BILL C-51:
PROPOSED FEDERAL REGULATION OF TRADITIONAL MEDICINE

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ABSTRACT

Bill C-51 was introduced in Parliament in 2008. The Bill included changes to the Canadian Food and Drugs Act that some argue would have a significant effect on the delivery of traditional medicine by Aboriginal healers in Canada. Although the Bill has “died on the order paper,” it is likely to be reintroduced by the current government in substantially the same form. The paper identifies the elements of the proposed changes in the federal government’s legislative policy towards the practice of traditional medicine, as contained in the proposed legislation, discusses their possible effects on the practice of traditional medicine and assesses the potential ramifications on the rights of Aboriginal persons to practice traditional medicine.

INTRODUCTION

On 8 April 2008, Bill C-51 was introduced in the Canadian House of Commons. This Bill was a comprehensive amendment to the Food and Drugs Act. The Bill caused controversy in the natural health sector and was the source of concern among a number of Aboriginal organizations (1). These concerns centre around the effect of the Bill on traditional healing. The Bill was not enacted. It died on the order paper when the 2008 federal election was called. It has not yet been reintroduced, but could very well be introduced in the same version or a modified one.

Lyle MacWilliam, who represented Okanagan-Shuswap from 1988 to 1993, told the Georgia Straight that he formed part of former Liberal health minister Allan Rock’s 17-member transition team that helped set up the Office of Natural Health Products, now the Natural Health Products Directorate. Mr. MacWilliam stated:

“Big pharma wants to make it as difficult as possible for people to get access to natural health products. The reason I say that is because many NHPs [natural health products] cannot be patented, so there is no profit in it for the drug industry. I think we are seeing the effects of a lobbying effort on behalf of big pharma.” (2)

Andrew McGivern, founder and director of Omira Health Centers, has stated:

“It will wipe them [natural health products] out. Hundreds of the products that you walk into a store and see on the shelves will be gone. Even without Bill C-52, it is already happening through the legislation that came out in 2004 [the Liberals’ Natural Health Products Regulations]. We have already lost 40 percent of our products. C-51 will accelerate that process.” (2)

Alan Cassels, drug-policy researcher at the University of Victoria, stated:

“If they are going to use the pharmaceutical industry’s standard of effectiveness, clinical proof; they [NHP providers] are going to have a lot of trouble reaching that bar. If you can’t patent something, then you can’t get a monopoly profit on it, so where are you going to get your money to do the clinical trial then?” (2)

Are these observations accurate? This paper will examine the issue of the effect that Bill C-51, as introduced in 2008, would have on traditional healing in Canada. In summary, the purpose of this paper is to try and answer the question: “Would Bill C-51 have an adverse effect on traditional healing?”
Traditional approaches to medicine and healing

Traditional healing can, of course, encompass traditional methods used by any ethnic group, whether Chinese, Aboriginal, South Asian or European. However, the emphasis in this paper is on traditional Aboriginal healing.

The World Health Organization and Health Canada both define "traditional medicine" as "the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness" (3).

As defined in the Report on the Protection of Heritage of Indigenous People, "Indigenous knowledge is a complete knowledge system with its own epistemology, philosophy, and scientific and logical validity...which can only be understood by means of pedagogy traditionally employed by the people themselves" (Battiste & Henderson, 2000, p. 41).

The Report of the Royal Commission on Aboriginal Peoples (1996) defines traditional healing as defined as practices designed to promote mental, physical and spiritual well-being that are based on beliefs which go back to the time before the spread of western "scientific" bio-medicine. When Aboriginal Peoples in Canada talk about traditional healing, they include a wide range of activities, from physical cures using herbal medicines and other remedies, to the promotion of psychological and spiritual well-being using ceremony, counseling and the accumulated wisdom of elders. (4)

First Nations' approaches to medicine and healing are holistic and encompass body, mind and spirit. Rather than intervening physiologically (e.g., surgery), it has been said that the job of an Aboriginal healer or medicine person is to kick start the body's natural healing mechanisms. Medicines in Aboriginal culture are powerful and it is important to show them due respect. In modern society, a prescription for medication can often be filled by pharmacists as a result of a 5 to 15 minute visit to a doctor. In the Western system, time is money. Traditional healers can help using a more detailed process of evaluation and treatment (5).

