HEALTH CANADA'S EXPENSIVE PROPOSED CHANGES TO EXPORTING AND IMPORTING:
Expected Impacts On Natural Health Products Under The Food And Drugs Act

Prepared by Shawn Buckley, LL.B., President of the Natural Health Products Protection Association on June 27, 2021. Latest revision July 23, 2021.

Health Canada has Gazetted Expensive Changes for Exporting and Importing

On June 12, 2021, changes to the regulations for exporting and importing drugs were published in the *Canada Gazette Part I*. Here is a link to the proposed changes

What does "Gazetted" mean?

The Canada Gazette is the official newsletter of the Government of Canada. Despite its integral part in our democratic process, many Canadians are unaware it exists. As it relates to the proposed changes to regulations for exporting and importing drugs, as described in this discussion paper, via the Canada Gazette, the Government of Canada:

- publishes proposed changes to regulations or new regulations for review, giving all Canadians access to information about regulations and laws that affect our collective rights and how legislation is applied to our daily lives
- waits for any public comment on the proposed regulation changes

Through staying informed on what's shared in the Canada Gazette, you can exercise your democratic right to participate in regulatory processes within Canada.

How the Proposed Drug Regulation Changes Apply to Natural Health Products (NHPs)

With two important caveats, the changes apply to drugs that are not NHPs.

The first caveat is that in practice, Health Canada already imposes the chemical drug requirements for importing on NHPs. The new bonded warehouse requirement, described in more detail below, has been imposed without any actual legal requirement by Health Canada for some time. In my law practice dealings with Health Canada they are relentless on imposing the bonded warehouse requirement on NHP companies.

The second caveat is that once the Self-Care Framework is fully implemented, NHPs and over-the-counter chemical drugs will be regulated in the same way, right down to requiring the same standards of evidence (which is why traditional use evidence will no longer be allowed for NHPs). Health Canada has been clear that under the Self-Care Framework the chemical drug fees will be applied to all Self-Care Products, including ones we now call NHPs. Although the new fees set out below currently do not apply to NHPs, they will when the Self-Care Framework is fully implemented.

Understanding the Self-Care Framework in greater detail

For more information, see the NHPPA Self-Care Framework Discussion Paper

Please note, however, that the time-line for the implementation of the Self-Care Framework has been adjusted since the Discussion Paper was written. Health Canada's new time-line can be found here: https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/forward-regulatory-plan/plan/self-care-framework.html

For a summary of time-line updates to the Self-Care Framework, see NHPPA's recent update

The Current Situation – Exporting

The *Food and Drugs Act* and Regulations were designed to make Canadian exporters efficient and competitive. If a manufacturer is not selling a drug (which includes an NHP) within Canada, the manufacturer did not have to comply with the requirements for selling a drug in Canada such as a product licence or establishment licence. This made perfect sense. If a drug is not sold in Canada why would the Canadian Government require compliance with Canadian drug laws? That would simply add unnecessary cost and complication.

A Canadian company manufacturing a drug for export only did have to ensure that the drug complied with all of the laws of the country to which is it being exported. So, for example, if a company was manufacturing a drug for sale to the United States, they would have to comply with U.S. drug laws, but not Canadian drug laws.

This was competitive as companies exporting only had to focus on the regulatory requirements for the country to which they were exporting.

In addition to ensuring the products complied with the law of the country exported to, Canadian exporters also had to comply with safety provisions of the *Food and Drugs Act* such as ensuring no fraud or adulteration.

The coming changes to exporting

Canadian companies will now have to have a yearly drug establishment licence. This carries many obligations including satisfying Health Canada on matters such as good manufacturing practices.

Aside from the administrative burden of having to comply with Canadian drug establishment licence requirements (in addition to any foreign requirements), the Canadian companies will now also have to pay yearly establishment licensing fees.

In Health Canada's Regulatory Impact Statement, they estimate that the yearly cost on a ten-year average will be $29,955 a year for a company exporting non-sterile drugs.

