INTERNATIONAL REGULATION
OF NATURAL HEALTH PRODUCTS

JOHN ROBERT HARRISON

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This book is dedicated to my wife, Barbara L. Harrison and our sons, William R. L. Harrison and Edward J. Harrison.

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CHAPTER 1

INTRODUCTION TO THE ISSUE

1.1 STATEMENT OF THE ISSUE

The overall objective of this study is to review the natural health product laws and regulations for Canada's primary natural health products (NHP) trading partners, namely, Australia, China, France, Germany, Hong Kong, India, USA, United Kingdom, and the European Union and identify priority areas where policy research should be focussed and then propose strategies to address these selected policy research areas.

The objective of the first phase of this study was to complete a literature and legislative review of the identified NHP regulatory components for countries that comprise Canada's main NHP trading partners. The objective of the second phase of this study was to compare and contrast these regulatory frameworks with that of Canada's NHP Regulations. The second phase reviews the initially collected information and directly compares the findings for other countries with the legislation and regulations covering NHPs in Canada. For this comparison a method was selected in which each identified topic in the Canadian NHP Regulations is compared with those of the other countries. Such an approach facilitates the identification of data gaps, areas of concerns in the legislation of Canada's main trading partners, and of areas requiring further scientific study.

The objective of the third phase of the study consists of a strategy
approach which sets out prioritized policy research needs that take into consideration the prior phases of this research.

In preparing this strategy approach, strategic objectives were first developed for the prioritized policy research needs for the Natural Health Products Directorate (NHPD), Health Canada and these objectives were:

- the safety of the products being manufactured and sold to Canadians and,
- processes to facilitate trade between Canada and other countries.

This is consistent with the mission of NHPD which is basically to ensure that all Canadians have ready access to natural health products that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

In addition to the three phases of the research listed above, a consultation process was held on May 25, 2004 with the NHPD, Management Advisory Committee (MAC) of Health Canada. The MAC commented on a draft document entitled “International Regulation of Natural Health Products: Comparison of Natural Health Product Regulations for Canada’s Primary Trading Partners.” This comparison document consisted of the second phase of the research described above and it focussed on NHP Regulations for Canada’s primary natural health product trading partners, namely, Australia, People’s Republic of China, France, Germany, Hong Kong, India, United States, United Kingdom, and the European Union. The main purpose of the consultation process was to have an outside body, knowledgeable on the topic of international natural health product regulations, comment on the comparison phase of the research.

1.2 BACKGROUND AND HISTORY

Natural health products (NHPs) are big business both in Canada and elsewhere in the world. The majority of Canadian products previously registered as non-prescription medicines are now NHPs. Consumers are buying these products in record volumes all in an effort to make themselves feel better, get better, and to possibly live longer. The NHP industry shows no sign of fading. Currently poised above the billion-dollar mark in Canada alone, surveys reveal that more than 50% of Canadians are consuming NHPs. Estimates in the Unites States compiled by the Natural Foods Merchandiser put the sales of natural products and supplements in 2003 at more than $20.5 billion.
The term, natural health products, signals different things to different people. NHPs are common items, yet elusive in definition for the average Canadian. A glimpse at the large-scale nature of NHP choices is evident in terms of the reference used in the 1998 federal report *Natural Health Products: A New Vision*. This report identifies four major types of NHPs: traditional medicines including Chinese, Ayurvedic and North American Aboriginal medicines; traditional herbal medicines; homeopathic preparations; and vitamin and mineral supplements. Each of these types of NHPs represents an exhaustive line of products, offered in powders, tablets, oils, capsules, liquids, herbal teas, and other extracted forms.

