



CENTRE FOR
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The Honourable Tony Clement, PC, MP
Minister of Health
Brooke Claxton Building, Tunney's Pasture
Postal Locator: 0906C
Ottawa, Ontario K1A 0K9

Re: Natural Health Products Review should revise licensing procedures to ensure NHP approvals are based on current scientific evidence regarding safety and efficacy, not selective consideration of dated, “traditional evidence.”

Dear Minister Clement:

We are writing on behalf of the Centre for Science in the Public Interest* to respond to the invitation for public comments on Health Canada's three-year review of its new Natural Health Products Regulations.

Introduction

While it is encouraging that the federal government has assumed a regulatory oversight role in the manufacture, packaging and sale of these products, we are concerned that Health Canada's efforts to implement the law have fallen seriously short, especially for products licensed solely on the basis of historical use (i.e., “traditional use”), such as is the case for many herbs and botanicals which comprise approximately 30% of all natural health product (NHP) sales in Canada.¹ License decisions based on historical and traditional use do not ensure that NHPs are safe and effective, but instead convey a level of official legitimacy that does not exist.

Furthermore, questions posed in the invitation for public comments appear to steer respondents' attention away from such important, cross-cutting concerns and toward narrow industry-oriented technical matters. As a result, the public consultation misses the mark and ignores tough questions concerning the safety and effectiveness of these products.

Health Canada's NHP licensing regime must protect and enhance the public's health and prevent economic fraud. Health Canada must ensure NHP safety and effectiveness based on modern scientific information, and not merely rubber stamp products based on outdated notions of historical

* The Centre for Science in the Public Interest (CSPI) is an independent health advocacy organization, focusing on nutrition and food safety, with offices in Ottawa, and Washington, D.C. CSPI's Canadian advocacy efforts are supported by more than 100,000 subscribers to the Canadian edition of its *Nutrition Action Healthletter*. CSPI does not accept funding from either industry or government.

and traditional use. As the federal Government noted at the time the Natural Health Products Regulations were promulgated:

“Through consultations with consumers and deliberations of the Standing Committee [on Health of the House of Commons], i[t] was clear that product users wanted assurances of safety, quality and efficacy, with evidence to support the health claims, through a system of pre-market review.”²

Standards of Evidence for safety and efficacy of NHPs

Health Canada’s licensing process accepts, at face-value, ancient medical lore—even when it has been contradicted by modern, well-designed, independently-funded³ research—as sufficient proof to meet the legal requirement for “safety and efficacy” of NHPs.⁴ Even then, Health Canada has decided to settle for “traditional” evidence of *use* (i.e., not necessarily proof of *effective* use) provided the product was used anywhere in the world at anytime in history for as little as 50 years.⁵

Health Canada feigns maintaining a high standard of evidence for proof of safety and efficacy when, for instance, it *suggests* non-compendial applicants undertake systematic literature searches “to review the totality of evidence...including both favourable and unfavourable data”⁶ and states that “the totality of evidence must be in support of the benefits of the product outweighing any risks.”⁷ However, even when Health Canada authors its own generic product monographs (vehicles for fast-tracking license applications for common products likely to be sold by a variety of manufacturers), it sets the bar much lower by sometimes even failing to cite recent, well-conducted peer-reviewed scientific research that contradicts traditional evidence. For instance, there is good, modern clinical trial evidence indicating that taking black cohosh⁸ is a useless and possibly even dangerous way to combat the symptoms of menopause despite promises made in Health Canada’s generic monograph for the substance.⁹ However, Health Canada’s monograph is silent on these important developments. Similarly, Health Canada’s generic monograph for garlic authorizes a discredited cardiovascular disease prevention claim even though, for instance, the American Heart Association stated earlier this year that garlic has “no measurable effect on cholesterol levels.”¹⁰

As of the date of this letter, Health Canada has published 92 generic monographs for single ingredient NHPs. We will continue to assess the adequacy of those monographs against the published scientific literature.

Clearly, Health Canada’s own generic product monographs either favour traditional-use documentation over evidence of modern randomized controlled clinical trials (though it expressly purports to rank the latter as more authoritative¹¹) or it simply does not seek out the evidence it says it asks non-compendial license applicants to provide. As a result, Canadian consumers of NHPs may incorrectly assume that Health Canada vets and validates evidence underpinning the traditional health claims it approves – when it apparently may only be confirming the claim was made, historically.

Risks of Insufficient Regulatory Scrutiny

By allowing its health-science imprimatur to be used to promote products solely on the basis of archival evidence of use, Health Canada misleads Canadians and diminishes its own credibility as an authority on modern health science, a gatekeeper of the Canadian supply of safe and effective medicines, and ultimately, a champion of public and individual health.