In my opinion, Health Canada's estimate is low. For example, Health Canada's estimate for applying for a chemical drug establishment licence is $694. So that no-one will think I am making this unbelievably low figure up, you can find in the Regulatory Impact Statement the following:

> p. 2270 The time involved in applying for and maintaining a drug establishment licence averages 19 hours annually. The average salary of personnel engaged in this work is $36.50 per hour, varying between $25 and $42 per hour. It is therefore estimated that the average cost to apply for a drug establishment licence would be $694 and the average cost to maintain it afterwards would be $694 per year.

My law firm engages in Health Canada licensing and the most charitable comment I can make is that Health Canada's estimate has no basis in reality. It would be just as silly to say BMW sells new cars for $694.

Yearly establishment licence fees are governed by the *Fees in Respect of Drugs and Medical Devices Order*.

Current yearly fees include:

- $27,000 if manufacturing non-sterile drugs;
- $41,626 if manufacturing drugs in sterile form;
- $27,359 for importing;
- $12,560 for distributing (although it is unclear if this will apply for distributing only to other countries);
- $4,937 for wholesaling (again unclear if this applies to wholesaling to foreign distributors only);
- $6,061 for packaging/labelling, and
- $2,560 for testing.

These yearly licensing fees are cumulative so, for example, if you were manufacturing, packaging and testing a non-sterile drug your yearly cost for the establishment licence would be $35,621 ($27,000 + $6,061, and $2,560).

These are just the Health Canada application fees.

In addition, a company would have:

- fees for preparing and obtaining the establishment licence annually;
- record retention fees, and
- training and good manufacturing practices compliance.

Health Canada's yearly estimate of be $29,955 is likely off by a factor of 2-3.

I know of some small exporters that I do not expect will survive these additional costs. I expect they will close or go underground.

A positive is that having some small exporters go under will at least illustrate what is coming under the Self-Care Framework. Under the Self-Care Framework all manufacturers and distributors will have the same establishment and product licencing fees regardless of whether the drug is chemical or an NHP. Many small and medium sized NHP companies will not survive the new fees.

Rent seeking

Rent seeking is a term used by economists to describe an expensive regulatory environment that eliminates small and medium sized firms because the regulatory cost and burden is too high. Rent seeking is supported by large firms as it eliminates much of the competition. Rent seeking is supported by the regulatory agency which gets to expand because it can charge high fees for licensing, inspections and administrative penalties.

Health Canada is claiming these changes are needed to adhere to trade agreements etc. In my opinion, this is really about rent seeking. **The proposed export changes are yet another move to eliminate small and medium sized businesses.**

The Recent Situation – Importing

Not long ago, a Canadian company could import a drug (including an NHP) and then export to other countries. So, for example, I am aware of a mid-sized Canadian NHP company that manufactures and sells for the Canadian market but would also import to its Canadian

warehouse location for export to other countries. The NHP company was able to utilize the same building and staff for shipping both domestically within Canada and internationally to other countries. This was efficient and complied with all laws (domestic and foreign).

Then came the Health Canada policy that for transshipping (bringing into Canada for export to other countries) you had to use a bonded warehouse. A bonded warehouse is a facility mandated to participate in the *Customs Bonded Warehouse Program* operated by the Canada Border Services Agency (CBSA). Complying with the bonded warehouse program adds further bureaucratic requirements which increase cost and complexity.

The policy imposing the use of bonded warehouses prevented the mid-sized Canadian NHP company, mentioned above, from shipping to their Canadian address and using their warehouse and staff for international shipping. To minimize their costs, they now import to a foreign location and ship from there.

In the end, Canadian jobs and investment were lost with no benefit to any Canadian.

There will be more companies that will lose out as Health Canada becomes aware of them and can now seize their stock, fine them, or impose administrative penalties for what was before an efficient business set up. **We will lose jobs and investment in Canada with no benefit to any Canadian.**

The "change" – importing

The change for importing is that Health Canada's bonded warehouse policy is now to become law.

