



NHP Marketing in Canada: A Survey of the Online Marketing of Natural Health Products for Cancer Treatment and Cure

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Bad Science Watch

Bad Science Watch is an independent Canadian consumer protection organization dedicated to promoting good science in public policy.

The following was prepared by volunteers and represents what we believe to be an honest, fair, and science-based evaluation. We are an independent body that is funded by private donations and we do not represent any corporate interests.

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Summary

The online marketplace has afforded unparalleled access to retailers seeking to market and sell to consumers who wish to scrutinize and purchase all manner of products. While Canadian advertising standards apply to all products advertised to Canadians, natural health products (NHPs) advertised directly to consumers must additionally adhere to authorizations granted by Health Canada when making claims in relation to specific diseases. In this study, we assessed whether or not online retailers of NHPs near Canadian city centres were advertising their products in ways that align with the products' Health Canada licenses as permitted under the Food and Drugs Act, 1985. A collective of volunteers were engaged to assess whether each sampled webpage contained claims regarding cancer, the precise nature of the claims, and the Health Canada registration status of the associated product. Of the 558 web pages evaluated by Bad Science Watch, 20% and 30% made direct or indirect claims respectively about cancer treatment. Only 2.3% made direct claims that are authorized by Health Canada. Our results indicate that Canadians are exposed to an alarming magnitude of potentially deceptive health product marketing claims that could endanger public health.

Introduction

Canadian Natural Health Products (NHPs) operate in a privileged marketplace under the Food and Drugs Act (FDA) (Legislative Services Branch, 1985). Schedule A of the FDA stipulates health conditions for which you cannot advertise a health product; conditions that include serious diseases like cancer and heart disease. As such, prescription drugs cannot be marketed directly to the consumer. However, direct marketing of NHPs¹ is permitted, but with a large caveat: retailers and manufacturers can only advertise products as a preventative for a Schedule A condition, and only if that claim is approved by Health Canada, receiving a natural product number (NPN). Therefore, under no condition must an NHP retailer or manufacturer market a product as a treatment or cure for any of these conditions (Health Canada, 2013).

Specifically, section 103.2 of the NHP Regulations state: *“A natural health product is exempt from subsection 3(1) of the Act with respect to its advertisement to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act”* (Legislative Services Branch, 2018).

In 2014, the non-profit organization Bad Science Watch looked at a homeopathic influenza remedy called Influenzinum and found that, despite not having Health Canada approval through the product's NPN, many retailers made claims of influenza prevention and treatment, and we became concerned

¹ Non-prescription drugs are also included in this exemption, but these are not the target of this investigation

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that this non-compliance with the regulations may be a wide spread problem in the NHP retail industry (Kruse et al.).

The popularity of NHPs necessitates effective regulatory oversight of therapeutic claims for both consumer protection and public health. A 2010 survey showed that 73% of Canadians regularly take NHPs, which include products such as vitamins, minerals, homeopathic medicines, and herbal remedies (Ipsos-Reid (Firm) and Health Canada, 2011). Recently the risks of NHP use and complementary has been shown with complementary medicine being associated with a 2-fold higher risk of death because it leads to a refusal of further treatment (Johnson et al., 2018). A study examining children receiving respite care in a Canadian pediatric hospice found that 49% of patients had potential NHP-medication interactions and 22% had potential NHP-NHP interactions (Beringer et al., 2015). Moreover, compared to taking prescription drugs alone, patients taking NHP-prescription drugs were 6.38 times more likely to experience an adverse effect (Necyk et al., 2014). With the substantial growth in online retailing since this survey, consumer access to NPHs has expanded. In fact, the most common source of patient information on CAMs was from the internet (75.4%) (Lee et al., 2018). While this online marketplace has provided increased access and competition, it has been exploited by retailers who fail to properly contextualize the health value of their products, relying on health claims not vetted or authorized by the appropriate regulatory authorities (Ashar et al., 2003; Morris CA and Avorn J, 2003; Page and Grod, 2009). To date, a comprehensive examination of NHP online marketing in Canada has not been performed.

The intent of this study was to develop and evaluate a methodology towards assessment of whether Canadian online retailers of NHPs are marketing their products in alignment with their market authorization provided by Health Canada. Due to the ambiguity around prevention claims, we focused on the prohibited treatment and cure claims, and rather than assess claims for the full range of Schedule A diseases, a single disease category was chosen. Specifically, promotional claims about cancer were assessed in the context of their market authorization using the Licensed Natural Health Products Database (Health Canada, 2007). Cancer is a suitable Schedule A disease for assessing unauthorized marketing of treatment claims as such unsubstantiated claims represent a palpable affront to public health and consumer protection.

