THE NEW CANADIAN NATURAL HEALTH PERODUCT REGULATIONS

IMPACT AND OPPORTUNITY FOR CHINESE MEDICINE

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A. BACKGROUND

THE CANADIAN MARKET AT A GLANCE

Canada's population is about 30 million, of which almost 90% lives primarily in the cities scattered throughout the Central and Western parts of the country within 160 kilometers of the border with the U.S.[1]. A recent study commissioned by Health Canada revealed that 71% of Canadians have used natural health products (NHPs)[2]. Awareness of and demand for NHPs are growing rapidly in Canada fueled by:

- An aging population;
- Increasing interest in health life style;
- Measures to control health care costs;
- Increasing acceptance of "alternative" treatments;
- Effective marketing by producers and suppliers;
- Rising acceptance by medical professionals; and
- Consumer disenchantment with conventional drugs and treatments.

Total retail sales of NHPs in Canada are $2.2 billion for 2005, with projected sales to increase by 9% to $2.4 billion by 2010[3]. Canada accounts for about 3% and 10% of the world and the U.S. market on NHPs, respectively (Figure 1, all in US dollars)[4,5].

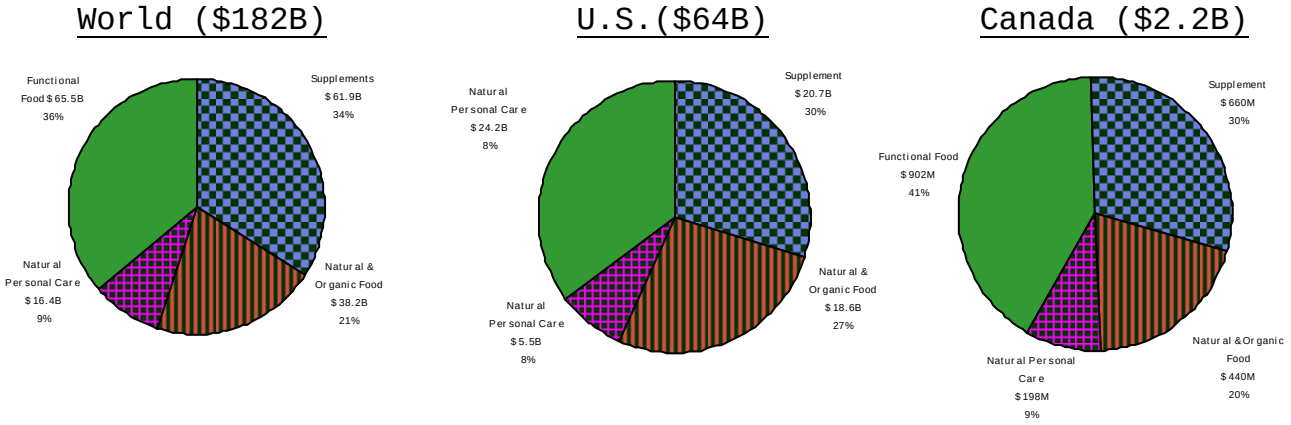

Figure 1. NHP Market Size of the World, U.S. and Canada

[1] 2001 Census of Canada. *Statistics Canada* (www12.statcan.ca/english/census01/home/index.cfm)
[2] Ipsos-Reid: Baseline Natural Health Products Survey Among Consumers. *Health Canada* 11/2005
[3] Valerie Bell: Natural Health Products in the Canadian Marketplace. *Natural Health Products Insider* 11/2005
[4] Global Nutrition Industry. *Nutrition Business Journal* 16 (8/9), 2003, 2005 (www.nutritionbusiness.com)
[5] Pharmaceuticals and Natural Health Products 2003. *The Trade Facilitation Office Canada* (www.tfoc.ca)

The Canadian NHPs industry is a significant part of the overall Canadian economy as supported by the following data in 2005:

Sales:	$2.2B
Number of products:	42,000
Number of enterprises:	>11,750
Suppliers (manufacturers/importers/distributors)	800
Retailers	10,950
Health food stores:	2,700
Traditional Chinese medicine retailers	650
Pharmacies	7,600
Others (direct/professional)	N/A
Employment:	25,000

Canada is a net importer of NHPs although exports have been increasing by about 2% annually. In 2004, Canada imported $217 million and exported $174 million NHPs. The value of imported NHPs and ingredients is equivalent to approximately 10% of retail sales in Canada[6]. Among these imports, the U.S. accounted for more than 50% while China came in second for 12% which is calculated to approximately $26 million [7].