In 2000, Health Canada's Office of Natural Health Products Transition Team worked diligently to define what they considered a natural health product. They described NHPs as composed of substances or combinations of substances found in nature, and energetically-potentized preparations, used for the purpose of maintaining or improving health or treating or preventing diseases or conditions. NHPs include, but are not limited to, the following classes of products: homeopathic preparations; vitamins; minerals; enzymes; coenzymes; co-factors; herbs or botanicals; naturally-occurring animal, plant and microorganism substances; and, a variety of molecules extracted from natural sources, such as amino acids, polysaccharides, peptides, naturally occurring hormones and biochemical intermediates, as well as naturally occurring molecules synthesized by chemical or biological means. It is NHP's health-enhancing potential that fuels the greatest interest.

In 1998, Health Canada began a process to examine the regulation of NHPs. A House of Commons Standing Committee on Health reviewed the regulations at that time and listened to the viewpoints of consumers, retailers, manufacturers, practitioners and others as to how these products should be regulated. Arising from this Committee was fifty-three recommendations that were accepted by Health Canada in 1999. A number of committee recommendations focused on research for NHPs. John Harrison, Manager, Office of Natural Health Products, Health Canada then, in 1999, held a research priority setting conference in Halifax, Nova Scotia. The recommendations from the participants of that conference were the following:

- that Health Canada immediately work with active researchers in the field to develop a strategy for achieving a Canadian Institute of Health Research (CIHR) for NHP research;
- that the research supported by Health Canada be of a initi-
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ating nature, that it gives priority to cross-cutting research across disciplines, that it is delivered within a framework of an NHP research network and that research supported be relevant to industry and health care practitioners; and

- that the initial research supported relate to the creation of a credible database and to research into the safety, efficacy and standardization of existing NHPs.

Following this conference, Health Canada has had a number of focused consultations and commissioned a series of discussion papers related to policy, research and the regulatory aspects of NHPs. Topics included adverse reactions, current issues in Botanical Quality and quality controls and product standards. Further to these useful initiatives, there was a Natural Health Product Research Conference held between February 20th and 22nd, 2004 in Montréal, Quebec by the Natural Health Product Research Society of Canada. This conference connected NHP researchers with all interested stakeholders, government and funding partners. At this conference the global aspects of NHP research and regulations were discussed.

On January 1, 2004, Health Canada's new NHP Regulations came into force. These new regulations define NHPs for regulatory and legislative purposes as vitamins, minerals, herbs, homeopathic products, traditional medicines, probiotics, amino acids, essential fatty acids and extracts or isolates from plant and animal matter. These are the substances that will be legally considered NHPs.

The formal definition of included NHP substances is found in Schedule 1 of the NHP Regulations and this is:

1. A plant or a plant material, an alga, a bacterium, a fungus or a nonhuman animal matter.
2. An extract or isolate of a substance described in item 1, the primary molecular structure of which it had prior to its extraction or isolation.
3. Any of the following vitamins; biotin, folate, niacin, pantothenic acid, riboflavin, thiamine, vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E.
4. An amino acid.
5. An essential fatty acid.
6. A synthetic duplicate described in any of the items 2 to 5.
7. A mineral.
8. A probiotic.
The range of functions for which such products are used include the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans; restoring or correcting organic functions in humans; or modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

Other governments have wrestled with defining NHPs. For instance, in 1994 the United States passed a *Dietary Supplement Health and Education Act (DSHEA)*, designed specifically to deal with dietary supplements. In the United States, homeopathic products are regulated under the *Food and Drug Act and Regulations* while in Canada this class of products is defined as a natural health product.

Canada’s new regulatory framework is unique in the world and includes directives and guidelines for effective and informative labelling of products, requirements for site licences and product licences and standards of evidence that respect traditional evidence. The development of this framework involved an extensive series of consultations over a period of several years with consumers, practitioners, industry and all other relevant stakeholder groups. At these consultations consumers expressed their concerns which included the safety and toxicity of NHPs; and the need to ensure that what is advertised on the label is what is in the bottle in terms of product purity, potency and quality.