According to Ms. Gloria Lee (6), a legally trained Cree and writer on traditional Aboriginal medicine,

"The four elements of the person are the Spiritual, Emotional, Physical and Mental. The physical manifestations of a weakness are seen as disease or bodily ailment. The disease is traditionally seen as a symptom of the weakness. The weakness may be derived within the spiritual, emotional or psychological aspects of the person. When a person is inflicted with a disease, the traditional view is that it is an offering of a teaching to the individual. The teaching will ultimately be of oneself but the person may choose to deal only with the symptom of physical manifestation of the weakness and not address the root of the disease itself. If the person chooses to treat only the disease and ignores the teaching which it is offered, then the disease will return. Physical manifestations may continue to appear until the individual accepts the teaching."

Background issues related to traditional medicine products

The common theme in the concerns expressed about Bill C-51 is the apprehension Elders' have about the government regulating traditional medicine or in some way controlling their activity. Elders have highlighted the fact that it was in their recent history that these ways were outlawed, and perhaps now, the government is finding another way to control their spirituality, healing and ceremonies. The legal issues arising from insurance from malpractice of traditional healers are a very current and real challenge for Aboriginal health facilities that have traditional medicine as a public service. Also, they feel threatened by any documenting of traditional medicine in health facilities (7).

According to the Rural Advancement Foundation Institute Report to the United Nations, over 80% of the world's people depend on Indigenous knowledge for health and security and 50% rely on Indigenous knowledge for crops and food (Dei, Hall & Rosenburg, 2000). The United Nations Sub-commission on Prevention of Discrimination and Protection of Minorities reports (7) that the annual market value of pharmaceutical products derived from medicinal plants discovered by Indigenous peoples exceeds U.S.$43 billion,
but the profits are rarely shared with Indigenous peoples. Traditional healers have employed most of the 7,000 natural compounds used in natural medicine for centuries; 25% of American prescription drugs contain active ingredients derived from Indigenous knowledge of plants (Daes, 1993, p. 1; Battiste & Henderson, 2000, p. 124).

Intellectual property rights regarding traditional medicine are also highly controversial, stemming from the historical and continued exploitation of Indigenous knowledge by Eurocentric prospectors. Although this is an issue not directly regulated under Bill C-51, it is important background since, today, large pharmaceutical companies mine Indigenous knowledge, acquiring patents and profits from it.


As plants and animals have been pirated from their communities, indigenous peoples have been forced to respond to protect the life in their territories and their traditional knowledge. In many cases, communities are finding out as much as a decade later that one of their sacred plants, animals, or methods has been patented. Some Indigenous peoples have been developing mechanisms to protect collective community-based rights over plants, animals, human genetic materials, and traditional medicinal and agricultural knowledge. (Harry & Shelton, 2001, 12) (7)

The various legal regimes that we call intellectual property attached exclusive property rights to this autonomous culture. It has been observed that modern Western legal regimes enhance the commodification of Indigenous culture so that this Indigenous culture could then be bought and sold in the marketplace (Battiste & Henderson, 2000, p. 250).

**Practice of traditional medicine**

The practice of medicine is regulated by provincial and territorial government, not by the federal government. For example, in British Columbia, acupuncture and Traditional Chinese Medicine (TCM) is governed by the College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia, which is an official professional licensing authority established in 1996 by the Government of British Columbia. It regulates the practice of Traditional Chinese Medicine (TCM) and acupuncture in that province. The College is a self-regulatory body that operates under the Health Professions Act and the Traditional Chinese Medicine Practitioners and Acupuncturists Regulation and Bylaws.

In Ontario, the Regulated Health Professions Act provides explicitly for the practice of Aboriginal medicine exempts it. Section 35 of that Act states:

35. (1) This Act does not apply to,

(a) aboriginal healers providing traditional healing services to aboriginal persons or members of an aboriginal community; or
(b) aboriginal midwives providing traditional midwifery services to aboriginal persons or members of an aboriginal community.

When considering the legal treatment of traditional medicine practices in general, we must remember that it is only since the 1970s that legal bans on certain healing and religious ceremonies such as the Sundance have been lifted. (7)

However, while traditional medicine is more than merely the administration of herbal products, the focus of Bill C-51 is only on therapeutic products, which include traditional medicine products, and not on the other categories of knowledge or skills that comprise most of traditional medicine. Therefore, this paper will turn its attention to the effect of Bill C-51 on traditional medicine in relation to only the products of that medicine.

