Canadian Coalition for Health Freedom (Feb. 3, 1999) and Submission of Citizens for Choice in Health Care (Feb. 5, 1999) to Parliamentary Standing Committee on Health (Parliamentary Committee Records).

¹⁵ TPD, Interim DIN Enforcement Directive, *available at* (last visited Mar. 1, 2002) www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmain.html. It was amplified by the release of a further document, the *Therapeutic Products Compliance Guide*, issued by the TPD on May 26, 1998, which sets out in detail the products that are and are not considered Products Subject to Special Measures (PSSMs) (see *infra*).

¹⁶ Interim DIN Enforcement Directive, *supra* note 15.

defines certain natural health-type products as “products subject to special measures” (PSSMs).¹⁷ These products are defined as:

traditional medicines (i.e., traditional herbal medicines as well as traditional medicines such as Chinese, Ayurvedic (East Indian), and Aboriginal (North American) medicines), homeopathic preparations, and vitamin and mineral supplements for human use, when in dosage form and for which prescriptions are not required.¹⁸

Included under this rubric are most capsule, tablet, and powder form natural health products, including vitamin and mineral supplements (despite the fact that conventional vitamin and mineral supplements can be approved with a DIN by reference to the Category IV monographs discussed above). Certain substances are specifically excluded from this category, including: any product for which a prescription is needed (Canada maintains, in the *Food and Drug Regulations*, a comprehensive list of the substances that must be dispensed by prescription);¹⁹ any product that claims to treat Schedule A conditions; products containing narcotics or restricted drugs; products that must be sterile; and certain other specified substances.²⁰

Notable substances popular with natural health product manufacturers that are not specifically PSSMs include: amino acids occurring singly or in a mixture outside of naturally occurring protein configurations; melatonin; ornithine; and EPA and DHA (Omega-3 fatty acids).²¹ Health Canada recently has added Ephedra to the list of exceptions.²²

The Interim DIN Enforcement Directive sets out the policy of Health Canada’s TPD that, where a PSSM lacking a DIN comes to the TPD’s attention, a letter will be sent to the manufacturer stating that they should have a DIN, but that *no other enforcement action will be taken*. In other words, enforcement action will be, in essence, restricted to a warning.

This raises the question of the legal status of the Interim DIN Enforcement Directive. It is most unusual in Canada for a government department to state openly that it will not enforce certain laws. The law cannot—or at least should not—be abrogated in this manner by the Civil Service. If it is a regulation, it must be withdrawn by the Governor-in-Council (the Federal Cabinet); if it is a statute, it must be repealed by Parliament. Nonetheless, it appears unlikely, as a result of officially sanctioned inaction and in the absence of a compelling health hazard, that Health Canada could successfully prosecute a natural health product manufacturer marketing a product that fits clearly within the definition of a PSSM for failing to have a DIN or for failing to meet many other requirements of the Food and Drugs Act.

On June 19, 2001, a representative of Health Canada, when interviewed by the Toronto *Globe & Mail* for an article on mail-order diet aids, stated, “It’s difficult to be very strict about enforcing the current rules . . . [because] they may change.”²³

The general approach used today by Health Canada to decide whether to pursue a natural health product for failure to comply with the Food and Drugs Act and the *Food*

¹⁷ *Id.* pt. 4, Definitions.

¹⁸ *Id.*

¹⁹ Food and Drug Regulations, *supra* note 4, Schedule F.

²⁰ *Id.*

²¹ Therapeutic Products Compliance Guide, *supra* note 15, section 2.1.

²² Health Canada issued a Voluntary Recall Letter and an advisory to the public regarding Ephedra and its derivatives on January 8, 2002. These documents can be found at Health Canada’s website, (last visited Mar. 1, 2002) www.hc-sc.gc.ca/english/protection/warnings/2002/2002_01e.htm.

²³ *Shedding Pounds-Or Dollars?*, GLOBE & MAIL, June 19, 2001, at R7.

and Drug Regulations is to ask whether it poses a risk to the public. Therefore, manufacturers of products containing dangerous ingredients can expect to be pursued. If the product merely does not do what it claims to do, or is incorrectly labeled, it is unlikely that vigorous enforcement action will be taken. The exception is where a natural health product clearly makes claims to treat a very serious disease (normally a Schedule A disease), and the use of which could prevent a user from seeking appropriate professional medical attention (such as products that claim to cure cancer). Health Canada also is unusually vigilant where natural health products are marketed to children or pregnant women.