Health Canada’s new NHP regulations came into effect in 2004. The major components of the Canadian regulatory framework for NHPs that were used for research comparison purposes were the following: Product Licensing including Standards of Evidence, Site Licensing, Good Manufacturing Practices and Adverse Reaction Reporting. Internationally, regulations and definitions of NHPs vary greatly from country to country. While on a national level regulations may address consumer needs, the lack of a mutually agreed legislative framework for the international scene can be a hindrance to international trade for these countries. Further, as consumers increasingly shop on-line, the laws and regulations in one country that are not rigorous can impact on the safety of consumers in another country.

Throughout the world there are problems associated with different regulatory requirements for NHPs. For example, in Europe, most natural health products such as homeopathic products are generally regulated as drugs. As a result, Canadian exporters of NHPs could have difficulty selling their products to Europe as drug regulations
are generally perceived as more stringent than the \textit{NHP Regulations}. For example, the Canadian good manufacturing practices for NHPs were not subject to the international mutual recognition agreements under which European NHPs are covered. This is an example of how differences in the regulation of these products can adversely affect Canadian trade with the world. Further, many of these regulations are quickly changing. Some of Canada’s major trading partners in this NHP field are the United States, the United Kingdom, Europe, China, Australia and India. Many Canadian businesses import the raw materials from countries such as China and manufacture, formulate or repackage from these materials.

From a regulatory viewpoint, international legislation can come in many different forms including: enabling, prohibitive, restricting, quality control or monitoring based and/or those incorporating inspections, proof of efficacy and basic self-regulation. The menu of statutory instruments can include legislation, regulation, standards, guidelines and licences and foreign countries could have in their regulatory framework one or more of these instruments. One key issue is how NHPs are defined. For this project the Canadian definition of a natural health product is used as the standard to compare with for other countries.
CHAPTER 2

REVIEW OF THE RELATED LITERATURE AND RESEARCH

This section describes the literature review on NHP Regulations and the legislative review for Canada’s primary trading partners. The list of trading partners was based on a brief survey of trade volumes for each of the available and indicated NHPs.

2.1 LITERATURE REVIEW OF NATURAL HEALTH PRODUCT REGULATIONS FOR CANADA’S PRIMARY NHP TRADING PARTNERS

The literature review was based on examining various sources of literature including journals, books and internet searching. This literature review included a search by a commercial literature search agency NERAC (www.Nerac.com), accessed through a company. Documents were selected and ordered for review. Additional searches were conducted through internet search engines, “snowball” techniques where references in documents were accessed, and referrals from members of our professional networks. Searches were conducted in English, French, German and Mandarin, using combinations of key words as listed in the design chapter.

Most of the detailed documents are accessible from the internet and their internet addresses are listed. Some of the documents are very lengthy and detailed such as the paper on “Herbal medicinal products in the European Union” prepared by the Association of
the European Self-Medication Industry. A second lengthy and useful document is the Harvard Law paper on DSHEA by S. Ray. For the purpose of this study, the papers, reports and documents considered to be most relevant and useful have been listed in the Reference List.

2.2 **Legislative Review of Natural Health Product Regulations for Canada’s Primary NHP Trading Partners**

For the purpose of the legislative review of the NHP Regulations, pertinent information was obtained from the documents reviewed for the Literature Review part of the project. In addition the applicable Acts, Regulations and Directives were accessed for each of the countries surveyed. English texts were accessed for Australia, Canada, India, the United Kingdom, the United States and the European Union. Texts were accessed in French for the France’s regulations, in German for Germany’s regulations and in Mandarin for China’s regulations. None of the German Acts and regulations were available in English and only a small part of the French and Chinese regulations were available in English. In addition, Codex Alimentarius documents were accessed as the results of the literature review suggested significant links between food, vitamin and mineral content and NHP’s. The EU Directives on food and food supplements were reviewed for these same reasons.

Information from the literature review was separated into categories. These categories were definition, legislation/regulations/guidelines, regulatory agency, marketing authorization, product licencing/registration, risk/scientific assessments/standards of evidence, site licencing, good manufacturing practices and adverse reaction reporting. Information from each category for each country was then entered into Tables (1-22). Tables for the following countries were prepared: Australia, Canada, China, France, Germany, Hong Kong, India, United Kingdom and the United States along with Codex Alimentarius and the European Commission.