When *ineffective* remedies are mass-marketed with the approval of Health Canada, they can cause lasting confusion in the public about health benefits. They can also harm the public by causing users to abandon *effective* remedies – including well-tested drugs, dietary changes, exercise or other proven health care interventions. For instance, Health Canada’s approval of a generic¹² cardiovascular disease treatment claim for demonstrably *ineffective* products like garlic could lead some consumers to abandon demonstrably effective treatments or to ignore sound advice to consume more fruits, vegetable and whole grains or other well-established bulwarks against heart disease.

Instead of attempting to correct these problems during the course of this consultation, Health Canada’s questionnaire indicates that the department plans to exacerbates them by permitting such demonstrably ineffective claims to be made in advertising, including ads pertaining to serious diseases listed in Schedule A of the Food and Drugs Act.¹³

Conclusion

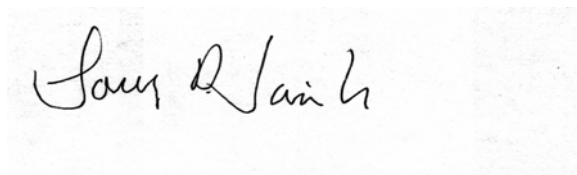
Cultural sensitivity and nostalgia should not be excuses for allowing unsafe or ineffective products on the market. Canadians are entitled to a supply of safe and effective natural health products. Scientific study—itsself merely an organized way of acquiring and evaluating experience—should provide useful information to guide Health Canada’s license application decisions. Canadians expect Health Canada to use modern methods of scientific inquiry and, at a minimum, Health Canada should certainly not ignore scientific evidence demonstrating the *ineffectiveness* of NHPs.

Later stages of this consultation should squarely address licensed NHPs whose safety and/or efficacy are seriously questioned by modern, well-conducted research, especially NHPs approved pursuant to generic monographs authored by Health Canada. We are troubled by the lack of resources for ensuring inspection of manufacturing facilities and ensuring independent (i.e., government or third-party) verification of good manufacturing practices,¹⁴ however, we advocate strengthening the standards of evidence for safety and efficacy before dedicating more resources to enforcement activities regarding manufacturing practices.

Sincerely,

[original signed by BJ]

Bill Jeffery, LL.B.
National Coordinator,
Centre for Science and the Public Interest



Larry D. Sasich, Pharm.D., MPH
Consultant Pharmacist,
Centre for Science and the Public Interest

RESPONSES TO QUESTIONNAIRE

Part I, Issue 1 -- Compounding of Natural Health Products

This issue is incorrectly and misleadingly described and does not provide sufficient information for the public to submit informed comments. Adopting the language and concepts used to describe this issue would be extraordinarily poor health policy that would place the public at risk of needless harm.

The suggestion that pellets be an allowed dosage form for natural health products is particularly troubling as is the use of “etc.” at the end of the list of example dosage forms. Pellets are typically surgically implanted and must be sterile.

This language would create another category of manufacturing, under the guise of compounding, that would expand operations under the current defective GMP guidelines for NHPs. These guidelines depend on attestations by manufacturers rather than government inspections to ensure quality.

Health Canada must examine the U.S. experience with pharmacy compounding to appreciate the potential for harm by allowing manufacturing to be conducted under the façade of compounding.

Part I, Issue 2 – Definition of Homeopathic Medicines

This issue is incompletely described and is likely misleading. It is unclear whether the phrase “proven remedies” relates to valid scientific proof or to the definition used by proponents and practitioners of homeopathy.

The standards for marketing and oversight of NHPs in Canada are now incredibly low. Altering the current definition of a homeopathic medicine from the requirement that a substance be referenced in a recognized homeopathic pharmacopoeia to any biomaterial or mineral, other than controlled substances or radiopharmaceuticals, would further weaken the regulation of NHPs, which is already based on the faulty premise of “buyer beware.”

The NHP regulations mislead the public by leaving the impression that safe and effective has the same meanings for NHP as OTC and prescription drugs.

Reference in a recognized homeopathic pharmacopoeia, in the absence of meaningful government oversight, will not prevent consumers from purchasing rogue products that will likely be promoted for unsubstantiated uses.

Part I, Issue 3 – Lowest Risk Products

This issue is misleadingly described and does not give the public sufficient context to provide informed comments.

The notion that the NHPD’s Compendium of Monographs defines lowest risk products is deeply flawed. The monograph for black cohosh is an example. It has taken almost 3 years for the NHPD to update this monograph with a weak statement about the liver toxicity caused by this herb. (Other

national regulatory authorities have taken much stronger actions on behalf of the public.) Furthermore, there is no mention in the monograph of high quality randomized clinical trials showing that black cohosh is of no benefit in managing the symptoms of menopause.