**Current regulatory burden on traditional medicine products**

Currently, the Natural Health Product Regulations (8) already enacted under the Food and Drugs Act prohibit anyone from selling a natural health product that does not have a product license. A natural health product includes “a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material.” Thus, a traditional medicine product is already regulated and requires a product license.

The regulatory burden of the current federal Food and Drugs Act, and its related regulations, appears designed to exclude sole practitioners and small businesses from the sale of traditional medicine products. Only a multinational pharmaceutical company will be in a position to market these products. While the objective of protecting
Canadians from harm caused by traditional medicine is a reasonable one, the enforcement practices of Health Canada in relation to natural health products reveal a different story.

Consider the case of Truehope and their product EMPowerplus, used to treat bipolar disorder. Health Canada’s own investigators concluded that the product should be classed as a category II health hazard (5) – meaning that the risk of harm is remote (6). Nonetheless, Health Canada issued a public advisory about the product and blocked access at the border (7). They then set up a 1-800 crisis line to deal with desperate Canadians in fear for their mental health, advising them to return to their doctors and go back on their psychiatric medications (8). All this without evidence of harm. In contrast, consider the case of Vioxx. Approved by Health Canada in 1999 as a treatment for arthritis, it was removed from the market in 2004 due to an increase in cardiac events associated with use. As stated by the Canadian Medical Association Journal, “It has now become clear that both the FDA and (by inference) Health Canada were aware of the increased risk of cardiovascular adverse events long before the drug was withdrawn from the market” (9). Or, take another example, Prepulsid, a drug to treat heartburn. At the inquest into the death of 15-year-old Vanessa Young (who died taking Prepulsid), it was revealed that Health Canada was aware that as many as 10 Canadians died while taking the drug, and that as many as 70 had died in the United States. Despite a strong warning going out in the US, Health Canada did not insist on one for Canada (10). It was also learned that Health Canada was haggling with the wording of a warning letter to physicians with maker Janssen-Ortho when Vanessa died. (9,11)

This shows that quite different standards are being applied by Health Canada in relation to traditional medicines and pharmaceutical drugs. According to the President of the Natural Health Products Protection Association:

“Currently, roughly 60% of natural health product license applications are failing. The majority of these license applications are for single ingredient products which are easier to licence than [sic] multi-ingredient products. The percentage of failed license applications is expected to increase as more multi-ingredient product license applications are considered. My estimate is an overall failure rate of 70%. This means that over 60% of the natural health products on the market will fail the licensing process and will become illegal [emphasis in original]. At that point the manufacturer can willfully withdraw them from the market or Health Canada can take enforcement action.” (10)

A review of countries that have adopted a drug-based model of natural health product legislation shows a trend towards fewer and more costly natural health products, to the point where the industry virtually ceases to exist. International supplement companies are already pulling out of the Canadian marketplace due to excessive costs and restrictions. The OHA believes that Bill C-51 will not improve this situation but will likely exacerbate it (11).

**Traditional medicine products as “Drugs” under Bill C-51**

This paper will now turn to the more specific consideration of the actual clauses in Bill C-51 and how they might affect the legal status of traditional medicine products being classified as “drugs.”

Under clause 15.1 (4) of Bill C-51, the minister of health will be able to “designate a therapeutic product – either individually or by class – as a prescription therapeutic product.” This clause allows the minister of health to make a traditional medicine product a prescription product and therefore move it out of reach for Aboriginal healers.

In clause 6 of the Bill, the word “practitioner” is defined as “an individual who is authorized under the law of a province to prescribe or dispense prescription therapeutic products.” This definition does not include a traditional Aboriginal healer.

On its website (12), Health Canada states that it does not intend to do this but, unfortunately, Health Canada has a history of restricting access to herbs where prescription drugs can be extracted from them or where an alleged toxic compound has been identified in them, regardless of the historical support for the safe use of...
the whole herb. Given the number of chemicals present in any given herb, it could be possible to find some toxic constituent in any of them, so the restriction to “prescription only” becomes completely dependent on the attitudes of the incumbent minister of health and Health Canada (11).