Methods

A cross-sectional content analysis methodology was developed to examine advertising/marketing practices of natural health product retailers in Canada. Content from Canadian NHP retailer websites was collected and catalogued for the use of keywords relating to cancer. The catalogued pages were

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evaluated to assess the congruency between health claims made on retailer websites for specific health products and those for which Health Canada issued an NPN.

Webpage Collection

Websites were extracted from a convenience sample of another project started in 2014. Canadian cities with populations exceeding 100,000 residents were input into the 'Search by Location' tool of the Canadian Health Food Association Retailer Directory. The output identified NHP retailers within a 100km radius of each city and corresponding publicly accessible websites were identified. An additional search was done using an online phone book (yellowpages.ca) to identify natural health products sellers. A manual search of websites that were known to us informally were added if they were not in the original list. Moreover, positive website hits were processed to ensure that the search words were visible to the consumer. Retailers were confirmed to have contact addresses in Canada. Web pages were archived and catalogued based on the search term cancer and its derivatives, including: tumor, and metastasis. The key word search was limited to English due to an insufficient number of fluent French speaking evaluators.

Web pages were sorted alphanumerically then assigned a data identification number according to their rank. Using a pseudorandom approach, each webpage was assigned a randomization number and sorted accordingly.

Volunteer Recruitment and Training

A total of 23 volunteers were recruited. Volunteers completed focused evaluator training within a virtual meeting space. Volunteers were provided project support resources in the form of regular update meetings, an evaluator training wiki and an issue tracking application. Ambiguity encountered throughout the evaluation process was mitigated by referral to a senior evaluator and/or utilization of a group issue tracking forum.

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Site Evaluation

Each webpage was evaluated by volunteers using a stepwise procedure to determine the precise nature of each health claim. All web pages were evaluated in accordance with the inclusion and exclusion criteria.

Inclusion Criteria

A webpage was included if:

1. It was a blog, endorsement, or advertisement including the word “cancer” AND
2. It was in reference to a discrete product name or brand of product made on a commercial website AND
3. It had an associated product price or indication of a method of purchase.

Bulk or raw ingredients were also included if they acted as NHPs according to Health Canada, including products manufactured, sold or represented for NHP use (Health Canada, 2006). Web pages classified as a ‘hit’ were eligible to continue to the evaluation phase.

Exclusion Criteria

A webpage was excluded if:

1. The site was password protected (therefore not accessible to the public), OR
2. The webpage advertised or endorsed generic ingredients not associated with a specific brand or product and did not make claims about its use, OR
3. A picture, product or description did not include a price or purchase mechanism, OR
4. Multiple products were sold on a single page, OR
5. The disease search term (i.e. cancer) appeared in the header, sidebar or webpage address estranged from the product.

Web pages ineligible according to the ‘hit’ criteria were recorded within a Google spreadsheet and further evaluated according to the methodological framework for false negative “hits” (see Appendix A).

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“Hit” Evaluation

Each webpage deemed a ‘hit’ was subjected to further evaluation through a data extraction process similar to that used by Ashar et al. (Ashar et al., 2003). The NHP Marketing Pilot Data Entry Form (Appendix B) served as a site abstraction tool for each evaluators’ site analysis.

Volunteer evaluators visited each ‘hit’ page and extracted the relevant parameters to fill each ‘hit’-specific form, documenting – according to the prescribed criteria – the nature of the page, the relevant product details, and how the product was advertised. Of note is the distinction between *direct* and *indirect* marketing claims. This classification was used in an attempt to explore the nature of claims being made; however, Health Canada makes no distinction between direct and indirect marketing claims. Refer to Appendix B for detailed tool methodology.

Inter-Rater Reliability

Inter-rater reliability was assessed by a peer review process utilizing sequential evaluation phases. During Phase I-A, 600 web pages previously assigned and assessed were randomly distributed across volunteers for a second assessment. ‘Hit’ evaluations that resulted in duplicates (pages that were evaluated already in Phase I) were utilized in analyzing inter-rater reliability by selecting a critical subset of questions from the pilot data entry form (Appendix B) for comparison. Two measures were employed to examine reliability: percent agreement, and Cohen’s Kappa: a metric that accounts for chance agreement in the sample (McHugh, 2012).