Appendix 1 lists the main web sites for the regulatory bodies covering NHPs in each country studied.

Generally, the information included in the tables showed that there are varied legislative regimes in the countries trading with Canada. However, the regulation regime of countries and future countries of the European Union will be streamlined into a common model based on the EU Directives that were initiated and approved since the first Directive was put into place in 1967. Notwithstanding
this streamlining process, differences still exist in the interpretation of EU Directives, their implementation, and the “grandfathering” of different regulations that existed prior to the EU Directives (e.g. the German homeopathic regulations, the German and French drug laws). The EU regulates all European countries through Directives, forcing member states to adhere to common rules. The EU also considers most NHPs as drugs, but allows the member States some leeway in certain areas such as herbal products and homeopathics. The EU Directives set out prohibition versus strict adherence to required regulatory wording for the member states. Each individual member state in the EU has incorporated the appropriate EU Directives into their national laws and regulations. This has led to varying implementations. In the vitamins and minerals and the fortified food areas, the EU is inclusive in its regulations and this means that only what is included in the EU Directives is allowed in regulations of the member states. Further, in China there are differences in the standards applied to approved medications, and traditional medicines that are produced according to methods transferred in an oral tradition from generation to generation.
CHAPTER 3

DESIGN OF THE STUDY

3.1 LEGISLATIVE AND LITERATURE REVIEW

For the legislative review, information was collected from many sources including the internet sites for each country and their responsible departments, specialized internet sites, individuals and the scientific literature. In many cases the actual text of applicable Acts, Regulations and Directives were accessed at each country’s web site and for the European Union (EU). Legislative documents were accessed in their original language (German, French, Mandarin) or in English where official translations existed.

Computer based literature searches were conducted using a variety of systems such as NERAC (nerac.com) and combinations of individual data bases such as Medline, CAB Health, Current Contents, the ERIC Database and Food Science and Technology Abstracts. In addition customized internet searches were conducted using tools such as the software “Copernic Meta”, the “DogPile” and the Google search engines and Internet Explorer. A wide variety of search terms were used including the names of countries types of natural health products, coupled with the terms - international, comparison, herbal, botanical, review, regulatory, phytopharmaceutical, regulation, laws, codes, ordinances, guidelines and traditional.
3.2 Consultation Process with NHPD, Management Advisory Committee

On May 25, 2004, a presentation by John Harrison on the subject “International Regulation of Natural Health Products: Comparison of Natural Health Product Regulations for Canada’s Primary Trading Partners” was given to the NHPD, MAC. From that presentation there was a discussion of this subject and the members of the committee were asked to provide written comments by June 5, 2004 to NHPD who, in turn, assembled the information and provided it to John Harrison. This information served as the main basis for this report along with the information from discussions held at that meeting. The MAC was also provided a copy of the Comparison document about a week before the May 25, 2004 meeting date so they could familiarize themselves with the document.

The following MAC committee members participated in the consultation; Yvan Bourgault (Canadian Homeopathic Pharmaceutical Association), Lawrence Cheng (Chamber of Chinese Herbal Medicine of Canada), Ron Dugas (La Societe du Langernate), Andre Gagnon (Natural Health Products Manufacturers of Canada), Albert Fok (Vancouver Chinatown Merchants Association), Connie Kehler (Saskatchewan Herb and Spice Association), Marie Provost (Guilde Des Herboristes La Clef des Champs Inc.), David Skinner (NDMAC), Paul Theriault (Direct Sellers Association of Canada) and Anne Wilkie (Canadian Health Food Association).