The risks of black cohosh clearly outweigh any known benefit in the treatment of menopausal women. Yet, a monograph remains in place for this herb signifying that it is safe and effective. Any attempt by Health Canada to categorize an NHP, *a priori*, as “low risk” is suspect and should not be allowed.

Part I, Issue 4 – NHPs Derived From Fish

The following phrase from the description of this issue,

“... given the lack of inspection component in the NHPR, ... export certificates are often not acceptable to these countries ...”

encapsulates one of the fundamental flaws in the Natural Health Products Regulations (NHPR). Issuing product licenses without resources for inspection misleads the public into believing that NHPs are subject to rigorous regulatory oversight, similar to over-the-counter (OTC) or prescription pharmaceuticals.

On-site inspections, by trained government inspectors, is the only strategy that can ensure that Good Manufacturing Practices (GMPs) are being followed. It should come as no surprise that some other countries will not accept fish-derived NHPs produced in Canada under the current NHPR.

The government must institute a stringent Good Manufacturing Practices (GMP) inspection regime for NHP producers, with stiff penalties for non-compliance.

Part I, Issue 5 – Personal Care Products

The description of this issue lacks sufficient information for meaningful public comments.

The regulatory definition for NHPs clearly precludes considering personal care products (PCP) as NHPs. Allowing preparations that currently fall under the Cosmetics Regulations to be marketed as NHPs would further erode the quality and safety of products available in the Canadian marketplace.

The current NHP Regulations allow the marketing of almost any biomaterial or mineral as beneficial based on a flawed review scheme that recognizes selective information and the flimsiest of evidence as acceptable.

In contrast to the Cosmetic Regulations, the NHP Regulations have a “... lack of inspection component ...” that makes it impossible to ensure the content, quality and purity of any marketed NHP.

The goals stated for NHP regulation will not be achieved without the requirement for rigorous onsite inspection of all facilities producing products for the Canadian market.

Part I, Issue 6 – Human Tissue in NHPs

The fact that a homeopathic medicine or a potentially commercialized traditional medicine may contain human tissue is extremely troubling in light of the fact that the NHP Regulations do not require inspection of manufacturing facilities or establish rigorous procedures to ensure that these products will not transmit disease to consumers. Homeopathic products may contain materials known as *nosodes* that are obtained from diseased tissue or secretions and should not be allowed to be sold as NHPs.

The use of human tissue in traditional medicine can be preserved and cultural diversity respected, by not allowing the commercialization of products containing human tissue or secretions. Traditional medicine only has meaning within the context of a culture's medical tradition. The commercialization and export of one small aspect of a culture to other cultures, at best, has no meaning to those of other cultures and, at worst, can be dangerous and misleading.

Part 3, Issue 1 – Good Manufacturing Practices (GMPs)

The absence of meaningful GMPs for NHPs and the lack of any requirement for rigorous onsite Health Canada inspections of NHP manufacturing facilities results in a regulatory scheme that fails to protect the public from potential hazards. The present NHP regulatory scheme also misleads the public by implying that NHPs are safe and of high quality, the same language that is used to describe safety and quality of prescription drugs, notwithstanding that the standards for the safety and quality for NHP and OTC/prescription drugs bear little, if any similarities.

Inspections by Health Canada of NHP manufacturing facilities is a basic, minimal step to protect the public's health.

Part 4, Issue 1 – Harmonizing NHP Clinical Trial Requirements with changes to the Food and Drug Regulations

The description of this issue lacks sufficient information for public to make meaningful comments. The description should be revised to provide sufficient information and the issue reintroduced for public consultation before any final decision is made by the government.

Part 5 Issue 1 – Lack of Advertising Regulatory Provisions in the Natural Health Product Regulations

It is especially important that substances with poorly substantiated health benefits not be advertised to the public, especially when the poorly substantiated benefits relate to serious illnesses such as those listed in Schedule A of the Food and Drugs Act.

The advertising a NHP prior to the time that a valid product license has been approved must be prohibited.

Part 5 Issue 2 – Professional-Use Claims

In the interest of public safety, products that fell under the Therapeutics Product Directorate (TPD) standards but have now been reclassified as NHPs should adhere to the same packaging and labeling requirements as they did under the TDP regulations. In addition, a disclosure should be made on labelling for these reclassified NHPs to inform consumers that a lower standard is used to define quality, purity, and stability for these NHPs compared to products regulated under the TPD standards.

The classification of the professional-use product Racemic Epinephrine Hydrochloride as a NHP appears to violate Health Canada's own regulations. Epinephrine is a naturally occurring hormone that has been synthetically produced for almost 100 years. Please refer to the Overview of the Natural Health Products Regulations Guidance Document, 2.2 Schedule 2: List of Excluded Substances, accessed 14-Apr-07.