From Health Canada's perspective, Canadian manufacturers or distributors can no longer be trusted to export drugs that were imported for foreign markets. They cannot use their non-bonded premises and staff to import for export as they were previously free to do.

There will be small business loss. The Canadian citizen gains nothing.

More Opportunity for Health Canada Penalties

In addition to fees and expenses, under the new changes, there will be more opportunity for Health Canada inspections and administrative penalties.

For both exporting and importing, the information given to Health Canada increases. The fees and expenses increase. Health Canada's "obligation" to ensure compliance increases.

These changes will increase the scope of Health Canada's inspections and the imposition of administrative penalties.

Because many companies that import and export also sell domestically, one has to assume that over time the increased costs will filter down to Canadian consumers.

Closing

This discussion paper is the opinion of the author, Shawn Buckley, and may not be the opinion of the NHPPA.

As with all Discussion Papers we welcome feed-back. We also welcome your financial support as our ability to bring an independent analysis of legal changes affecting NHPs depends upon your backing.

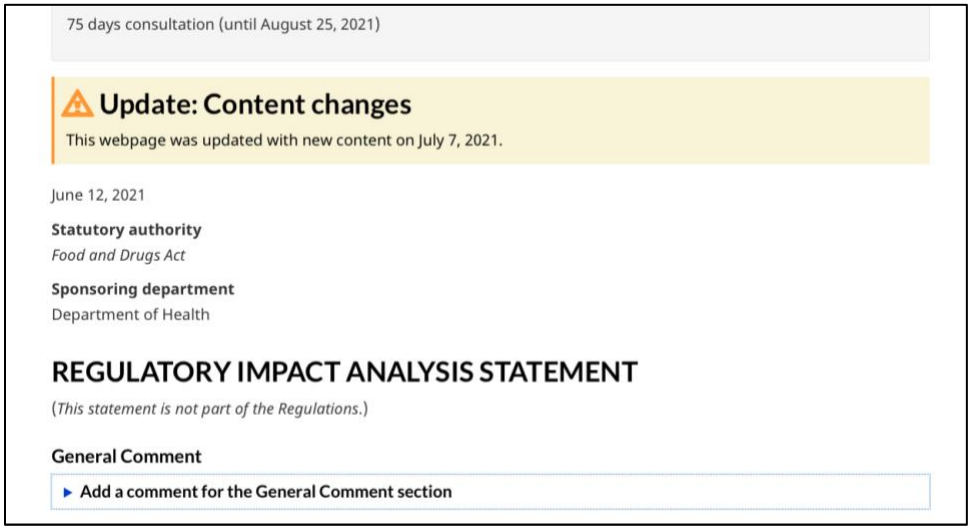
Take action

To comment on proposed regulations, Canadians can access the comment section of the Canada Gazette online at: https://gazette.gc.ca/consult/consult-eng.html

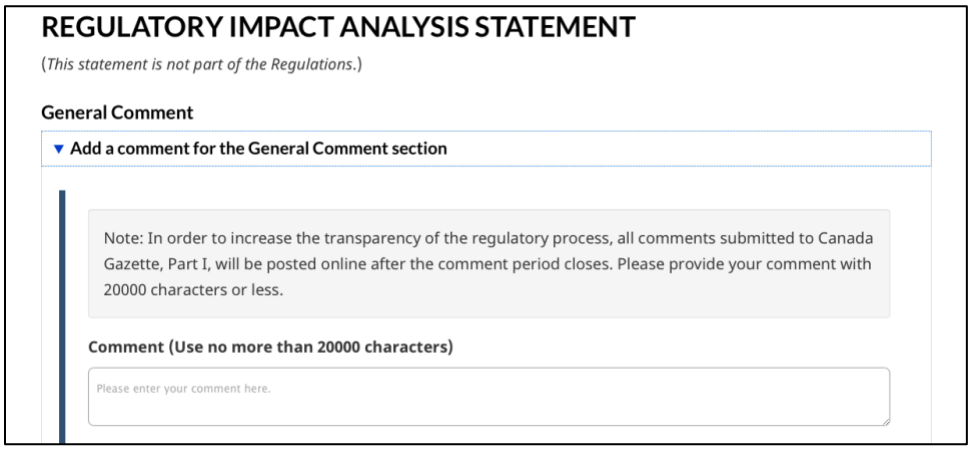
If you are reading this prior to August 25, 2021, while the comment period is still open, we encourage you to visit the Canada Gazette to comment on the proposed regulations.

