

Original Article

The Canadian Natural Health Products (NHP) Regulations: Industry Compliance Motivations

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This qualitative study explores corporations’ motivations to comply with new natural health products (NHP) Regulations in Canada. Interviews were conducted with representatives from 20 Canadian NHP companies. Findings show that the rationale for compliance differs for large compared to small and medium-sized enterprises (SMEs). Large firms are motivated to comply with the regulations because of the deterrent fear of negative media coverage, social motivations, ability to comply and maintaining a competitive market advantage. In contrast, SMEs are motivated to comply due to the deterrent fear of legal prosecution and a sense of duty.

Keywords: dietary supplements – herbs – policy

Introduction

New regulations require adherence in order to be effective. Debate continues about how best to ensure compliance of target groups with government regulations. Some argue that governments must guarantee that regulations are effectively enforced through appropriate monitoring and sanctions (1,2). Others believe that target groups will comply with regulations, regardless of government actions. For example, the Harrington Paradox describes how most firms comply with the Environmental Protection Agency (EPA) programs of the United States, despite the minimal penalties and few violators actually sought out by the EPA (3). Despite this, regulatory scholars have traditionally studied the enforcement strategy of the agency responsible for implementing regulations (4,5). More recent accounts have focused on the compliance of target groups with regulations. For example, Laeque *et al.* (6) describes who appears to be complying with the new Canadian Natural Health Product (NHP) regulations and identifies factors such as firm size and knowledge of the regulations that are associated with likelihood of compliance. One question that remains is why do firms attempt to comply with

regulations? This paper sheds light on the debate by exploring the motivations of Canadian firms for complying with the NHP Regulations. Understanding what variables motivate industry compliance can help inform the implementation and enforcement stages of the Regulations (7).

Background

This study focuses on compliance with Canada’s new NHP Regulations and the new requirements of the NHP industry, which are described below.

The Natural Health Products Regulations

The NHP Regulations were implemented on January 1, 2004 by Health Canada. NHPs, now a subcategory of drugs, are defined in the Regulations as products such as vitamins, minerals, homeopathic medicines and others. The most important aspect of the regulations is the requirement for pre-market approval from the Natural Health Products Directorate (NHPD) of Health Canada for all NHP products new to the Canadian market and re-approval of all existing products during a 6 year transition period. A company that sells a NHP on the Canadian market must obtain a natural product number (NPN) from the NHPD for all new and existing NHP products. This number is granted upon submission of a product licence

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application (PLA), which demonstrates the safety, quality and efficacy of the product. The first compliance deadline for submitting a PLA for high-risk products was June 30, 2004. Each NHP sold in Canada must have a product licence by January 2010.

In addition to completing PLAs for each of their products, companies that manufacture, package, label or import NHPs were required to apply for site licenses by December 31, 2005. To be granted a license, the site must demonstrate compliance with good manufacturing practices (GMPs) through submission of a quality assurance report prepared by an individual with appropriate training, education and/or experience in GMPs. GMPs were developed to be appropriate for NHPs, and include standards on cleanliness, quality assurance and record-keeping. Details of the GMP standards are available on Health Canada's web site (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf_e.html) and include employing measures to ensure an effective overall approach to product quality control and risk management. For example, the company must have clear procedures in place to maintain distribution records and facilitate product recalls.

Overview of the NHP Industry in Canada

Information on the NHP industry in Canada is limited because provincial drug plans do not reimburse purchases of NHPs and neither the industry nor the government monitor annual sales of NHPs (8). Prior to implementing the NHP Regulations, Health Canada conducted a Business Impact Test (BIT) to predict the impact of the Regulations at the industry level. The BIT described the NHP industry as comprised mainly of small and cottage businesses. For example, 55% of respondents were with a company with fewer than 19 employees. Furthermore, 75% of respondents said their company had fewer than 50 employees. The BIT defined small business as firms with less than 20 employees, medium size firms as having 20–49 employees, and large firms as greater than 50 employees.

The NHP Regulations represent a significant change in regulatory burden for this industry. In many cases, companies need to make significant changes in their operations. It is important to note that the data collection for this study was in the first year of a 6 year phase-in of the new regulations. At this time, there was much concern over how NHP companies would respond to the new standards. Thus, company motivations to make these changes appeared important to explore. Four main compliance motivations identified in the literature are as follows: deterrent fears, duty to comply, social motivations and ability to comply.