Results

The criteria for the webpage search and collection is outlined in the Methodology Section. In total, 31686 web pages were collected in 2016 from November to December based on their inclusion of the ‘cancer’ search criteria, and 2324 were assigned for screening. This did not exclude cases where the term was contained in the metadata, or in any context not concerning the marketing of a cancer remedy. Sample size was determined using a confidence interval of 95% and after Phase I we determined that approximately 50% of pages would be making cancer claims.

Table 1: Results of Webpage Analysis

Number of websites	Web pages with word “Cancer”	Original sample size prior to evaluation	No. of unique true positive “hits”	Web pages with direct claims	Direct Claims compatible with NPN	Web pages with indirect claims	Indirect claims compatible with NPN
172	31686	2324	558	113	2	166	1

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Only pages assessed as ‘hits’ (see Methodology Section for hit criteria) were evaluated using the NHP marketing pilot data entry form (Appendix B) during the first round of assessment. The sites were screened during Phase I and II and excluded from further analysis based on the context of the search term ‘cancer’. The sites were further reduced upon reassessment, considering duplications (for example, the same parent site with multiple pages for an identical NPN), false positives, and other errors. In total, evaluation was performed on 708 web pages, with 150 duplicates, leaving 558 unique pages.

Of the unique pages, 20% made a direct claim of treatment or cure, while 30% made an indirect claim. Only 3 out of the 558 pages made any type of claim permitted under their NHP. The study also captured sites which were thought to make claims through ways that were not definitively stating treatment or cure, but rather implying it. These were classified as ‘Unclear,’ and made up 3.2% and 6.3% of direct and indirect claims, respectively. Only 13% of sites listed the product NPN directly on the site and only 2.3% of sites mentioned approval by a regulatory agency.

A total of 68 ‘hits’ were evaluated twice as part of the inter-rater reliability assessment. The results of this assessment can be found in Table 2. See Appendix B for details about survey questions.

Table 2: Inter-rater reliability results.

Survey Questions	Q. 1B	Q. 2A	Q. 2B	Q. 3A	Q. 3B	Q. 4A
Percent Agreement	95%	80%	73%	63%	59%	98%
Cohen’s Kappa (κ)	0.75	0.68	0.42	0.35	0.27	0.79

Discussion

The results of this study illuminate an alarming reality: unauthorized claims in reference to cancer are not rare among online Canadian retailers of NHPs. While the precise form of these claims was observed to be diverse, unauthorized claims of cancer treatment or a cure-all represent a risk to consumers who may find these claims convincing enough to supplement or even replace conventional therapies as part of an alternative regimen to conventional care; a practice with documented consequences (Johnson et al., 2018). Additionally, with 15% of Canadians surveyed in 2010 reporting adverse effects or reactions to NHPs, evidence-based marketing materials are crucial to mitigate consumer risk (Ipsos-Reid (Firm) and Health Canada, 2011).

The prevalence of unauthorized claims across major Canadian online retailers further raises concerns regarding the monitoring and enforcement of marketing claims by Health Canada. Either these efforts

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fall short on proactivity, or deterrents are not strong enough to prevent retailers from taking calculated risks by marketing their products with unsubstantiated and potentially false health claims.

While the results of this study indicate an appreciable risk to Canadian consumers, a descriptive analysis was not performed to classify the precise nature of each claim regarding its contextualization within marketing material and how this might ultimately impact informed consumption. Additionally, the lack of data regarding consumer trends and habits in relation to NHP purchasing precluded a quantitative assessment of impact to Canadian consumers. We did collect representative language from the websites but did not have the resources to perform a narrative analysis. Examples of these can be found in Appendix C.

It is also important to mention that while NHP sellers are exempt from the prohibition of prevention claims for Schedule A diseases, disorders, or abnormal states, it was difficult for us to separate claims for prevention from claims for cure due to ambiguous language in product marketing. Both claims were often made in the same sentence. As such, it is possible that our study captured a significant number of cancer prevention claims alongside claims for treatment or cure. Given that prevention claims are often as poorly supported as the claims for treatment or cure and given that many of these prevention claims are not a part of the product licence, we felt that ambiguous prevention claims that could be taken as claims of treatment or cure are still a serious risk, so we did not want to limit to obvious treatment or cure claims only.

Further research should investigate such trends, how claims for treatment or cure of Schedule A conditions affect consumer purchasing patterns, and the resultant health and economic outcomes.