Visit Canada Gazette, Part I, Volume 155, Number 24: Regulations Amending the Food and Drug Regulations (Exports and Transhipments of Drugs)

1. Locate the comment section(s) you would like to leave feedback within. The first comment section is near the top of the page under "General Comment", shown below. Each section of the document has its own comment section.

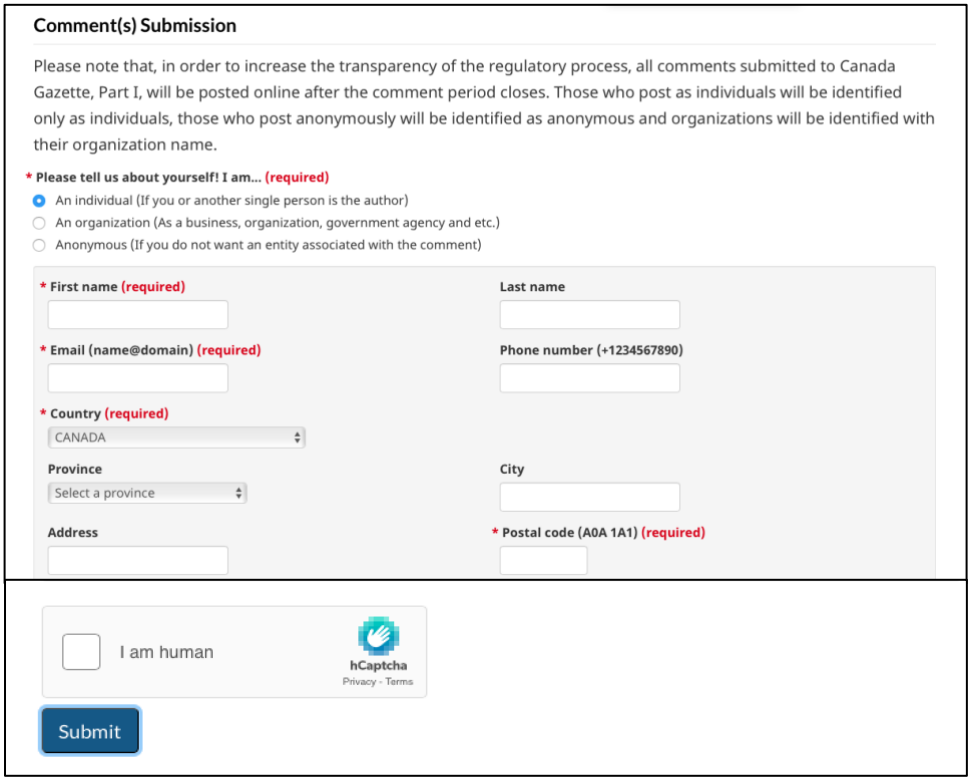


2. Once you've located the comment section you would like to leave feedback within, click the small blue arrow to the left of the text to reveal the comment section.



info@nhppa.org | www.nhppa.org | www.charterofhealthfreedom.org | 1.519.648.2050

3. When you have added comments to the section(s) you would like to, navigate to the bottom of the page to the "Comment(s) Submission" section.



4. As seen above, you can complete the Comment(s) Submission as an individual. But you may also complete the comment(s) submission as an organization or anonymously, which are not shown above.

5. Once you have completed all fields in the Comment(s) Submission section, click submit to send your comment.