The definition of “drug” is not being changed by the Bill, but an important section (s. 3) of the current Act would be repealed by the Bill. The effect of repealing this section means that the current definition of “drug,” which is dependent upon an exclusive list of diseases which are affected by a “drug” in Schedule A, would no longer be used to interpret the meaning of the term “drug.” Since the Schedule A list would not be used to define “drug,” the ambit of the existing term “drug” would have much greater reach legally under Bill C-51. The term “drug,” therefore, would be broad enough to encompass traditional medicine products used for any therapeutic purpose, not just for treatment of a disease listed in Schedule A.

It has been publicly argued by Health Canada that, under Bill C-51’s legislative framework, therapeutic products will be risk-managed using a progressive licensing approach. The argument goes that since natural health products are generally safe when produced in accordance with their particular quality standards, licensed natural health products pose relatively little risk to consumers, which is why they will continue to be marketed over-the-counter and not under-the-counter prescriptions. As stated repeatedly on Health Canada’s website (11):

There is nothing in Bill C-51 that changes the regulatory status of natural health products from over-the-counter, as they are now, to prescription...Since the Natural Health Products Regulations came into force in 2004, there have been no amendments to convert a product from a natural health product to a prescription drug.

Despite this assertion, clause 15.1 (4) of the proposed Bill would provide the government with power to designate any natural health product and traditional medicine a prescription drug, making it available by prescription only. The fundamental change being made in Bill C-51 is to demolish the distinction between “over the counter (OTC) products” and “drugs.” The Bill groups them all as “therapeutic products.” Hence, the issue of prescription and OTC products is no longer relevant from a legislative point of view, since they are both seen as fundamentally the same kind of product. The Bill provides that the licensing process for them may be identical. It should be kept in mind that the approach of Health Canada is to treat the principles of traditional medicine as being the same as Western medicine, that is, that products work through chemistry, not through spirit as in Aboriginal medicine or as in Qi (energy) in Traditional Chinese Medicine.

On 4 November 1998, the House of Commons Standing Committee on Health tabled its report, titled Natural Health Products: A New Vision. The report contained 53 recommendations, all of which were accepted by the government on 2 March 1999. The first recommendation read:

Health Canada, in conjunction with a new separate Natural Health Products Expert Advisory Committee (EAC) should set out an appropriate definition of natural health products (natural health products) and amend the Food and Drugs Act accordingly.

However, Bill C-51 did not follow this recommendation and did not create a third class of product called natural health products (13). As a result of concerns raised by the natural health products industry, the government proposed making amendments to the definition of “drug” and “therapeutic product” in Bill C-51. The proposed amendment would create a new category of therapeutic product called a “natural health product” that is very similar to the existing definition in the regulations. It would cover a plant, any plant material, an alga, a bacterium, a fungus or any non-human animal material manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or for use in restoring, correcting or modifying organic functions in human beings.

While this amendment might have solved the major concern of traditional medicine products as “drugs,” there would still be the possibility that Health Canada could define a traditional medicine product as a drug, notwithstanding the new class
of natural health product. This has already been done under the current Act, notwithstanding the limited definition of drug.

The case of *R. v. Synergy Group of Canada Inc.* illustrates the problems with Health Canada's approach to the regulation of the natural health products industry (14). The following facts and discussion are taken from the judgement in the case.

In this case, the defendants made claims that Empower Plus was useful for the treatment of depression and bipolar disorder. Health Canada took the position that this brought the supplement within the definition of a "drug" within the meaning of the Food and Drugs Act, even though the product was clearly a vitamin/mineral supplement. Health Canada advised the defendants that they could not sell or distribute the supplement in Canada without a Drug Identification Number or D.I.N. However, in order to get a D.I.N., the product would be required to undergo extensive testing designed for drugs or pharmaceuticals through the Therapeutic Products Directorate of Health Canada. In the normal course, this would typically involve the testing of one active ingredient over the course of several years and at considerable expense. Such a drug testing regime was not suited to a vitamin/mineral supplement, or other health food products, which typically could have numerous active ingredients. The vitamin/mineral supplement in Empower Plus, for example, had approximately 24 ingredients. It would not be possible for the defendants to obtain a Notice of Compliance and then a D.I.N. for Empower Plus, and Health Canada was well aware of this fact.