THE CANADIAN REGULATIONS

Before the new *Natural Health Products Regulations* came into force on January 1, 2004, NHPs were sold as either drugs or foods in Canada under the Food and Drugs Act and Regulations because there was no such a category for NHPs.

In the past most NHPs marketed in Canada were regulated as foods and made no claims. When classified as a drug, NHPs had to comply with the rigorous pharmaceutical drug review process, including proof of safety and efficacy through clinical trials, and receive a Drug Identification Number (DIN) to be sold.

As more and more Canadians discovered the potential health benefits of NHPs and started using NHPs, it became apparent to the Canadian health authorities that neither the drug regulations nor the food regulations were appropriate for the category of NHPs. As a result, a new policy was developed for NHPs and Health Canada published the *Natural Health Products Regulations* in the Canada Gazette, Part II on June 18, 2003.

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[6] Valerie Bell: Natural Health Products in the Canadian Marketplace. *Natural Health Products Insider* November 2005. Sales are in US dollars.

[7] Pierre Richer and Stuart Rothman: International Market Research – Natural Health Products. *Industry Canada* 2004 (www.stregis.ic.gc.ca)

B. OVERVIEW OF THE NEW REGULATIONS

The *Natural Health Products Regulations* are administered by the Natural Health Products Directorate (NHPD), Health Products and Food Branch, Health Canada. These Regulations are intended to ensure that all Canadians have readily access to Natural Health Products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

The provisions of the new Natural Health Products regulations include definitions, product licensing (PL), site licensing (SL), good manufacturing practices (GMP), clinical trials, labeling and packaging requirements, as well as adverse reaction reporting.

DEFINITIONS

The NHP definition has two components: function and substance.

Functions (as permitted claims):

a) Treatment claims: disease diagnosis, treatment, mitigation.
b) Risk reduction claims: disease prevention.
c) Structure-function claims: maintaining and promoting health.

Substances include:

a) A plant, an alga, a bacterium, a fungus or a non-human animal material
b) An extract or isolate of the above
c) Vitamins
d) Amino acids
e) Essential fatty acids
f) Synthetic duplicates of the above
g) Minerals
h) Probiotics

These definitions are important to the application of the new regulations.

PRODUCT LICENSING

NHP Regulations require individuals to obtain a product license before they can sell a natural health product in Canada and NHPD assigns a Natural Product Number (NPN) to a product when it issues the product license.

Types of Product License Applications:

- Compendial
- Traditional Claim(≥50 years history of usage)
- Non-traditional Claim
- Homeopathic
- Transitional DIN Product

1. Compendial Applications

A compendial application cites a monograph in NHPD's *Compendium of Monographs*. The monographs provide information regarding the minimum specification requirements, the acceptable non-medicinal ingredients as well as support for the safety and the claim of the natural health product.

2. Traditional Claim and Non-traditional Claim Applications

The majority of NHPs including the products of traditional Chinese medicine (TCM), or in a broad term, Chinese medicine (CM), belong to these two categories. The product license application submission requirements are:

- Product License Application Form
- Evidence Summary Report
- Safety Summary Report
- Quality Summary Report with Finished Product Specifications
- Proposed Label Text

Application Review Process:

Level 1: Verification

NHPD screens the applications it receives from the company and its contact information, and gives each application a file number and submission number. NHPD then sends out an acknowledgement notice confirming receipt of the application.

Level 2: Processing

NHPD checks verified applications for completeness to ensure that the appropriate supporting information is submitted for the type of submission and is in an acceptable format.

Level 3: Assessment

When the application reaches this level, the application form and supporting information are assessed for compliance with the *Natural Health Products Regulations*.

Level 4: Decision

NHPD will issue a product license if:

- the applicant submits an application to the NHPD that is in accordance with *Natural Health Products Regulations*;
- the applicant submits to the NHPD all additional information or samples requested;
- the applicant does not make a false or misleading statement in the application;
- the issuance of the license is not likely to result in injury to the health of a purchaser or consumer.

SITE LICENSING

The system of site licensing requires that all manufacturers, packagers, labelers, and importers in Canada be licensed. Sites must have procedures in place for distribution records and product recalls. Sites must meet GMP requirements. The regulations also set out circumstances for refusing, suspending or canceling a site license.

Site License Application Requirements:

To apply for a site license, applicant must provide a site license submission including the application form along with a *Quality Assurance Report* prepared by a quality assurance person or a third-party auditor with the applicable education, training and experience to assess compliance with GMP requirements outlined in the *Natural Health Product Regulations*. A valid GMP inspection report by a Health Canada inspector can also be used in place of the *Quality Assurance Report*.