Motivations for Compliance

Deterrent Fears

General deterrence theory is based on the assumption that businesses are profit-driven and that regulatory compliance at the firm level occurs when non-compliance costs, through the form of fines, sanctions or imprisonment, exceed compliance

costs (9). Deterrent fears develop from the fear of negative outcomes due to non-compliance with regulations. Fear can be either specific, due to enforcement actions on individual firms, or general, from the regulations. General deterrence fears include: fear among the regulated group because of the expectation that violators of the law will be persecuted, fear from exposure of non-compliance via lawsuits, or fear from the perception of forthcoming imposing regulations (1,10). No research has been conducted on deterrence and compliance behavior during the early implementation stage of regulations.

Duty to Comply

An important aspect of effective regulations is that citizens feel a need for the regulations, and that firms recognize their responsibility to comply. This motivation reflects the value system of the regulated individuals. Two factors are important in this motivation: the individual/firm's general principles regarding one's civic duty to comply with laws and one's perceptions about the legitimacy of the law in question (7,10). Inherent in the obligation to conform to regulations is that the regulated firms understand the need for regulation in order to prevent public harm (7,10). Duty to comply with regulations has also been called normative motivation, moral or ideological compliance, or perceived obligation.

Social Motivations

Social motivations occur when a firm/individual complies with the rules in order to gain the respect of other individuals or groups, regardless of whether the complying firm agrees with the regulations. Winter and May (2001) state that social motivations may be instigated by other firms, trade associations, regulatory inspectors, external advocacy groups, the media, family and friends.

Ability to Comply

Given the diversity of firm size and location within a particular industry, some firms will be more capable of complying with regulations in comparison to other firms. Ability to comply with regulations is mainly affected by knowledge of the regulations and the financial/technical resources of a firm. As reported in a previous paper, we found that NHP firms that were non-compliant with the NHP Regulations were unaware of their responsibilities, rather than intentionally avoiding compliance (6). Thus, employees must be aware of the regulations and understand their complexities as a precursor to regulatory compliance. That is, compliance with regulations is only likely when feasible for a firm.

Two other factors may influence the motivation to comply. These factors are as follows: enforcement practices of the regulatory agency and the attitudes and beliefs of regulated entities (10). These motivations and factors may interact in complex ways. For example, knowledge of the rules may have a positive effect on deterrent fears. Or, acceptance and trust among the regulated about inspectors may positively affect

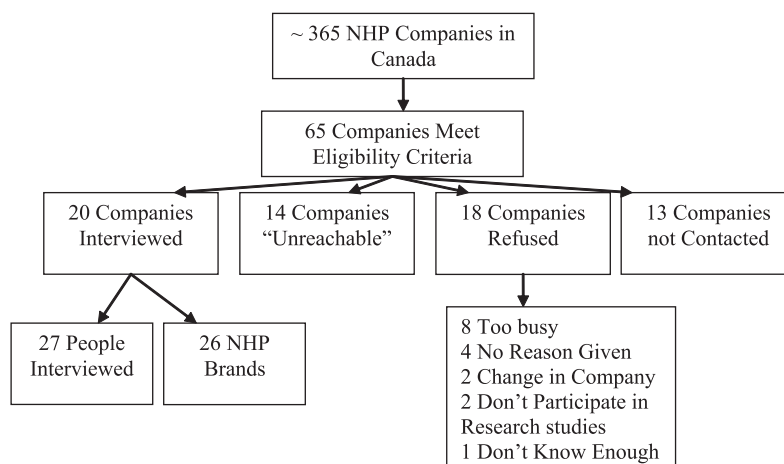


Figure 1. Number of companies interviewed for the study (6) taken from Laeeque *et al.* [The Canadian Natural Health Products Regulations: industry perceptions and compliance factors. *BMC Health Serv Res* 2006;6:63].

one's sense of duty to comply with regulations. These interactions have not been studied to a great extent and require further research.

Methods

An applied ethnography (11) was employed that incorporates qualitative research methods in order to explore the motivations of NHP companies that are complying with the new Regulations.

Interview Sample

Criterion-based, purposeful sampling (12) based on business size, location and specialty was used to select NHP companies. Companies that sold chondroitin and/or glucosamine were selectively chosen because a PLA for these products was required to be submitted by the first compliance deadline of June 30, 2004. Of the ~364 NHP businesses in Canada, 65 met the eligibility criteria of the study, which were (i) manufactures, packages or labels glucosamine or chondroitin, (ii) located in Canada and (iii) able to participate in an interview in English.

Semi-structured interviews were conducted either by telephone or in-person with the person responsible for regulatory affairs and/or writing the NPN applications. Interviews were continued until data 'saturation' was reached. Saturation is the point at which no new information is being identified with respect to the key themes emerging from the data analysis (13). This is normally expected after completion of 15–30 interviews. The interviews were scheduled for ~1 h and were audiotaped and transcribed verbatim.

Data Gathering and Analysis

Corporate motivations were identified through direct questioning in interviews and by spontaneous comments of participants regarding their decision to comply with the

Regulations. Participants also completed a form regarding the number and date by which the company submitted PLAs for chondroitin and glucosamine. Data collected from the interviews were independently analyzed and coded by three different researchers using qualitative content analysis (14). The data from interviews were stored and managed using NVIVO (15).

It should be noted that this study is unique because it was conducted at the very early stages of a 6-year implementation period. It is possible that motivations for compliance may change later in the implementation period or after the new NHP Regulations have been fully implemented. Our results provide insight into why companies are (or are not) attempting to comply early in the implementation process.

Results

Companies Interviewed

Figure 1 depicts the companies interviewed. NHP companies of various locations, specialties and sizes were included (Table 1). The majority of companies that were involved in the study are based in Ontario ($n = 11$), British Columbia ($n = 3$) and Quebec ($n = 3$); however, companies in Alberta and Manitoba were also interviewed. Companies interviewed also ranged in size and included nine defined as large, six defined as medium and five defined as small businesses. The smallest company interviewed had only 3 employees and the largest company employed over 500 people. Overall, most of the companies in the study are responsible for several hundred NHP products and have annual sales of less than 10 million. However, company sales ranged from less than half a million dollars to over 200 million in annual sales. Most of the companies primarily focus their sales in Canada. Seventeen of the 20 companies interviewed were attempting to comply with the new regulations (6).

Table 1. Company characteristics of the 20 interviewed companies (6)

Description	No. of companies
Size	
Small (<19 employees)	5
Medium (20–49 employees)	6
Large (>50 employees)	9
Annual sales (Can)	
<10 M	8
10.1–49.9 M	5
>50 M	4
Confidential	3
No. of products	
<99	2
100–499	13
500–999	4
>1000	1
Market focus	
Local	0
Regional	1
National	15
International	9

Taken from Laeeque *et al.* (6).

Findings

Given the similarity in their perceptions, findings from interviews of individuals from small and medium companies have been combined and are referred to as small and medium-sized enterprises (SMEs). These findings are contrasted with findings from large companies.

Large Companies

Participants from large companies expressed the following four main reasons for deciding to comply with the NHP Regulations: deterrent fears, social motivations, the ability to comply and maintaining a competitive advantage.

Deterrent Fear of Negative Media Coverage

One participant stated that failure to comply with the Regulations would lead to harmful media coverage of the company and their products. Thus, the company has decided to comply with the Regulations to be protected from damaging media reports of non-compliance.

Social Motivation: Increasing Consumer Confidence of NHPs and the Industry

Other reasons for complying with the Regulations were social in nature. A few large firm representatives felt that companies should comply with the Regulations because consumers need

to know that when they purchase a product, what is written on the label is contained in the product.

The reason we are going forward is, we believe it [NHP Regulations] needs to be implemented. . . . The consumer that buys . . . a brand and they don't have a benefit, they will say, 'glucosamine doesn't work.' So now they don't use the product anymore. . . . So unless we get the Regulations in place we are not going to keep the consumer base. We will kill our own brands. That is why our company is still going forward. (Firm 15, Large)

Ability to Comply

Some participants simply stated that the firm is already compliant with the NHP standards. All of the large firms in the study have either vitamin or mineral products with a Drug Identification Number (DIN) and thus are compliant with the drug regulations under the Food and Drugs Act. Thus, adhering to the new NHP Regulations was not a major undertaking for the firm:

We did comply with good manufacturing practices for all our DIN products in the past. We are probably more stringent than the current NHP guidelines because we have produced DIN products for all our vitamins and mineral supplements. To adhere to the new licence requirements I don't think was a major undertaking. (Firm 12, Large)

Maintaining a Competitive Advantage

For strategic reasons, many large firms have decided to embrace the Regulations, and attempt to gain a market advantage over other firms. A perceived market advantage is gained because a company that obtains a NPN is able to sell the product with a new health claim before other companies. The NPN is considered a positive feature of the product and industry members assume consumers will respond favorably to a product with an NPN versus a product without a NPN:

The whole point of applying [for a NPN] isn't to become compliant with the Regulations. It's not to get your red tape out of the way. That's not why everyone is rushing to comply. The whole point of applying [for a NPN] is to get your claim. So you can say 'this product cures cancer' compliantly, or whatever your claim is. That's the whole point- it's all marketing driven. (Firm 4b, Large)

Another strategic reason to comply with the Regulations is to maintain a key position within the NHP industry. Many participants felt that the process of attaining a product licence

is lengthy and expensive. Thus, some smaller firms will no longer be able to comply with the Regulations and survive in the industry. Thus, a firm can sustain a good position in the NHP industry by complying with the standards of the Regulations and encouraging other firms to follow the standards and squeeze others out of the market:

They [the NHPD] don't know what to expect and by us being in there early, working with them [the NHPD], we are actually helping them define what information should be expected. And we want to set the bar high. (Firm 4a, Large)

SMEs

Unlike large firms, three SMEs were non-compliant with the NHP Regulations due to lack of knowledge of their responsibilities. These SMEs did not invest the time required to learn about the new Regulations. SMEs' motivations for compliance also differed from large firms. SMEs are complying with the NHP Regulations because of deterrent fears and the duty to comply with Regulations.

