Reviewer's report

Title: The Canadian natural health products (NHP) regulations: Industry perceptions and compliance factors

Version: 2 Date: 13 March 2006

Reviewer: Colin G Rousseaux

Reviewer's report:

General

General comments:
The object of this manuscript is stated as “to explore who is complying with Canada’s new NHP regulations; and understand the factors that affect regulatory compliance.” The methods used were descriptive using “key informant interviews” of employees of the Natural Health Products (NHP) industry. These interviews were then evaluated using “qualitative content analysis.” Although this manuscript addresses an important question regarding compliance in the NHP business since the introduction of Natural Health Product Regulations, there are some questions, and observations, that make it difficult to determine how the conclusions we reached. As BMC Health Services Research considers: case reports, databases, debates, research, software, study protocol and technical advance articles, this manuscript is within the scope of the journal. This is not a review, but rather a description of an observational study aimed at describing what the impact the Natural Health Products Regulations on various factors.

Generally, this manuscript is long for a descriptive study. A descriptive study needs to address prevalence or incidence as a manner of describing this event. Similarly, there are a lack of data given to support the methodology and results.

Specific comments:
1. The questions:
   a. “Who in the interview sample is complying with Canada’s new NHP regulations” and
   b. “To understand the factors that affect regulatory compliance”

   Both of these questions are new but are poorly defined. Evidence as to what constitutes compliance is not given, except for a response from the interviewees, which may or may not be truthful depending on corporate pressures. A confirmation of corporate statements could have been verified with Health Canada.

   The second question is impossible to answer due to the nature of the sample taken and groups not being mutually exclusive. Even in describing a new disease or taxa, the researchers are bound to describe what makes the finding different to the normal, i.e., description of taxonomic differences. More of the comments on methodological issues can be found below.

2. “Methods are they appropriate and well described in sufficient detail to allow replication of the work?”

   No, the methods are poorly described and the study would not be able to be repeated with the information available:
   a. It is understood that this is a qualitative descriptive study. Such studies require that the interviewees be selected on inclusion criteria (given) and exclusion criteria (not given).
   b. “Semi-structured interviews were given either by telephone or in-person.” What potential bias has been introduced when considering both methods as the same?
   c. “We asked to speak to the person responsible for regulatory affairs and/or writing the NPN applications.” What steps were taken to verify that the person really was the person responsible for regulatory affairs? Often companies have several RA officials, but only one who is the director. Individuals who write the applications might not know the state of all submissions.
   d. What happened to non-responders and how did this affect the sample?
e. It is unclear as to how the surveys were developed and the rigor in which the surveys were applied - “semi-structured interviews.”
f. “The interview questions changed as the research proceeded” implies that data output was biased as to when the survey was applied. In fact, unless there is evidence to the contrary, it appears as though vague questions were asked regarding some of the endpoints described, which became better defined as the research progressed. Such changes are acceptable in a pilot trial, but not as the definitive research project resulting in a full manuscript.
g. Data gathering and analysis: This section is not described in adequate detail to understand what data were obtained and how they were analyzed. The question given as an example “…focused on perceptions of individuals regarding the Regulations, such as: whether the Regulations are necessary and whether they agree with the goal of the Regulations.” Were the data collected a quantal yes/no, or were there “maybes” that could not be included in the yes and no outcomes?
h. This reviewer is not familiar with qualitative content analysis and assumes that such analysis streams findings into themes. No data were available for review, except for details on the methods and sample group (Figure 1 – 3). Descriptions of findings in results were available.

3. Results: “Are the data sound and well controlled?”

No data were reported for most outcomes; however, summary statistics were available for “characteristics of the 20 companies interviewed,” “company compliance status for the priority one compliance deadline of June 30”, and “companies interviewed for the study.” Definition of endpoints was poor, so that even if outcome data were provided the validity of the grouping would be difficult to assess.

a. Companies interviewed resulted in a survey of 20. No uncertainty and precision estimates were given or calculated.
b. The verbal description of the results is harder for the reader to evaluate than when the summary data is provided. Such a data table should support the comments in the results, rather than having a long description (and some discussion) in the results.
c. As this is a purely descriptive study the number of variables assessed and how they relate to the sample size should have been addressed in the methods.
d. “Business size and compliance…” is clear but shows the difficulties of a small sample size. Again there was no validation of the quotes given by industry. Health Canada should have been contacted for verification purposes. What is semi-compliance?
e. Perceptions: this section describes the situation but does not give any assurance as to the number of responders and responses. For example, what do the terms “majority” and “many” mean in terms of a response – 60%, less, more?
f. Level of agreement with the NHP regulations needs to be supported by data. Again the comments regarding “many” as to how much and the term “helpful” needs explaining – helpful for?
g. “SMEs representatives are the most dissatisfied…” with what aspect of the regulations? Was the intent, the workload, or other factor responsible for the dissatisfaction? How was dissatisfaction expressed and measured? Was it a company position or a perception by the individual questioned?
h. “Perceptions of compliance.” This section contains elements of discussion, whereas the results only should be reported in this section. Data would help the reader a lot with the comments made as discussion. The comments regarding issues are useful and add to the discussion; however, a list of responses and classification of the response would help the reader with “seeing the research.”
i. “Knowledge of the regulations.” It would be good to see how many “representatives from large firms were very knowledgeable of the regulations.” It would also be important to quantify “most, others,” etc.

4. Does the manuscript adhere to the relevant standards for reporting and data disposition?
As this is a social science manuscript there may be different standards; however, outcome data were not summarized but vaguely presented using non-specific adjectives such as many, few, majority, etc.

5. Discussion: Are the discussions and conclusions well balanced and adequately supported by the data?
It is difficult to comment on this section, as data could not be reviewed to correlate with the discussion. The discussion does state some of the limitation of the study including selection criteria.
(glucosamine) and that some companies did not respond. These limitations are two of many in this study and those need to be clarified. The remainder of the discussion tended to reiterate the results with little reference to others’ findings in similar situations. The discussion is far too long to be supported by the content of this study.

6. Title: Does the title accurately convey what was found?
The title does describe the work and the intention of the work.

7. Abstract: Does the abstract accurately convey what was found?
As it was difficult to evaluate the data and outcomes, it is also difficult to assess the abstract. The subdivided nature of the abstract is new to this reviewer.

8. Is the writing acceptable?
Yes, although there is an opportunity to condense this manuscript. As this manuscript appears to be a pilot study, then publication as a note or short communication would be more appropriate. There the requirements for data might be less than that for a full size publication.

Conclusion:
This manuscript contains a descriptive study, which was undertaken on a sample size of twenty. There are severe deficiencies in this manuscript, which might be addressed by the authors through a major compulsory revision. This reviewer recommends to the editor that following the editor’s and editorial board’s positive decision, that the work be published as a short communication, as one would expect that this work is a pilot study for a more detailed cross-sectional study.

---------------------------------------------------------------------
Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

---------------------------------------------------------------------
Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

---------------------------------------------------------------------
Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions