Author's response to reviews

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

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Dear Editor of BMC Health Services Research

RE: The Canadian natural health products (NHP) regulations: industry perceptions and compliance factors

Referee #1: Jacqueline Low

Major Compulsory Revisions

1. The sentence has been deleted from the introduction.

2. This sentence has been worded and clarifies which included removing the jargon “target group compliance.”

3. Agreed. These sentences have been moved to the methods section as recommended.

4. Examples have been added as requested.

5. These sections are in the Background already and so have not been moved.

6. These two sentences have been moved as requested.

7. The text under Companies interviewed has been moved to the methods section as requested.

8. A quotation to illustrate “painful” has been added.

9. The quote has been changed as requested.

10. We did not intend to imply that non-enforcement leads to non-compliance. This section has been removed from the paper.

11. Sub-heading changed as suggested.

12. This section has been reorganized and clarified as requested.

13. A quote has been added as requested.

14. This is discussed in additional detail later in the discussion.

15. The statement that our informants did not question the legitimacy of the regulations at all has been removed from the discussion.
16. Limitations have been moved to a new section at the end of the discussion.

17. The phrase has been removed.

18. “other programs” has been clarified as requested.

19. We changed this sentence as part of our efforts to shorten and streamline the discussion and an example is no longer relevant here.

Minor Essential Revisions

1. Third person has been used throughout as it is more formal.

2. “Theoretically” has been removed as suggested.

3. “Appear” has been removed as suggested.

4. “the regulated” phrase has been changed as suggested.

5. Sentence removed as suggested.

6. Phrase added as suggested.

7. Wording completed as suggested.

8. Change in brackets completed as suggested.

9. Thus removed and sentence re-worded.

10. Changed full stop as recommended.

11. Sentences deleted as recommended.

12. In most cases Regulations are capitalized because the word does refer to the NHP regulations. In other cases it is not capitalized.

13. Sentence has been re-worded.

14. Sentence has been re-worded.
Referee #2: Mark Miller

Major Compulsory Revisions
1. List of Abbreviations now provided as an Appendix.

2. It is beyond the scope of this paper to provide specific details about the safety standards. However, an additional summary statement about the safety standards has been provided as well as a reference to where the details can be found.

3. Yes, the backlog of submission is years and this information has now been included in the background.

4. The deadline of June 30 has been clarified and we specifically added an explanation of what happens to new entrants after that date in the background of the paper (they need pre-market approval prior to bringing the new product to market).

Minor Essential Revisions
1. It is extremely difficult to estimate costs per sku to comply. We did ask our interviewees about this, but it ranged from very little to thousands of dollars depending on many things such as whether the company was already compliant with the new GMP standards or had to do significant renovations, whether they were using consultants to complete their PLAs and whether they were submitting products for which monographs exist. Average amounts do not seem to mean anything and the range is so large it also does not appear to be helpful at this point.

2. Given the request from Dr. Rousseaux to try to shorten the discussion, we have decided not to review the European context. Although interesting, it is beyond the scope of this paper as it would considerably lengthen the discussion.

3. None of our interviewees mentioned globalization or potential impact on sales internationally in this context, so it is not possible to comment on this.
Referee #3: Colin Rousseaux

General Comments
1. Qualitative research does depend on the truthfulness of responses from interviewees. The interviewer needs skill to develop a rapport with the interviewee and to ask questions in such a way as to provide a “safe” environment for the respondent to be honest. Most of our interviews lasted almost an hour and involved more than a simple question about compliance with a yes/no answer. The entire interview was about the firms’ attempts to comply and many respondents were frank in about their inability to meet the NHPD’s deadlines. To make this clearer in the paper we have added the interview guide as an Appendix. It is not possible to verify corporate statements with Health Canada because information about who has applied for PLAs is confidential. However, clarification of what we defined as “compliance” has been added to the paper.

   With respect to the comments about our inability to answer “b. understand the factors that affect regulatory compliance” --- we have re-worded this objective slightly to provide clarity. The purpose of qualitative studies is to elucidate the range of responses in a group. We are confident that we have been able to do this. Qualitative research does not allow us to generalize or to find the relative importance of different factors. We have clarified this in the limitations of the study.

2a. There were no exclusion criteria – i.e., provided they met the inclusion criteria, no one was excluded from the study. This has been clarified in the text.
2b. Generally, in-person interviews are considered better because it is easier to establish a rapport with the person being interviewed. However, based on our previous experience (and confirmed by the experience with this study) there was no systematic change in the quality of the data with the telephone interviews as long as the interviewer is experienced using the interview guide. However, we have noted this a potential limitation to the study.
2c. No specific steps were taken to verify the person we interviewed really was the person responsible for regulatory affairs; however, all the people we interviewed were able to answer our questions suggesting we did find the right people. In several cases (usually with larger companies) we actually met with several different individuals as part of the interview because more than one person was involved in the regulatory affairs process. During the interview, if the interviewee could not answer a question, but indicated that the information could be obtained from another individual, this would have been followed up by the interviewer (but no such cases occurred). Finally, in most cases the firms we met with were small and one person was responsible for all regulatory affairs so the concern that that individual might not know the status of all applications was really not an issue.
2d. Where possible, we obtained the reason for non-response (see Figure 1). Since we reach saturation in the key themes, it is unlikely they would have added to information about our key themes. We also reviewed the list of companies that refused to participate. These companies did not differ significantly from participants in terms of company location, size, or products sold. However, it is not possible to tell if they were complying or not with the regulations. A statement to this effect has been added to the limitations discussion of the paper.
2e. The surveys allowed us to collect technical and quantitative data (e.g., number of NHPs the company sells in Canada). The questions are now provided in an Appendix. In each case, the surveys were sent ahead of the interview. At the end of the interview, any questions not completed were reviewed with the interviewee in an attempt to complete the questionnaire. This information has now been added to the methods section of the paper.