Site License Application Review Process:

Level 1: Verification

NHPD screens the submission it receives for the company information and gives each submission a file number and submission number. NHPD sends out an acknowledgment letter to the applicant confirming receipt of the submission.

Level 2: Processing

NHPD checks application form for completeness and that the appropriate supporting data are provided for that submission. This supporting data includes the Quality Assurance Report Form and Quality Assurance Person Qualifications Form.

Level 3: Assessment

When the application reaches this level, the application form and supporting information are assessed for compliance with the *Natural Health Products Regulations*.

Level 4: Decision

NHPD will issue a product license if:

- the applicant submits an application to the NHPD that is in accordance with *Natural Health Products Regulations*;
- the applicant submits to the NHPD all additional information or samples requested;
- the applicant does not make a false or misleading statement in the application.

Foreign Manufacturing Site:

For NHPs manufactured at foreign sites, the Canadian importers must provide evidence that imported products meet GMP and Canadian *Natural Health Products Regulations* or equivalent standards. One of the following types of evidence is required from importers with respect to the foreign sites:

- the Quality Assurance Report and prepared by a quality assurance person or third-party auditor who has the technical expertise and training relating to each activity being reviewed;

- an audit, inspection report or equivalent based on a memorandum of understanding or mutual recognition agreement between a foreign regulatory agency and Health Canada;
- a license from the accepted regulatory authority in a designated country or association of countries.

GOOD MANUFACTURING PRACTICES

GMP is to be employed to ensure product safety and quality. This requires that appropriate standards and practices regarding product manufacture, storage, handling and distribution respecting NHPs be met. The provisions cover specifications (product), premises, equipment, personnel, sanitation program, operations, quality assurance, stability, records, sterile products, lot or batch samples, and recall reporting.

CLINICAL TRIALS

Clinical trials are required for products with new conditions of use and products with no prior history of use in humans. In order to obtain approval from NHPD for a clinical trial, a Clinical Trial Application must be submitted to the NHPD. The requirements for clinical trials are designed to protect the rights, safety and well-being of clinical trial participants and other persons involved in conducting and evaluating clinical trials.

LABELING

Standard labeling requirements are established to ensure consumers can make informed choices. Examples of the required label information include the product name, the quantity of product in the bottle, recommended conditions of use, including the recommended use or purpose, dosage form, method of administration, recommended dose, and any cautionary statements, warnings, contra-indications and possible adverse reactions associated with the product, as well as any special storage conditions.

ADVERSE REACTION REPORTING

The adverse reaction reporting system for NHPs assists Health Canada to issue advisories, when appropriate, to the public. The regulations require product license holders to monitor all adverse reactions associated with their products. Serious adverse reactions must be reported to Health Canada.

TRANSITION OF NHP REGULATIONS

As of January 1, 2004, the *Natural Health Products Regulations* come into force and apply to all NHPs. The transition provisions allow time for training, education and public awareness to help businesses of the NHP industry comply with the Regulations. The provisions set out a two-year transition period for site licensing, from January 1, 2004, to December 31, 2005 and a six-year transition period for product licensing, from January 1, 2004 to December 31, 2009. Outlined in Figure 2 below is an overview of the transition period