The requirement to have a DIN prior to sale is, of course, not the only requirement imposed on companies marketing products regulated as drugs by Canada's regulatory regime. In addition, there are labeling, recordkeeping, reporting and recall requirements, establishment licensing provisions, and good manufacturing practice (GMP) standards that must be met. Because natural health products are drugs in Canada, all of these legal requirements also must be met. Like the DIN requirements, however, where the product falls into the PSSM "exemption," the regulator has been slow to enforce such requirements on natural health product manufacturers, distributors, and retailers. A counterpart document to the Interim DIN Enforcement Directive, the "GMP and Establishment Licencing Enforcement Directive" was issued to cover this area.²⁴ This officially sanctions a similar "non-enforcement" approach to the provisions of the *Food and Drugs Regulations* calling for establishment licensing.

B. Equality of Enforcement

Different regions of Canada experience different levels of enforcement. In the west of the country (British Columbia, Alberta, Saskatchewan, and Manitoba), incidents of enforcement are relatively low, perhaps due to the manifest public interest in self-medication in these provinces. Also, the popularity of distribution through multilevel marketing schemes makes enforcement difficult. In Ontario, the province used by many companies for their headquarters, warehousing, and importation operations, enforcement is more common, except against Chinese herbal remedy-type natural health products. The province of Quebec also has a high enforcement rate. The Atlantic Provinces (Newfoundland, Prince Edward Island, Nova Scotia, and New Brunswick) are those in which the laws are enforced most vigorously.

As recently as 1997 (prior to the issuance of the Interim DIN Enforcement Directive), enforcement of the laws was sometimes based on the ethnic origin of the seller, or the perceived "ethnicity" of the product itself. For example, individuals and shops of Chinese origin could sell unapproved products, but the same products could not be sold by people of non-Chinese origin. This situation was brought to light in a case heard by the Canadian Human Rights Commission, an administrative tribunal tasked with hearing human rights complaints. A British Columbia man complained that he and his company were being discriminated against on the basis of race because no enforcement action was taken against importers and retailers of Chinese ethnic origin (who were selling products without DINs and with Schedule A claims), but enforcement action was taken against him. In 1998, an appeal tribunal of the Canadian Human Rights Commission overturned an earlier decision, and found Health Canada had discriminated against the complainant.²⁵ The Commission issued a comprehensive order requiring Health

²⁴ Issued on January 1, 1998, and available on the TPD website at (last visited Mar. 1, 2002) www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmain.html.

²⁵ *Bader v. Canada* (National Health and Welfare), [1998] C.H.R.D. 1, No. T.D. 2/98, reversing [1996] C.H.R.D. No. 1, No. T.D. 1/96.

Canada to equalize its enforcement procedures. The Commission forbade unequal enforcement based on the ethnicity of the user or consumer of the product, the ethnicity of importers and retailers, or the so-called "ethnicity of product" as between "ethnic" and "Western" products.

Health Canada reacted by issuing a policy entitled "Compliance and Enforcement Strategy" on June 1, 1998, which purported to set out that enforcement must not use the prohibited criteria identified by the Commission.²⁶ It is open to debate whether, in the absence of the resources to do much enforcement of any kind, this policy has had any real effect.

V. INITIATIVES FOR CHANGE

A. *Advisory Panel on Natural Health Products*

In May 1997, Health Canada established a committee to examine the issues surrounding natural health product regulation in Canada. The committee was comprised of government regulators, representatives from various interest and industry groups, and senior bureaucrats. Its mandate was to propose a regulatory framework for natural health products in Canada. It produced its final report on May 13, 1998. The most important recommendation of the Advisory Panel was that Canada adopt a combination premarket licensing and postmarketing notification system for such products, depending on the type of product and the claims made for it. More importantly, the Advisory Panel rejected a DSHEA-type regime.

B. *Report of the Parliamentary Standing Committee on Health*

The Canadian Parliament has a number of standing, multiparty committees that study the direction new legislation and regulation should take. One such committee is the Parliamentary Standing Committee on Health. On November 13, 1997, the Minister of Health requested that the Committee conduct a study on natural health products. The Parliamentary Standing Committee heard submissions from a large number of individuals and organizations. One of the main submissions they considered was the report of the Advisory Panel on Natural Health Products, discussed above.