Part 5, Issue 3 – Self Care

NHPs making health benefit claims that could result in a consumer postponing needed care – care that is based on rigorous scientific standards – are unsafe for self-selection and self-care. The present regulations, coupled with the lack of effective government oversight, allow the marketplace to be filled with untested products that are promoted for unsubstantiated uses.

Rational NHP regulations would only allow the marketing of products that have undergone, basic animal toxicity testing; that are subject to GMP guidelines which ensure quality; that prohibit the promotion of health benefit claims without sufficient evidence (not the present meaningless standard of evidence); and that carry adequate safety warnings.

These requirements would help ensure that all Canadians have ready access to NHPs that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

Part 5, Issue 4 – Sampling

Samples of prescription and nonprescription drugs distributed to healthcare practitioners serve no useful health purpose. This practice by manufacturers is purely promotional. It is a fallacy to believe that practitioners can gain any useful information about the value of a sampled product in the uncontrolled setting of the everyday practice of medicine.

There is no reason, and certainly no public health imperative, to harmonize the NHP Regulations the Food and Drugs Act to allow the sampling of NHP to health professionals, especially considering that the NHPs do not have to meet the rigorous safety and efficacy requirements that apply to drugs.

Allowing the sampling of NHPs to health professionals would only needlessly increase the exposure of unsuspecting consumers to untested products that are promoted for unsubstantiated uses. The only benefit would be economic, to the NHP producer, and to the health professional seeking to supplement income.

REFERENCES

¹ Many substances that are now subject to regulation as “natural health products” include toothpaste, vitamins, minerals, special types of soap and medicinal cremes that were previously regulated as cosmetics or over-the-counter drugs and, as such, have long been subject to a modicum of regulatory scrutiny. However, hundreds of NHPs marketed as herbal remedies are either new to the market or were long-marketed in Canada without regulatory oversight (and often without explicit health claims that are now permitted under the new regulations). Herbs and botanicals comprise an estimated 30% of NHP sales in Canada. (*Canada Gazette, Part II*, 2003, Vol. 137, No. 13 at 1593.)

² *Canada Gazette, Part II*, 2003, Vol. 137, No. 13 at 1592.

³ Some proponents of NHPs seek to advance the cause of their products by claiming that “Big Pharma” uses oppressive lobbying and commercial practices for synthetic drugs to quash the market for competing NHPs and, thereby, deprive consumers of them. This view, however, requires that consumers be concerned about some self-serving commercial practices (i.e., for drugs) and faithfully accepting of others (for NHPs). In any event, because many large pharmaceutical companies are beginning to market their own lines of NHPs, this distinction is becoming even less useful, if it ever was.

⁴ Required by subsection 5(g) of *Natural Health Products Regulations*, SOR/2003-196. Sections 4, 5, 8 and 9 of the *Food and Drugs Act*, R.S.C. 1985, c. F-27 also state, in regards to food and drugs:

4. No person shall sell an article of food that (a) has in or on it any poisonous or harmful substance;...

5. (1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

8. No person shall sell any drug that

(a) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or (b) is adulterated.

9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

⁵ E.g., see: Natural Health Products Directorate, “Evidence for the Safety and Efficacy of Finished Natural Health Products” (Ottawa: Health Canada, December 2006) at 5.

⁶ *Ibid.* at 2.

⁷ *Ibid.* at 3.

⁸ In a letter to Minister Clement dated May 24, 2007, we raised concerns about the safety and effectiveness of black cohosh--an herb marketed as a remedy for symptoms of menopause--licensed pursuant to a Health Canada generic monograph containing serious errors and omissions. See: <http://www.cspinet.org/canada/pdf/BlackCohosh.pdf> .

⁹ Pursuant to section 6 of the *Natural Health Product Regulations*, Health Canada’s generic product monographs can be used as the basis for fast-tracking product license applications – i.e., a product license conforming to the monograph will be obtained in as few as 60 calendar days unless Health Canada objects.

¹⁰ Health Canada’s generic monograph for garlic, dated May 7, 2004, approves the claim “Helps maintain cardiovascular health.” However, according to a statement of the American Heart Association dated February 27, 2007, garlic in both raw and supplement form have “no measurable effect on cholesterol levels.” See: <http://www.americanheart.org/presenter.jhtml?identifier=3047842>

¹¹ Natural Health Products Directorate, “Evidence for the Safety and Efficacy of Finished Natural Health Products” (Ottawa: Health Canada, December 2006) at 16.

¹² *Supra*, note 10.

¹³ Health Canada, “Fact Sheet: Schedule A Health Claims for Natural Health Products” (dated May 9, 2007) which indicates that Health Canada is working to revise (and shorten) the list of diseases, and exempt NHPs from making prevention claims regarding diseases that remain on the list.

¹⁴ See pp. 38, 41 of *Charting A Course: Refining Health Canada’s Approach to Regulating Natural Health Products*.