While inter-rater reliability was generally favourable, there is appreciable room for improvement, particularly concerning the classification of indirect claims of cures. Further emphasis on the distinction between direct and indirect cure claims in training material may improve volunteer classification, although it is possible that this is an inherently difficult and subjective task due to the nature of these types of marketing claims. Regardless, Health Canada does not differentiate between direct and indirect claims; both must satisfy the product authorization.

This study has uncovered an alarmingly high prevalence of unauthorized marketing claims supporting the sale of NHPs and has described a feasible volunteer-driven methodology for assessing these claims. Future efforts should endeavor to increase the scope of assessments into additional disease domains and across additional retailers. Health Canada needs to take strong action against websites non-compliant with regulations. The non-evidence-based scientific claims by the alternative medicine industry is a serious public health threat that warrants specific attention from the government.

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Appendix A: Methodological Framework

Phase	Purpose	Action
I	Determine time requirements for webpage assessment.	Each evaluator was assigned 25 web pages (1 evaluator assigned 50) for an evaluation total of 600. 'Hit' criteria assessment and extraction of pilot entry form data.
I-A	Identification of false positive error rate for 'hits'. Examine inter-rater reliability of assessments.	Evaluators assessed previously screened web pages for 'hit' classification accuracy. Evaluations of true positive 'hit' web pages were performed to determine inter-rater reliability of extraction process.
I-B	Identification of false negative error rate for 'hits'.	To refine our evaluation process to reduce the number of false negatives in future phases.
II-A	Determine what percentage of web pages qualify as 'hits'.	Each evaluator was assigned 75 web pages for evaluation: 2324 total 'Hit' criteria assessment and extraction of pilot entry form data.
II-B	Identification of false positives.	Evaluators assigned 50 web pages to complete a secondary 'Hit' criteria assessment.
II-C	Evaluation of false positives.	Web pages identified as false positives are reassigned and evaluated according to the NHP marketing data entry form (Appendix B)
III	Sample size determination	Removal of duplicates and assessment of false positive and false negatives errors: 708 total web pages
IV	Data Analysis	

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Appendix B: NHP Marketing Pilot Data Entry Form

Form Field	Description	Example or Options
Evaluator Initials	Unique initials assigned to each evaluator.	KS
Data ID Number	Number found in evaluator excel spreadsheet.	12345 (up to five digits)
Parent Website	Main retailer website.	www.naturalhealth productwebsite.com
Retailer name	Name of the company <u>selling</u> the NHP. (May be unique from the manufacturer.)	Super Natural Health Products Emporium
Brand Name (Product name)	Name of the specific product being sold. Assessment: <ul style="list-style-type: none">• Search the product on the Health Canada NHP Database and enter the name as listed.	Super Berry Powder

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Form Field	Description	Example or Options
<p>Q1-A: What is the product's Natural Products Number (NPN) or Homeopathic Medicine Number (DIN-HM)?</p>	<p>Any natural health product licenced by Health Canada requires an NPN (or DIN-HM).</p> <p>NPN may be found:</p> <p>On the product webpage or searched through the Health Canada NHP Database.</p> <p><i>Trouble Shooting:</i></p> <ul style="list-style-type: none"> -If no NPN is listed write "No NPN found". -If the NPN provided does not match the actual NPN, use the NPN number that corresponds with the advertised product and note the discrepancy in question 3-C. -If NPN licence is not longer active (as indicated on the database), also include "Inactive". -If you have multiple active licence numbers for the same brand name, use the most recent active NPN. 	<p>12345678</p>
<p>Q1-B: Does the webpage list the product's NPN or DIN-HM?</p>	<p>This includes readily legible in the picture of the product.</p> <p>Select one option: Yes / No</p>	
<p>Q2-A: Is there a DIRECT claim of treatment or cure for cancer?</p>	<p>In the description of the product, search for whether the seller is making a DIRECT claim of treatment or cure for cancer. Direct Claim: marketer makes it clear that the product is directly linked to the reversal or treatment of cancer.</p>	<p>Examples of direct claims:</p> <p>"Super Berry Powder kills cancer cells".</p> <p>"Super Berry Powder can be used to reduce the symptoms of depression and anxiety that may come with experiencing cancer".</p>