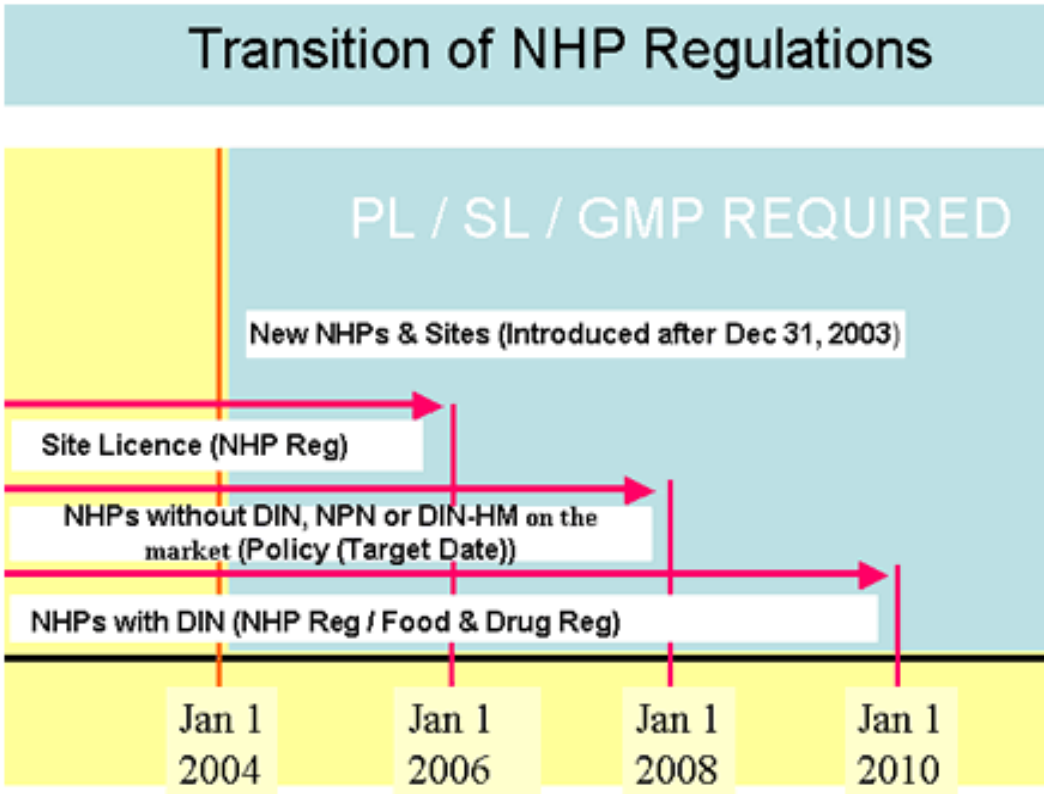

Figure 2. The Transition of the NHP Regulations

Illustrated in Figure 3 below are Health Canada's product category priority approach scheme and its respective timeline.

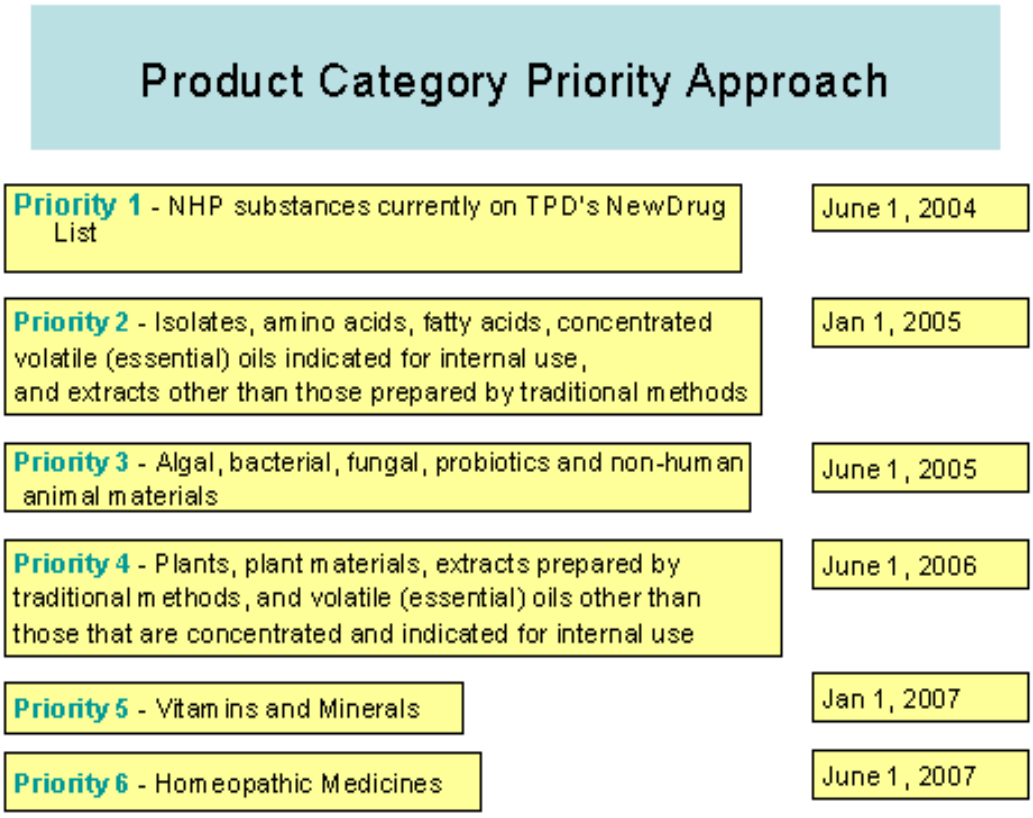

Figure 3. The Product Category Priority Approach

C. IMPACT OF NEW REGULATIONS ON CHINESE MEDICINE

Before the new *Natural Health Products Regulations* was introduced, CM products was classified as food and sold primarily at Chinese grocery stores or herbal products stores in the Canadian Chinese communities to ethnic Chinese, which is only 3% of the population in Canada.