The Honourable Judge G.M. Meagher stated in his judgement in this case (the numbers in square brackets before the following paragraphs indicate the paragraph reference in the original judgement):

[8] At this time, the users of Empower Plus were being monitored through the Truehope program. If an individual stopped taking the supplement, or was denied access to the supplement, that person would revert within a matter of days to an earlier state of depression or bi-polar behaviour characterized by aggressiveness, mood swings, and violence to one's self or to others with a very real risk of personal injury and, in some cases, death. Conventional treatment with various drugs or pharmaceuticals and regular attendances with psychiatrists was not considered to be a viable or desirable alternative because of the serious negative side-effects associated with such medications.

[19] Under the new legislative and regulatory regime for natural health products that came into force in January 2004, a similar product to Empower Plus was submitted and eventually received approval. More significantly, in March 2004 the new federal Minister of Health granted an exemption to the Defendants for the Empower Plus supplement pursuant to the terms of a ministerial agreement that remains in force today. The supplement continues to be sold, distributed and monitored in Canada by the Defendants, Synergy and Truehope, under this agreement.

[20] Regardless of the foregoing, in May 2004, Health Canada instituted six charges against the Defendants for breaches of the Food and Drugs Act and Food and Drug Regulations during the period of January 1, 2003 and December 31, 2003. At the commencement of this twelve day trial on March 13, 2006, the prosecution entered Stays of Proceedings on five out of six charges. This Health Canada prosecution has proceeded on count number 3 - that the Defendants, between January 1, 2003 and December 31, 2003, unlawfully sold a drug for which a Drug Identification Number (D.I.N.) had not been assigned contrary to the provisions of the Food and Drugs Act and Regulations. The charge carries a maximum penalty on summary conviction for a first offence of a fine not exceeding $500.00, or for a term of imprisonment not exceeding three months, or to both. The Crown conceded at the outset of the trial that, in the event of a conviction, the Crown was only seeking a fine.

[67] Another course of action suggested by the Crown as a reasonable legal alternative was that the Defendants could have sold their rights in the supplement to a company in the United States and negotiated a contractual relationship for a percentage of profits to continue the support program. The following conclusions can be made from consideration of this case. An administrative
arrangement for sales of a product with the minister does not preclude being prosecuted by Health Canada. The adverse effect on patients' health from a decision to order withdrawal of the product from the market is irrelevant to the decision to prosecute. Finally, the solution proposed by the prosecutor was for the Canadian manufacturer of a natural product to sell out to an American company, since an American company, but not the Canadian one, would have the financial resources necessary to get through the regulatory barrier. It is natural for an observer to ask whether an Aboriginal healer in such a situation would be treated any differently.

Need for a market authorization
The Bill creates a revised definition for the term "sell," in relation to therapeutic products, so that the term "sell" when used in the Act would apply to the distribution of a single therapeutic product to a single individual. The effect of this change means that the giving of a traditional medicine product, which is a therapeutic product, to a child by a family member is within the scope of the definition of "sell" and is covered by the regulatory scheme of the Act.

Clause 12(1) of the Bill provides, "No person shall advertise, sell or import for sale a therapeutic product that does not have a market authorization or is not a designated therapeutic product."

Unless a product is exempted by regulation as a "designated therapeutic product," it cannot be sold, which includes giving it to a single individual, unless the product has a market authorization or the product is exempted by designation under the regulations.

The process of getting a market authorization is time consuming and expensive and is designed to require the manufacturer of a product to demonstrate safety and efficacy. (There are issues related to just how effective a market authorization is in protecting the public from dangerous products, but a discussion of that issue is beyond the scope of this paper.) The resources to do this would undoubtedly be beyond that of any Aboriginal healer.

There is a power in the Bill for regulations to be enacted by the Governor in Council (Cabinet) to exempt anything it wants from the application of the Act. Clause 30(1)(2.13) provides that regulations may be made "exempting from the application of this Act or the regulations or a provision of this Act or the regulations a food, therapeutic product or cosmetic or class of foods, therapeutic products or cosmetics and fixing the conditions of the exemption."

Traditional healers in Canada would therefore have to rely on the hope that their products, indeed all their products, would be exempted by Health Canada and that new regulations would be created exempting them from the need for market authorization. Would such faith in Health Canada doing this be well placed? Given the cases to date, I am not sure it would be.