On November 4, 1998, the Standing Committee released its report, entitled *Natural Health Products: A New Vision*.²⁷ The Committee made 53 recommendations. Chief among these recommendations was that a separate regulatory body be established to deal with natural health products. The Committee also recommended the adoption of a licensing scheme, largely as recommended by the Advisory Panel.

C. *Minister's Announcement*

On March 26, 1999, the Minister of Health held a press conference at a Toronto health food store where he announced that the Government had accepted all 53 of the Standing Committee's recommendations. He then set up a transition team to create a new regulatory body that was to implement the recommendations of the Standing Committee.

²⁶ TPD, Compliance and Enforcement Strategy, available at (last visited Mar. 1, 2002) www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/strategy.html.

²⁷ REPORT OF THE STANDING COMMITTEE ON HEALTH, NATURAL HEALTH PRODUCTS: A NEW VISION (Nov. 1998) (available from the Research Branch of the Library of Parliament).

VI. THE NATURAL HEALTH PRODUCTS DIRECTORATE

The end result of the various consultative processes was the creation of the Office of Natural Health Products. The Office subsequently was renamed the Natural Health Products Directorate (NHPD). Located in Ottawa, Ontario, it eventually will be responsible for regulating natural health products in Canada. Dr. Philip Waddington, a doctor of naturopathic medicine, was appointed as the Directorate's first Executive Director on January 5, 2000.

The NHPD is a directorate within the Health Protection Branch (HPB), itself a component of Health Canada. The Executive Director will report to the Assistant Deputy Minister in charge of the HPB. More importantly, the NHPD will not be a part of the TPD, which is perceived as the "drug" side of the regulatory bureaucracy (formerly known as the Drugs Directorate, the TPD is seen by many in the industry as hostile to natural health products).

The NHPD established a transition team and conducted a series of public hearings to gain input on how natural health products should be regulated in Canada. On March 31, 2000, the transition team issued its final report entitled *A Fresh Start*.²⁸

VII. LEGAL FRAMEWORK OF PROPOSED APPROACH TO REGULATION

The proposed framework for the regulation of natural health products (as embodied NHPD's *A Fresh Start* report) addresses:

- product licensing;
- site licensing;
- GMPs;
- labeling and packaging provisions; and
- adverse reaction reporting.

Following its *A Fresh Start* report, the NHPD issued the *Proposed Regulatory Framework for Natural Health Products* in March 2001. This document contained draft-enabling regulations. A second, revised working draft of the proposed regulations was released on September 21, 2001.²⁹

One of the most important questions about this new regulatory regime is when it will be implemented. The NHPD published the *Draft Natural Health Products Regulations* for comment on December 22, 2001.³⁰ This was followed by a period for the receipt of comments (until March 22, 2002). Publication of the final version of the regulations realistically cannot be expected before the summer of 2002, and is likely to slip further. Therefore, the end of 2002 or the beginning of 2003 is likely a more realistic time to expect the *Draft Natural Health Products Regulations* to come into force.

The *Draft Natural Health Products Regulations* do not address the underlying problems with the Food and Drugs Act; rather they attempt to address the problem solely by regulation. For instance, there is no attempt to introduce a definition of "natu-

²⁸ OFFICE OF NATURAL HEALTH PRODUCTS, *A FRESH START: FINAL REPORT OF THE ONHP TRANSITION TEAM* (Mar. 31, 2000) (available from the Natural Health Products Directorate (NHPD) of Health Canada).

²⁹ Both documents available from the NHPD website at (last visited Mar. 1, 2002) www.hc-sc.gc.ca/hpb/onhp/welcome_e.html.

³⁰ *Draft Natural Health Product Regulations*, 135(51) CANADA GAZETTE PART I 4912 (Dec. 22, 2001) [hereinafter *Draft Regulations*]. The *Canada Gazette Part I* is a government publication in which proposed regulations are set out for public comment.

ral health product” into the Food and Drugs Act, as opposed to the *Food and Drug Regulations* (which means that they would remain a subcategory of drug) or to repeal Schedule A. The problem with Schedule A is addressed to some extent by using the regulations to give to the Minister the power, under the Food and Drugs Act, to exclude natural health products from the operation of Schedule A.³¹

Pending the promulgation and implementation of the *Draft Natural Health Products Regulations*, the NHPD with the cooperation of other offices within the HPB has published an “Interim Management Strategy for Natural Health Products.”³² This policy sets out that there is to be increased cooperation and stakeholder consultations during the transitional period. This presumably means that, prior to any enforcement action being taken, the TPD will consult with the NHPD and perhaps the CFIA. There has been no obvious difference in enforcement activities, however, since the promulgation of the “Management Strategy.”