As previously discussed, medicinal herbs, nutraceuticals and dietary supplements have a 43% share of the $2.2 billion NHPs market in Canada. Recently, herbal/botanical supplement including CM is the product category growing at almost 30%

annually, while single herb sales are down[8]. Unfortunately NHPs imported from China to Canada have been largely in the forms of raw materials and ingredients with very little value added. There are basically no major brands in the highly fragmented CM marketplace in Canada. Even CM in finished product form, price is usually very low because of small demand by limited number of consumers.

The new *Natural Health Products Regulations*, however, classified CM products along with other traditional medicine products as NHPs, which are a subset category of drugs. The new regulations have presented opportunities and challenges to CM products.

The strengths of CM compared to other NHPs are its long history of traditional use with demonstrated clinical effectiveness and good safety. However there are marked differences between CM and Western drugs in many perspectives as follows[9]:

CM	Drugs
• Authoritarian (top down)	• Independent (bottom up)
• Static	• Changing constantly
• Accepting	• Challenging
• Old	• New
• Timeless	• Modern
• Spiritual	• Biological
• Belief based/Anecdotal	• Evidence based

OPPORTUNITIES

The new regulations open the doors for the CM products to markets not only in the Chinese Communities but also to main stream markets. The market is moving from single herbs toward comprehensive multi-herb formulas which favor CM. Furthermore, personalized medicine or supplements which shares similar philosophy and theory with CM is becoming increasingly popular.

The product licensing system will help CM gain consumer confidence on product safety, quality and efficacy, as

[8] Mark Blumenthal: Herd Sales Down 7.4% in Mainstream Market. *HerbalGram* 66:63, 2005

[9] Paul Lietman: Globalization of Chinese Herbal Medicines - An Academic Perspective from John Hopkins and the National University of Singapore. *Medicine In the 21st Century Tri-Conference & Bio-Forum*. Shanghai 2004

demonstrated and proven by thousands of years of traditional use and experience. The permitted treatment claims, risk reduction claims and structure/function claims based on CM's traditional use will allow more and more consumers beyond the traditional ethnic Chinese markets overseas to better understand the full benefits of CM. Demand for CM will increase. Sales and profits of CM will boost as a result.

Over 50% of NHPs companies in Canada export to the U.S. market. Of these exporters, more than 75% shipped to the U.S.. The majority of exporting firms (77%) exported finished functional food or nutraceutical products for sale at the wholesale or retail level. About 44% exported raw materials or ingredients for use in functional foods or nutraceuticals, while one-third exported semi-finished products for further processing before sale[10]. Canada and the U.S. are free trade on NHPs based on the NAFTA agreement. In general Canadian NHPs command a 20-25% price premium over the comparable products in the U.S..

Therefore, huge additional opportunities have emerged for certain qualified CM to use Canada as a gateway to enter to the U.S. market which size is more than one-third of the global market and about 10 times bigger than the Canadian market[11].

CHALLENGES

The implementation of the new regulations is definitely a challenge to CM suppliers including manufacturers, importers and distributors. To obtain a product license, the manufacturer has to provide sufficient evidence that the product is manufactured with complete GMP compliance and also the product is effective, safe and with good quality. Historically CM had been perceived by a great number of mainstream Canadian consumers as products with anecdotal evidence and little modern scientific evidence on efficacy.

In the case of safety, the new regulations require products be thorough reviewed by NHPD prior to release on the market. As a result of pollution, manufacturing and agriculture practices, heavy metal and pesticide contaminations are reported from time to time on CM from China.

[10] Functional Foods and Nutraceuticals Survey. *Agriculture and Agri-Food Canada* 2003 (www.statcan.ca/Daily/English/031006/d031006c.htm)
[11] Pharmaceuticals and Natural Health Products 2003. *The Trade Facilitation Office Canada* (www.tfoc.ca)

Further, culture and tradition is generally more difficult to globalize than science. It is not uncommon to expect that CM will still face significant hurdles in its march to the mainstream market if we do not adapt and make changes to modernize CM from all aspects in production, product development, clinical research, dosage form, administration route, and marketing (i.e. packaging, labeling, communication etc.).

STRATEGIES

To fully take advantage of the new regulations and maximize CM potentials, one must manage delicately and rightly the convergence of CM and modern scientific medicine. Selecting appropriate products, focusing on simple key product attribute(s) and securing NPN application and approval followed by creative marketing can be the most effective way to successfully advance CM into the mainstream market internationally.

D. CONCLUSION

The new Canadian NHPs regulations provide a unique opportunity to China for globalization of Chinese medicine and its entry to the mainstream markets in Canada and likely the U.S. with approved benefit claims supported by traditional use and modern scientific research.