

Bill C-51 Considerations Ontario Herbalists Association (OHA)

Bill C-51 is a sweeping attempt to update the *Food and Drugs Act* to reflect the realities of today's market, and to support the policies already being implemented by Health Canada and the Natural Health Products Directorate (NHPD). The OHA recognizes the need to update the *Food and Drugs Act*. Penalties and powers under the previous Act are insufficient to deter abuses that place consumers at risk, such as deliberate tampering with products or falsification of clinical trial results. However, we feel that Bill C-51 may have far-reaching and likely unintended implications for the Natural Health Product (NHP) market.

Although it is impossible to be certain of the full implications of this Bill without legal counsel, the OHA believes that, with a few minor revisions, Bill C-51 does not offer an immediate threat to the practice of herbal medicine. This is due to the existence of specific exemptions for herbalists under existing NHPD Compounding and Raw Materials policies. However, there are a number of disturbing changes which may affect herbalism in the future and which could affect the availability of natural health products (NHPs), including herbs, on the general market.

General Concerns

The most significant problems appear to lie in combining drugs and NHPs under the single umbrella of "drugs" within the definition of "therapeutic products" in section 6 of the Bill. Attempting to regulate very high and very low risk products together is likely to result in an inappropriate regulation of both. Traditional and historical evidence of efficacy, which is important for the regulation of NHPs, is not mentioned, while clinical trials are emphasized. The changes in the Bill seem to reflect a disturbing tendency towards excessive caution and market limitation of NHPs, when these products more closely approximate the risk profile usually associated with foods.

A review of countries who have adopted a drug-based model of NHP legislation, shows a trend towards fewer and more costly NHPs, to the point where the industry virtually ceases to exist. International supplement companies are already pulling out of the Canadian marketplace due to excessive costs and restrictions. The OHA believes that Bill C-51 will not improve this situation, and will likely exacerbate it.

The 1998 Standing Committee on Health recommended that NHPs be regulated under a separate category, distinct from both food and drugs. This was not implemented at the time because it would have required changes to the existing Food and Drugs Act. The OHA is disappointed that the government has not taken the opportunity presented by the current Bill to implement more of the changes recommended by that Committee. The current proposals under Bill C-51 appear to reinforce the unfortunate trend toward a pharmaceutical model for NHPs.

Specific Areas of Amendment

In addition to the overall definition of “therapeutic products” within the Bill, the OHA has some specific concerns which need to be addressed in the next revision of this Bill.

In section 30, the Governor in Council may make regulations regarding: (Z 14) exempting a person or class of persons, and (Z 15) exempting an activity or class of activities, from the application of this Act. This allows for the existing exemptions from the Act for herbalists, which are part of the NHPD Compounding and Raw Materials policies. However, we would like to see a clause which specifies that existing exemptions are automatically regarded as granted on implementation of this Bill.

The definition of “controlled activity” (6) has been expanded to include “collection”. This was intended to capture collection of blood and tissue products; however it could theoretically include harvesting of herbs. This definition needs further clarification within the Bill and we have been told that such an amendment will be considered.

As previously mentioned, in section 6, “therapeutic product” is defined as: a) a drug, b) a device, c) cells/tissues/organs. As NHPs currently exist within a separate Directorate, we would like to see this changed to include NHPs as a category. Again, we have been assured this change will be suggested.

In section 6, the word “practitioner” is defined as “an individual who is authorized under the law of a province to prescribe or dispense prescription therapeutic products”. This definition is not the same as the definition already in use in NHP regulations. This must be addressed.

Under Bill C-51, the Minister of Health will be able to “designate a therapeutic product – either individually or by class – as a prescription therapeutic product”. { 15.1(4)} While Bill C-51 repeals the current Schedules A and F restrictions of the Food and Drugs Act, it leaves all herbs and NHPs under an easily amended regulatory structure. This has both positive and negative implications. Unfortunately, Health Canada has a history of restricting access to herbs where prescription drugs can be extracted from them or where an alleged toxic compound has been identified in them, regardless of the historical support for the safe use of the whole herb. Given the number of chemicals present in any given herb, it could be possible to find some toxic constituent in any of them, so the restriction to ‘prescription only’ becomes completely dependent on the attitudes of the incumbent Minister of Health and Health Canada. It may not be possible to satisfactorily change this in the Bill but the issue could be of concern in the future. The OHA will remain vigilant.

Under this Bill, inspectors are to be given sweeping powers of search and seizure; persons or companies from whom goods are seized are expected to pay ‘storage’ and transportation costs, and potential penalties are raised to levels suitable only for large

manufacturers and pharmaceutical corporations. The OHA strongly believes that there should be an onus on the inspection service for cost-effective and timely resolution of disputes and that there must be a provision for appeal to an independent body or ombudsman. This has implications for Bill C-52 (the companion Bill to C-51) as well. Bill C-52 could introduce the search and seizure powers without the passage of Bill C-51. It is imperative that these checks and balances be included in C-52 as well.

One further significant area of concern is the provision in the Bill allowing the Governor in Council to make the regulations necessary to “harmonize” Canadian standards with those of the WTO and North American Free Trade agreements. This effectively allows for (and may actually require) the introduction of regulations such as CODEX into the Canadian marketplace without consideration by parliament, and without recourse by the consumer or manufacturer. The OHA would like to see modifications to allow for more discussion and public input regarding specific ‘harmonization’ efforts.

Summary

Overall, Bill C-51 supports those changes already made by Health Canada and the NHPD. This is not likely to be an immediate threat to herbalists. There are existing concerns regarding the costs and regulations already being implemented for NHPs but these NHP regulations remain unchanged under Bill C-51. However, the inappropriate pharmaceutical model is reinforced and this model could continue to influence future NHP policies and regulations.

Due to this, and to the individual issues identified, the OHA is unable to support the Bill as presented. Changes are required if public access to NHPs is to be truly considered, and if herbalists and other natural health practitioners are to be allowed free access to the products they are trained to use.

However, the OHA sees the current popular demands to ‘stop Bill C-51’ as inappropriate. Changes to the old *Food and Drugs Act* are necessary, but we do encourage members to contact their federal Member of Parliament, the Minister of Health, Tony Clement, and Prime Minister Stephen Harper to express their own concerns and to request that parliament take our continued access to a wide variety of natural health products very seriously.

Board of Directors, Ontario Herbalists Association

Letters should be addressed to:
The Honourable (name), House of Commons, ON, K1A 0A6

You can find your federal member of parliament at the following URL:

<http://www2.parl.gc.ca/Parlinfo/Compilations/HouseOfCommons/MemberByPostalCode.aspx?Menu=HOC>

A complete copy of the Bill is available at:

<http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=3398126&>