VIII. THE *DRAFT NATURAL HEALTH PRODUCTS REGULATIONS*

Although all the types of natural health products to be covered are not yet determined, the *Draft Natural Health Products Regulations* do set out specific substances to be considered natural health products at section 1(1) and Schedule 1.³³ Certain substances also are excluded specifically in Schedule 2.³⁴ This article does not intend to provide an in-depth review of the *Draft Natural Health Products Regulations*, however, it is worth noting that besides defining “natural health product,” the *Draft Natural Health Products Regulations* have provisions regarding product licensing,³⁵ site licensing,³⁶ GMPs,³⁷ clinical trials on human subjects,³⁸ and general labeling and packaging provisions.³⁹ The *Draft Natural Health Products Regulations* do make provision for prescription natural health products.⁴⁰

A. *Product Licensing*

The *Draft Natural Health Products Regulations* set out that each natural health product (NHP) must be licensed by the NHPD prior to sale in Canada. An application for a license will require information including:

- information about the manufacturer;
- common and proper name of the product;
- a full description of the product, including all ingredients;
- proposed shelf life;
- drafts of product labeling;

³¹ Section 30(1)(j) of the Food and Drugs Act permits the Minister to make Regulations “exempting any food, drug, cosmetic or device from all or any of the provisions of this Act and proscribing the conditions of that exemption.”

³² The “Interim Management Strategy for Natural Health Products” can be found on the NHPD website at (last visited Mar. 1, 2002) www.hc-sc.gc.ca/hpb/onhp/ims_e.htm.

³³ These include some substances that were *not* PSSMs, such as amino acids, and essential fatty acids.

³⁴ These include antibiotics, parenteral substances, tobacco, radiopharmaceuticals, and biologics.

³⁵ *Draft Regulations*, *supra* note 30, ss. 4-19.

³⁶ *Id.* ss. 20-32.

³⁷ *Id.* ss. 33-53.

³⁸ *Id.* ss. 54-74.

³⁹ *Id.* ss. 75-96.

⁴⁰ *Id.* s. 96.

- information that supports the product's safety; and
- information that supports the recommended use of the product.

The most contentious areas will be the “information that supports the safety of the product” (safety) and “information that supports the recommended use” (efficacy). After the extensive iterative process to develop a new regulatory regime for natural health products set out above, the test for the issuance of an NHP license remains that existing for drugs—showing safety and efficacy. In fact, this is very similar to the current drug system.

The standards of proof, however, will be lower. In many cases, the manufacturer will be able to rely on NHPD Attestable Monographs for standardized NHPs (as can now be done for certain common drugs). In other words, an attestation by an officer of the manufacturer that the product for which a license is sought meets an existing monograph will satisfy the safety and efficacy requirements. These Attestable Monographs will likely cover a large number of typical NHPs (herbs, homeopathics, traditional medicines), as well as vitamin and mineral supplements, amino acid or EFA supplements, and other designated products. The NHPD has undertaken to provide the NHPD Attestable Monographs prior to *Canada Gazette Part II* publication of the finalized *Food and Drug Regulations*.

A further welcome change from the drug regime pertains to the scenario of a product that is a vitamin, mineral, homeopathic preparation, or botanical being sold for its traditional use (i.e., without new, unproven claims), for which the license will be deemed issued 60 days from the submission of the license application. For the purpose of this 60-day automatic license issuance, a “traditional use” is defined as:

- (a) in the case of a vitamin or mineral, use as a nutritional supplement;
- (b) in the case of a homeopathic preparation, use as a homeopathic preparation, remedy, or medicine; and
- (c) in the case of a botanical-derived substance, use that is well documented, according to accumulated experience over an extended period of time.

This amounts to the most significant lowering of the scientific evidence barrier vis-à-vis full-fledged drugs.

If the NHPD objects prior to the expiry of the 60-day period, there will be an opportunity for dialog between the manufacturer and the NHPD to clarify the situation. Where the NHPD requests further information, the 60-day time period stops for the period of time it takes for the manufacturer to provide an adequate response to the NHPD.