Deterrent Fears

SMEs employees were also motivated by deterrent fears. Participants felt that enforcement actions, such as preventing the sale of some NHPs that have an extensive history of use in humans, are unfair. Employees of SMEs are particularly fearful of inspections and the level of strictness of enforcement actions.

Duty to Comply

Representatives from SMEs are complying with the Regulations because of their legal responsibilities. A participant explains:

[the NHP Regulations] are the laws governed by the country and basically what I am doing here is saying 'okay, how do I do that? What process do I do to meet that law?' (Firm 7, Small)

Discussion

The main finding of this paper is that the motivations for compliance for large firms differ from compliance motivations of SMEs. The four motivations of corporate compliance are discussed below.

Deterrent Fears

Both large firms and SMEs were motivated by general deterrent fears (rather than specific deterrence), although the type of motivating fear differs. Large firm representatives were fearful of negative media coverage if the firm were found

to be non-compliant with the Regulations, a fear that has not been identified in previous research. SMEs were fearful of enforcement actions. In essence, both firm types are concerned about the reputation of their business with either consumers or government officials. Studies of other industry sectors have reported similar results. For example, in the chemical and electroplating industries which have been subject to over 20 years of government regulation, SMEs were more responsive to deterrence compared to large firms that were concerned about maintaining the trust of the public (16). Thus, differences in the type of deterrence fears of large firms and SMEs may continue from the early to the later stages of regulatory implementation.

Duty to Comply

For SMEs that were aware of their regulatory responsibilities, a strong motivation for compliance is their legal duty to comply with the Regulations. Duty to comply is related to one's understanding of civic duties and the perceptions of the legitimacy of the law. As shown previously, all participants in the study felt that the Regulations are necessary (6). Therefore, the duty to comply may be more influenced by one's sense of responsibility rather than the legitimacy of the law.

Social Motivations

Large firm representatives were motivated to comply with the Regulations because they wanted to enhance the public perception of NHPs and supporting the NHP Regulations was seen to be one way to do this. NHPs and complementary/alternative medicine in general are increasingly considered part of health care systems around the world (17) and regulations that enhance the quality of NHPs are generally seen as a necessary step in this process. This is not to say that SMEs were not motivated by social causes but that social motivations appear to be more contributory to compliance for large firms than SMEs.

Ability to Comply

The ability to comply with regulations is affected by a firm's administrative infrastructure and knowledge of the requirements. Large firms are better able to comply with the Regulations compared to SMEs because employees are familiar with the drug regulations and several have had products registered as drugs. Thus, large firms already have the resources in place to be fully compliant. The ability to comply appears to be the main motivating factor for large firms. In contrast, SMEs are being exposed to a new set of regulations without any previous experience.

Laeque *et al.* (6) explored the factors that are important for regulatory compliance by comparing responses of non-compliant companies with compliant companies. The important factors for firm compliance were found to be perceptions of the regulations, business size and knowledge of the regulations. This study highlights the central role that knowledge of

the regulations (correlated closely with firm size) has on ability to comply and thus motivation to attempt to comply with regulation.

Research Limitations

The major limitation of the study is the large number of participant refusals. However, in the study, a maximum variation sample and saturation are achieved, ensuring that a range of opinions and perceptions are captured.

Conclusion

This study probed the motivations for firm compliance with regulatory requirements. Firms comply for different reasons and these vary according to business size for the Canadian NHP regulations. Large firms are motivated to comply with the regulations for reputation reasons (e.g. fear of negative media coverage), social motivations, the fact that they have the resources to comply with relative ease and the belief that complying will result in a potential competitive advantage. Motivations for SMEs differ in that they are more likely to be due to fears of legal prosecution if they are non-compliant and also a corporate duty to comply with the law.

Consumer perceptions and media coverage of compliance status are important factors for policymakers to consider when planning compliance strategies. Strict enforcement policies, such as inspections of industry premises, are expensive and time-consuming for a regulatory body, but likely necessary to ensure compliance. However, successful implementation of regulations requires creative actions of the implementing agency to stimulate the motivations of various sized firms. For example, publicly available lists of products that have been approved or companies with site licenses may enhance the likelihood of compliance more effectively than increasing enforcement strategies.

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Received April 17, 2006; accepted October 13, 2006