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Form Field	Description	Example or Options
	<p>Select one option: Yes / No / Unclear</p> <p><i>Trouble shooting:</i></p> <ul style="list-style-type: none"> -Treatment for generalized signs/symptoms associated with disease are not considered direct claims. -Claims for treatment of signs/symptoms explicitly associated with cancer may be direct claims. 	
<p>Q2-B: Does the DIRECT claim for treatment or cure align with the NHP's Health Canada Licence?</p>	<p>Compare NHP's licence (Licenced Natural Health Products Database) with claims made on the products webpage. ⁱ</p> <p>Select one option: Yes / No / Unclear / Not applicable ⁱⁱ</p>	
<p>Q3-A. Is there an INDIRECT claim of treatment or cure for cancer?</p>	<p>In the description of the product, search for whether the seller is making an INDIRECT claim of treatment or cure for cancer.</p> <p>Select one options: Yes / No / Unclear</p> <p><i>Trouble Shooting:</i></p> <ul style="list-style-type: none"> -Treatment for generalized signs/symptoms associated with disease are not considered direct claims. -Claims for treatment of signs/symptoms explicitly associated with cancer may be direct claims. 	<p>Example of indirect claim:</p> <p>"Super Berry Powder contains magical berries. Magicalberries are known to contain cancercurene. Cancercurene is an antioxidant that kills cancer cells."</p>

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Form Field	Description	Example or Options
<p>Q3-B: Does the INDIRECT claim for treatment or cure align with the NHP's Health Canada Licence?</p>	<p>Compare NHP's licence (Licenced Natural Health Products Database) with claims made on the product's webpage.</p> <p>Select one option: Yes / No / Unclear / Not applicable^a</p>	
<p>Q3-C: Quote any language in regards to cancer treatment/cure claims that is misleading.</p>	<p>Include any particular words or phrases that may be found to be misleading, or to be indicative of taking advantage of loopholes in the claims regulations.</p>	<p>"Super Berry Powder controls cancer cells."</p>
<p>Q4-A: Is there a mention of endorsement by a regulatory agency? (Health Canada, FDA, USDA)</p>	<p>Examine the webpage to assess claims of product endorsement by a regulatory agency.</p> <p>Select one option: Yes / No / Unclear</p> <p><i>Trouble Shooting:</i></p> <p>-“Licenced” or “approved” are allowed terms</p>	<p>Examples:</p> <p>Health Canada, FDA or USDA</p>
<p>Q4-B: Which agency or organization is mentioned?</p>	<p>Select one or more of the following options: Health Canada, FDA, USDA, Other or Not Applicable</p>	

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Form Field	Description	Example or Options
<p>Q5: Does the webpage provide references to support their claims?</p>	<p>Select one or more of the following options: Clinical studies, Traditional use claim, None (no evidence mentioned), Not applicable, Other (list)</p>	
<p>Q6-A: Does the product licence list any contraindications or side-effects?</p>	<p>Reference the Licenced Natural Health Products Database to note any contraindications, side-effects or possible adverse reactions.</p> <p>Select one of more of the following options: Contraindications, Side-effects & adverse reactions, None</p> <p><i>Trouble Shooting:</i></p> <p>In the absence of product specific information refer to the Health Canada monograph of pre-cleared information used to licence the product.</p>	<p>Example:</p> <p>Health Canada Database: "Do not use if you have high blood pressure. Do not use if pregnant."</p>
<p>Q6-B: Are there any contraindications or side-effects mentioned on the product webpage?</p>	<p>Does the webpage provide ANY warnings or contraindications about the use of this product? (This may or may not include those made on in the Health Canada database).</p> <p>Select one or more of the following options: Yes, contraindications / Yes, side-effects & adverse reactions/ None</p>	<p>Product Webpage: "Do not use if pregnant."</p>

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Form Field	Description	Example or Options
Q6-C: Do the contraindications on the NHP webpage match those in the Health Canada product licence?	Select one option: Yes / Partially / No / Not applicable ^a If only some of the contraindications are listed on the webpage, select "Partially".	
Q6-D: Do the side-effects / adverse reactions on the NHP webpage match those in the Health Canada product licence?	Select one option: Yes / Partially / No / Not applicable ^a If only some of the side-effects / contraindications are listed on the webpage, select "Partially".	

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Appendix C: Sample Cancer Claims

Direct Claim	Indirect Claim
"Alterative, diuretic, tonic, antiseptic, heart stimulant, anti-syphilitic, anti-cancerous, and nervine."	"Bloodroot extracts have also been promoted by some supplement companies as a treatment or cure for cancer."
"It is also important in the prevention and treatment of breast and colon cancer..."	"Scientific studies uncovered potent anti-cancer benefits linked to this plant"
"Chewed, or in tea, used for snake bites, spider bites, cancers, toothaches, bums, hard-to-heal sores and wounds, flu, and colds."	