The manufacturer will have an obligation to notify the NHPD within 60 days of the first sale of a product. Certain minor changes to the product or its labeling will require the manufacturer to inform the NHPD, although a new license will not be required for these minor changes. Products also will be required to meet certain limits of variability, currently proposed as 85-120% of the amount listed on the label for volatile ingredients.

Among certain other administrative powers, the NHPD will retain the ability to withdraw licenses and to order that sales of any product cease if it is a risk to health. The *Draft Natural Health Products Regulations* suggest that there be a one-year transitional period for already-marketed NHPs. To take advantage of this “grandfathering” period, a NHP needs to have been properly marketed (that is, with a DIN or correctly

marketed as a PSSM, not merely tolerated or overlooked) prior to the implementation of the *Draft Natural Health Products Regulations*. Whether any given NHP should use this path has not been addressed.

B. *Site Licensing*

Under the *Draft Natural Health Products Regulations*, each person or organization in the manufacture-distribution chain will require a site license. If a product is manufactured or packaged at a site, a site license will be needed. Importers and distributors also will need a site license. In order to get a site license, each applicant must show that the site meets all GMP requirements.⁴¹ Unlike NHP licenses, no default period is proposed. Minor changes to site licenses will be dealt with by post-change notification to the NHPD. The site license will need to be renewed every three years.

Other proposed aspects of the site-licensing requirement are:

- a site license would not be required for growers who handle and treat products in their raw form;
- an application for a site license need contain only information relevant to the activity carried on at the particular site;
- site inspections are not envisioned as part of the licensing program; and
- the transition period for site licensing is expected to be longer than that for product licensing—two years.

C. *Good Manufacturing Practices*

GMP requirements will apply to natural health products under the *Draft Natural Health Products Regulations*. They will affect both product and site licenses. They provide that no one shall sell a NHP unless it has been manufactured, packaged, labeled, imported, distributed, and stored in accordance with the prescribed GMPs,⁴² and that all licensed sites in which NHPs are manufactured, packaged, tested, imported, and distributed must be designed, constructed, and maintained in a manner that ensures the activities are conducted under sanitary conditions. Site license GMP standards will be very similar to those for drugs. The GMP provisions also require adequate training of personnel, appropriate Quality Control supervision, conformance to specifications, stability testing, recordkeeping, sterility requirements, and sampling requirements.

D. *Labeling and Packaging*

The labeling requirements⁴³ under the *Draft Natural Health Products Regulations* are not relaxed greatly from those for drugs. Each label must set out:

- the common and proper name of the natural health product, or, when applicable, the medicinal ingredient it contains;
- the brand name of the natural health product, if applicable;
- adequate directions for use;
- any cautions, warnings, contra-indications or possible adverse reactions associated with the product;

⁴¹ For manufacturers, this would include attestations that buildings, equipment, practices, and procedures comply with applicable good manufacturing practices (GMPs). For importers, the application also would need a GMP inspection report. Distributors' site license requirements would be less onerous.

⁴² *Draft Regulations*, *supra* note 30, s. 33.

⁴³ *Id.* ss. 75-96.

- a precise quantitative list of all of the medicinal ingredients contained in each dosage unit;
- a qualitative list of the nonmedicinal ingredients contained in the product;
- the plant or animal part from which the product is obtained;
- the physical form of the product;
- the net amount of the product, expressed in terms of weight, measure, or number;
- the recommended storage conditions, if any;
- the lot number;
- the NHP product license number;
- the expiry date; and
- the name and address of the licensee, or if the licensee is outside Canada, the name and address of the Canadian distributor.

Where a NHP is available over-the-counter, adequate directions for use in both English and French must be provided. Obviously, these requirements will affect some potential license holders more than others. In any case, a long phase-in period of three years is proposed for already-marketed products to meet the new labeling requirements.

E. *Adverse Reaction Reporting*

The *Draft Natural Health Products Regulations* also make provisions for adverse reaction reporting. The intention is that they will be based on reactions to the product, and not to the medicinal ingredient, although the two often will be inseparable. Serious adverse reactions occurring in or out of Canada are to be reported to the NHPD within 15 days. Information on nonserious adverse reactions is to be recorded and kept by the license holder, although it need not be submitted to the NHPD unless requested. Like the labeling requirements, a three-year phase-in for adverse reaction reporting is proposed.