3.3 Comparison of Regulatory Frameworks

Information from each of the countries studied was compiled in comparison tables, and in extensive outlines of the legislative contents. From these compilations, an analysis comparing the Canadian regulatory framework with that of a number of countries was completed. The following specific regulatory areas were covered: definition of a natural health product, product licensing, standards of evidence, site licensing, good manufacturing practices, adverse reaction reporting and fortified foods. The following areas were discussed and analysed: level of regulation, standard of evidence, good manufacturing practices and good agricultural practices, adverse reaction reporting and trade with Canada. A set of eleven appendices outline the regulatory framework for each of the countries studied.
3.4 Strategy Approach for Prioritized Policy Research Needs

A list of strategies for the consideration of NHPD was prioritized based on their effectiveness and ease of implementation. The strategies covered trade considerations, trade strategies, safety strategies and mutual recognition agreements.
CHAPTER 4

RESULTS AND FINDINGS

4.1 LEGISLATIVE AND LITERATURE REVIEW

As a first step in this study a literature and legislative review was prepared on Natural Health Product Regulations for Canada's primary natural health products (NHP) trading partners, namely, Australia, China, France, Germany, Hong Kong, India, USA, United Kingdom, and the European Union. The Canadian NHP definition was used to compare similar classes of products for these other countries. Further, the major components of the Canadian regulatory framework for NHPs that were used for research purposes were the following: Product Licensing including Standards of Evidence, Site Licensing, Good Manufacturing Practices and Adverse Reaction Reporting.

Overall the more useful areas of the scientific literature in comparing international regulatory regimes for products such as herbal medicines, dietary supplements or homeopathic drugs were found on the web sites of international organizations such as the World Health Organization, the European Agency for the Evaluation of Medicinal Products and the Association of the European Self-Medication Industry. Another fruitful area was the Harvard Law papers prepared by Harvard undergraduates and graduates. There were only a limited number of scientific international regulatory comparison papers published in the open literature with the exception of World Health
Organization conference proceedings and other related clinical pharmacology conference proceedings. Most of the published scientific papers are already outdated when published as the regulatory areas of natural health products around the world are undergoing swift changes. In addition, the actual (translated) texts of current Acts and regulations were accessed to obtain relevant information.

Tables (1-22) were prepared for each country, providing sections for certain aspects of the Canadian NHP regulatory framework and including the main governmental regulatory authority for each country. Certain countries such as Australia have a regulatory regime very comparable to Canada’s while others such as China mainly export only one type of NHP (e.g. Chinese herbal medicines). This is reflected in the type of Acts and Regulations each country has in force.

This review reveals a fast-paced change and revision of national and international regulations for NHPs such as herbals, vitamins, minerals and homeopathic medicines. Many changes in the European countries were precipitated by the implementation of European Union Directives.

### 4.2 Consultation Process with NHPD, Management Advisory Committee

The presentation by John Harrison was well received by the MAC members. Comments were solicited during and after the presentation and MAC members were invited to submit written comments. MAC members present at the presentation either made comments during the meeting or submitted comments after the meeting.

Many good comments were received from the Committee members and many of these comments were more future oriented and strategic rather than reactive to the presentation of May 25, 2004.

It is important to point out that many of the suggestions made and questions posed by the MAC fell into areas that were not directly within the terms of reference of the Comparison document yet the suggestions and comments were pertinent and very useful for possible future projects that could arise from the findings of the Comparison document and become extensions of topics related to this subject area.

The following points were raised by the Committee members:
- overall they wanted to know the regulatory and business trends that were occurring in the countries reviewed in the Comparison document;
- Italy was noted as having new regulations that address the
bulk herb situation and that NHPD might wish to examine these in more detail;