Establishment licenses
Bill C-51 would create another regulatory obligation called an establishment license, which would be required before anyone conducted any "controlled activity." The legislative objective is to prevent any "controlled activity" from taking place, unless the person doing it has an establishment license.

Clause 13 of the Bill provides, "No person shall conduct a controlled activity unless they are authorized by an establishment license to do so."

The Bill then defines "controlled activity" as meaning "(a) in relation to a therapeutic product manufacturing, collecting, processing, preserving, labelling, packaging, importing for sale, distributing, wholesaling or testing, and (b) in relation to a designated therapeutic product manufacturing collecting, processing, preserving, labelling, packaging, importing, distributing or testing."

The effect of these two provisions means that collecting or processing medicinal plants for traditional medicine purposes would require an establishment license, unless regulations were passed exempting these activities.

Need for clinical trial license
Bill C-51 created new legislative provisions for clinical trials. A "clinical trial" means, among other things, "an investigation in respect of a therapeutic product for use in human beings that involves human subjects and that is intended to discover or verify the therapeutic product's clinical, pharmacological or pharmacodynamic effects..."
Clause 10 of the Bill provides that no clinical trial may be conducted unless the person has been issued a clinical trial authorization.

It can be argued, therefore, that research on traditional medicine involving finding out the therapeutic effects of traditional medicines on humans would be restricted by the requirement to get a clinical trial authorization for research into traditional medicine products, even if they have been in the food chain for a long period of time. Again, this could be subject to possible exemption by regulation, but the Act does not assume any such exemption would be made.

Conclusions

Traditional healing in Canada is conducted by Aboriginal healers in accordance with a world view that is holistic and spiritual. The practice of traditional healing encompasses a wide range of ceremonies and practices that include the collection, preparation and administration of medicinal herbs.

Bill C-51 would have an adverse effect on traditional healing in the following ways:

1. Bill C-51 would regulate the collection, preparation and administration of medicinal herbs by traditional Aboriginal healers. These traditional medicines would be defined by the Bill as therapeutic products. They are potentially subject to classification, under the Bill, as drugs and in particular as prescription drugs. If so classified, they could not be administered by a traditional Aboriginal healer, since such a healer is not defined by the Bill as a “practitioner.”
2. Bill C-51 would also establish a legislative scheme that would require traditional medicines to obtain a market authorization, unless they are exempted by regulation.
3. Bill C-51 would further establish a legislative scheme that would require a traditional healer using traditional medicines to obtain an establishment licence to collect, process, preserve, label, package, distribute or test a traditional medicine product, unless exempted by regulation.
4. Finally, Bill C-51 would establish a legislative scheme that would require a clinical trial authorization for any investigation into the therapeutic benefits of traditional medicines on human subjects, unless exempted by regulation.

The effect of these provisions would be to make the use of traditional medicine products subject to a burdensome and expensive regulatory regime that could preclude the practice of traditional Aboriginal medicine in Canada. The fact that pharmaceutical companies in the past have mined Indigenous medicine for products to patent makes this an issue of real concern.

On a final note, any reduction of traditional healing in Canada would probably have an adverse effect on the health of Canadians, particularly in the Aboriginal community. Traditional healing is a low-tech and low-cost sector that provides non-prescription products to Canadians. The potential reduction in supply of traditional products would increase the cost of health care in a time when the cost of prescription drugs is soaring in Canada. (The use of prescription drugs is the fastest growing category of health spending. According to the Canadian Institute on Health Information, spending on prescription drugs has increased fivefold since 1985 and reached a total of $21.4 billion in 2004. This represented an average expenditure of $681 per Canadian [15].)

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APPENDIX 1.

Important provisions of Bill C-51 and related legislation

"sell" includes offer for sale, expose for sale or have in possession for sale – or distribute to one or more persons, whether or not the distribution is made for consideration – and, in relation to a device, includes lease, offer for lease, expose for lease or have in possession for lease; [C-51]

"advertisement" includes a representation by any means for the purpose of promoting directly or indirectly the sale of a food, therapeutic product or cosmetic; [C-51]

"clinical trial" means
(a) an investigation in respect of a therapeutic product for use in human beings that involves human subjects and that is intended to discover or verify the therapeutic product's clinical, pharmacological or pharmacodynamic effects, to identify adverse events in respect of the therapeutic product, to study the absorption, distribution, metabolism or excretion of the therapeutic product or to ascertain its safety or efficacy, or
(b) an investigation in respect of a drug for use in animals that produce food, that are intended for consumption as food or in which the use of the drug could affect human health; [C-51]