IX. APPLICABILITY OF OTHER REGULATORY REGIMES

A. *Patented Medicine (Notice of Compliance) Regulations*

Canada has a system, similar to that enacted by the Hatch-Waxman Act⁴⁴ in the United States, which allows holders of drug patents to list the in-force patents pertaining to a particular drug on a Register maintained by Health Canada. The regulations setting this out are called the *Patented Medicine (Notice of Compliance) Regulations*.⁴⁵ Once patents are listed against a drug, any second-entry version of a drug in the same dosage form, route of administration, and containing the same medicine cannot be marketed without the second-entry manufacturer addressing the patents of the manufacturer who listed patents against that drug. This often results in expensive and prolonged litigation.

Under the *Draft Natural Health Products Regulations*, NHPs will remain a subcategory of drug under the Food and Drugs Act. Therefore, absent amendments to the *Draft Natural Health Products Regulations* or to the *Patented Medicines (Notice of Compliance) Regulations*, a manufacturer could theoretically list patent(s) against a NHP, and by doing so engage the operation of the *Patented Medicines (Notice of*

⁴⁴ Formally, this statute is known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b (1994); 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. §§ 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

⁴⁵ Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 as amended. These

Compliance) Regulations.

As a practical matter, it is the nature of most NHPs that no patent protection will be available for them, as many are considered tried or traditional remedies and, therefore, are not amenable to patenting. Over the long term, as the NHP market matures and manufacturers invest in increased research and development regarding these types of products, it is entirely possible that patented NHPs could arise. Were this to happen, it is conceivable that they could be caught by Canada's Hatch-Waxman-type regime.

B. *Patented Medicines Prices Review Board*

Patented medicines in Canada have their price levels supervised by the government pursuant to the patented medicines prices provisions of the Patent Act.⁴⁶ The Food and Drugs Act establishes the Patented Medicines Prices Review Board, which has the authority, within certain limits, to control the prices of medicines under patent in Canada. For the same reason noted above, as the *Draft Natural Health Products Regulations* currently are constituted, it is possible that patented natural health products, as a subset of "drugs" under the Food and Drugs Act, could come under the supervision of the Board.

It is hoped that the final version of the *Draft Natural Health Products Regulations* will specifically exempt NHPs from the operation of both the *Patented Medicine (Notice of Compliance) Regulations* and the supervision of the Patented Medicines Prices Review Board.

X. CONCLUSION

The current regulatory situation for natural health products in Canada is unsatisfactory. It does not satisfy traditional science-based regulators, as the Interim DIN Enforcement Directive allows what amounts to nonenforcement against the most common categories of natural health products. It does not satisfy natural health product manufacturers and marketers, as there is no certainty in the governmental reaction to their products. Also, without a consistent system properly embedded in law, rather than bureaucrat-made policy, there is no basis for the regulators to interact in a useful way with the companies and with the other government departments concerned, most notably Canada Customs.

The *Draft Natural Health Products Regulations* will be a great improvement, because they will provide greater certainty for all players and protection of the public through the use of a continuum of proof requirements for safety and efficacy that depend on the ingredients and claims of the product. The *Regulations* also will add to the legitimacy of the natural health products industry. The *Draft Natural Health Products Regulations* are complex, and their ultimate success may depend upon the willingness of the government to devote sufficient resources to develop, elaborate, administer, and enforce them. Without adequate support, no system, no matter how well planned, can succeed. Also, understaffing could result in tremendous delays in the implementation of this much-needed regulatory initiative.

Finally, it is deplorable that "natural health product" must be defined as a subset of "drug" in a regulation, rather than being added to the Food and Drugs Act by Parliament. Aside from the objection of many natural health products marketers to their

regulations are made under the Patent Act, R.S.C., c. P-4 (1985) as amended (Can.), and not under the Food and Drugs Act.

⁴⁶ Patent Act, *supra* note 45, ss. 79-100.

products being considered a type of drug, such an approach to regulating the industry requires the use of the Minister's power to exempt certain drugs from the operation of the Food and Drugs Act and the *Food and Drug Regulations*. This Byzantine approach complicates matters for the regulated industry, and may introduce unanticipated difficulties, such as the potential applicability of the *Patented Medicines (Notice of Compliance) Regulations* or the products being subject to the jurisdiction of the Patented Medicines Prices Review Board.