- for Canada and the other countries studied (with new regulations), they suggested it would be useful to know what the trends were in the NHP industry once new regulations came in and members asked if there were an increase in the number of companies or did the existing companies start selling more products or expanding a product base;
- why some countries were more stringent than others in terms of regulations;
- what was the impact of new regulations on the NHP industry in the countries reviewed and this comment was made in the context of increased regulations for industry;
- they brought up the subject of whether the existing regulations as well as emerging regulations had been included in the Comparison document and it was explained to them that, where possible, both aspects of regulations were included; the example was given of the Australian-New Zealand joint initiatives for complementary medicine regulations that had been included in the Comparison document, as well as the proposed EU regulations and Directives;
- the subject of Canada’s Bill C-420 that had been considered by the last Parliament was discussed and the recent testimony of Dr. Phil Waddington to the House of Commons Standing Committee on Health was mentioned;
- Japan, a country not included in the Comparison document, has deregulated this area of NHPs to some extent;
- it was suggested that Mexico, Brazil and Japan be further studied as Mexico is part of NAFTA, Brazil produces various NHPs and Japan is deregulating this NHP area.

### 4.3 Comparison of Regulatory Frameworks

In preparing the comparison of regulations and legislation for NHPs in Canada to those of Canada’s main trading partners, the framework of the Canadian legislation was used as the starting point. The Canadian NHP Regulations were separated into the following components:

- definition of natural health products,
- product licensing,
- standards of evidence,
- site licensing,
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- good manufacturing practices/good agricultural practices
- adverse reaction reporting, and
- fortified foods and their regulation.

For each of these topics, the Canadian example was used as a basis for comparison. For each of the main trading partners, information was briefly described in the comparison, and the details were placed in Appendices 2-12.

4.3.1 Definition of a Natural Health Product

This section addresses the definition of an NHP in Canada and provides the comparison of the Canadian definition with that of Canada's main trading partners. Definitions are varied in different countries and include or exclude certain classes of products.

Canadian Situation

The NHP definition in Canada has two components: function and substance. The function component refers to the natural health product definition capturing those substances that are manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation of prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- restoring or correcting organic functions in humans; or
- modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the medicinal ingredient in a natural health product. These substances include, but are not limited to, traditional herbal medicines, traditional Chinese herbal remedies, Ayurvedic and Native North American medicines, homeopathic medicines, vitamins and mineral supplements, probiotics and essential fatty acids.

Included NHP substances are listed in Schedule 1 of the NHP Regulations:

1. A plant or a plant material, an alga, a bacterium, a fungus or a nonhuman animal matter.
2. An extract or isolate of a substance described in item 1, the primary molecular structure of which it had prior to its extraction or isolation.
3. Any of the following vitamins; biotin, folate, niacin, pantothenic acid, riboflavin, thiamine, vitamin A, vitamin B₆, vitamin B₁₂, vitamin C, vitamin D, vitamin E.
4. An amino acid.
5. An essential fatty acid.
6. A synthetic duplicate described in any of the items 2 to 5.
7. A mineral.
8. A probiotic.

International Comparison

The Canadian definition was compared with those of Canada’s main trading partners. On the whole, the definitions deal with the functionality of the NHPs, where the substance in certain cases modifies the conditions required under the functionality. For several trading partners, all NHPs fall under the concept of “drug” or “medicine.” This is the case for the European Union (EU) and therefore generally covers Germany, France and the United Kingdom. As the EU allows member states to modify the requirements under the EU Directives based on prior regulations, certain substances have been integrated in the member state's regulations. This is particularly true for homeopathic medicine in Germany and France, and herbal medicine in Germany, China and India use the functionality principle and classify NHPs as drugs or food. However, China also recognizes Traditional Chinese Medicine, and health food products as separate substance classes. The United States and Australia base their definitions on substances and their workings, over functionality.

Australia defines complementary medicine (CM) as a therapeutic good consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and a traditional use; these include herbal medicines, homeopathic medicines, vitamins and mineral supplements, traditional medicines such as Ayurvedic medicines, traditional Chinese medicines, other nutritional supplements, and aromatherapy oils. Traditional use means use of the well documented and designated active ingredient according to the accumulated experience of traditional healthcare practitioners.

China defines the NHPs in three categories: Drugs are articles that are used in the prevention, treatment and diagnosis of human diseases and intended for the regulation of the physiological functions of human beings, for which indications, usage and dosage are established, including Chinese crude drugs, prepared slices of crude