2f. It is standard practice to vary the interview questions as more knowledge is gained and themes are refined in qualitative studies. This is why the analysis and the data collection occur simultaneously.[1] Just to clarify, the quantitative survey questions did not change over time; only the qualitative interview guide questions. This has been clarified in the paper.

2g. We collected primarily qualitative data in unstructured interviews. The purpose is to attempt to understand the respondents’ feelings and perceptions. Thus there are no a priori categories. We did not collect responses in quantals but rather in full unedited verbatim text. Qualitative research is often completed because it is not possible to know what questions to ask in a standardized questionnaire or what response categories should be provided. The questions were open-ended and require explanation and detail, not a simple yes/no answer.

2h. Yes, content analysis is the process by which verbatim text is coded into content categories called themes. We have added several additional sentences to clarify this in the analysis section of the paper. This paper does not focus on all themes, just the ones relevant to explanations firms provided about why they are (or are not) complying with the regulations.

3. “Data” in qualitative studies such as this one are the quotations from interviews provided. A quantitative survey provides numbers as data and since we did have a small quantitative component to the data collection, these numerical data are provided in the tables as is customary. However in qualitative studies, no numbers are collected. The raw data that is provided to support the results is in the form of verbatim text as we have done throughout the results section. In qualitative studies, endpoints are not defined a priori, but rather derived from the data collected from the respondents (in the respondents’ own words).

3a. We interviewed respondents from 20 companies, so yes, we do have some small amount of quantitative data from each of these from the survey. However, given the small sample size and the fact that this was not the focus of our project, we have provided only raw counts and in some cases basic descriptive statistics. Because of the qualitative study design, this is not intended to be a representative sample and the numbers are reported simply to provide the reader with a description of who we interviewed. The data presented cannot be extrapolated to all Canadian NHP companies that sell glucosamine or chondroitin or to the NHP industry in general. This is a purposefully selected sample and thus it is not valid to conduct additional statistical tests on this small amount of quantitative data.

3b. Most of our results are from the qualitative interviews which were the primary focus of the study. By necessity and convention, qualitative results are presented in narrative form with quotations as substantiation. The quantitative data provide supporting
information that helps to describe the firms in our study, but is not intended to be the focus of the result section.

3c. Qualitative studies do not have “variables” and we do not select the sample size a priori in the manner that quantitative studies do with sample size calculations. Rather, qualitative studies explore complex questions of how and why. Responses are then categorized into themes that cannot be pre-determined. Data collection continues until a point we call saturation[1] – when no new information is being collected about the key themes.

3d. The sample size is small in quantitative terms, but this is a qualitative study and thus it is adequate as described above. It was not possible to contact Health Canada to verify responses because the identities of companies that have submitted PLAs is confidential. Semi-compliance is defined on page 12 as “some of company PLAs submitted by the deadline.”

3e. Qualitative research does not allow us to judge the relative importance of perceptions or factors because it is not a random or representative sample. The goal of qualitative research is to identify the range of responses. Thus while we can indicate generally that the perception was common in our sample by use of words such as “many,” it is misleading to say 40% because that is meaningless without a generalizable sample. It is generally not acceptable to report qualitative findings quantitatively (i.e., to report how many people said something or how many times a certain topic was identified or discussed).

3f. Level of agreement is supported by qualitative data – the quotations. This information did not come from the quantitative survey, but rather from the interviews. The use of “many” is described above. The term “helpful” has been clarified as requested.

3g. As the paper states, the SMEs were dissatisfied with the regulations because they felt they were inappropriate given the level of risk associated with NHPs. We have clarified, that these are all perceptions of the individuals we interviewed from SMEs.

3h. As explained above, there are no numerical data to report. The data we are reporting on are qualitative verbatim text. These are results because they are descriptions of the themes.

3i. As noted above, it is not possible to provide quantities for these. The purpose of qualitative studies is to provide the range of responses and to develop theories about relationships that can be tested in other designs.

4. This is a case where different standards apply. This is a qualitative study thus it is not possible to provide specific numbers/quantities for qualitative data as they are meaningless at best and misleading at worst because they are not derived from a representative sample.

5. Additional limitations have been identified and discussed as noted above and in response to other reviewers’ comments. We have shortened the discussion where possible.

6. No comments required.
7. We have provided a structured abstract, a common format for many health-related journals.

8. This is not a pilot study, but rather a qualitative study. It is expected to provide the foundation for additional work in this area.

We look forward to hearing from you.

Sincerely,
Heather Boon, PhD
Assistant Professor

References