"controlled activity" means
(a) in relation to a therapeutic product – manufacturing, collecting, processing, preserving, labelling, packaging, importing for sale, distributing, wholesaling or testing, and
(b) in relation to a designated therapeutic product – manufacturing, collecting, processing, preserving, labelling, packaging, importing, distributing or testing; [C-51]

"designated therapeutic product" means a therapeutic product designated as such by regulations made under paragraph 30(a)(d); [C-51]

"establishment licence" means a licence issued under section 19.2; [C-51]

"market authorization" means an authorization issued under section 18.7; [C-51]

"practitioner" means an individual who is authorized under the law of a province to prescribe or dispense prescription therapeutic products; "prescription therapeutic product" means a therapeutic product designated as such by an order made under subsection 15.1(4); [C-51]

"drug" includes 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; [FDACurrent definition not being changed]

"therapeutic product" means
(a) a drug,
(b) a device,
(c) cells, tissues or organs that are distributed or represented for use in
(i) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, or
(ii) restoring, correcting or modifying the body structure of human beings or animals or the functioning of parts of the bodies of human beings or animals, or
(d) a combination of two or more of the things referred to in paragraphs (a) to (c); [C-51]

"natural health product" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in
(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
(b) restoring or correcting organic functions in humans; or
(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that...
is or includes a substance set out in Schedule 2. [Natural Health Products Regulations current]

10. No person shall conduct a clinical trial in respect of a therapeutic product that does not have a market authorization unless they are authorized by a clinical trial authorization to do so. [C-51]

11. No person shall conduct a clinical trial in respect of a therapeutic product unless they do so in accordance with the regulations. [C-51]

13. No person shall conduct a controlled activity unless they are authorized by an establishment licence to do so. [C-51]

15.1 (1) No person shall sell a prescription therapeutic product unless
   (a) they are a practitioner who is authorized to prescribe the prescription therapeutic product;
   (b) the sale is made under a prescription that was received by or transferred to them in the prescribed manner;
   (c) the sale is to a person who belongs to a prescribed class of persons; or
   (d) the sale is made in the prescribed circumstances. [C-51]

   (2) No person shall advertise a prescription therapeutic product to a person other than a practitioner unless they are authorized by the regulations to do so. [C-51]

   (3) No person shall import a prescription therapeutic product unless
       (a) they belong to a prescribed class of persons;
       (b) they are a practitioner;
       (c) they are an individual, the product is on their person at the time that it is imported, the product is for their use or the use of an accompanying dependant and the quantity does not exceed the quantity required for a go-day period; or
       (d) the importation is made in the prescribed circumstances. [C-51]

   (4) Subject to the regulations, the Minister may, by order, designate a therapeutic product —either individually or by class—as a prescription therapeutic product for the purposes of this section. [C-51]

18.7 (1) Subject to the regulations, the Minister may, on application, issue a market authorization to a person in respect of a therapeutic product other than a designated therapeutic product if the Minister is of the opinion that the person has established that the benefits that are associated with the therapeutic product outweigh the risks. [C-51]

19.2 (1) Subject to the regulations, the Minister may, on application, issue an establishment licence to a person authorizing them to conduct, in respect of the one or more therapeutic products or classes of therapeutic products specified in the licence, the specified controlled activity in the specified premises. [C-51]

30. (1) The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, including regulations [C-51]

   (z.13) exempting from the application of this Act or the regulations or a provision of this Act or the regulations a food, therapeutic product or cosmetic or class of foods, therapeutic products or cosmetics and fixing the conditions of the exemption; [C-51]

   (z.14) exempting a person or class of persons from the application of this Act or the regulations or a provision of this Act or the regulations in relation to a food, therapeutic product or cosmetic or class of foods, therapeutic products or cosmetics and fixing the conditions of the exemption; [C-51]

   (z.15) exempting an activity or class of activities from the application of this Act or the regulations or a provision of this Act or the regulations in relation to a food, therapeutic product or cosmetic or class of foods, therapeutic products or cosmetics and fixing the conditions of the exemption; [C-51]