

Dear Member of Parliament:

There are nearly 200,000 different natural health products (NHPs) in Canadian stores, representing a \$5 billion per year industry in Canada. Many of us use these products (like vitamins, minerals, herbal remedies, and even some sunscreens) every day, sometimes multiple times per day, to care for ourselves and our families. That's why it's vital that they be safe and of high quality.

I am writing to advise you of important work being undertaken by Health Canada to improve the regulatory oversight of NHPs so Canadians can use them without worry. I know many of you are receiving questions from your constituents on this matter, and I hope this information will help you in responding.

In 2021, the Commissioner of the Environment and Sustainable Development completed an audit of the NHP program, which found both strengths and areas for improvement. In [response to the audit](#), Health Canada committed to undertaking a number of activities to improve the safety of these products. I am pleased to say that Health Canada is making good progress on its commitments.

Improved labelling—To help Canadians make an informed choice, last year, we introduced new requirements to make NHP labels easier for Canadians to read and understand.

Protecting Canadians—This year, we passed legislation allowing us to take more action if a serious risk to health is identified with an NHP. Health Canada will now be able to order a recall of a product if necessary, or add warnings to support its safe use, which it couldn't do before.

Strengthening NHP oversight—Now, we are proposing fees for industry to allow us to expand our oversight of NHPs to create an even safer marketplace for consumers. This will let us support industry in complying with standards through education and guidance, and do more site inspections. This will ensure a safer marketplace, so we can provide continued access to safe and high-quality products that Canadians can rely on.

Small- and medium-sized businesses are the backbone of our economy, and we know they care for the wellbeing of all Canadians.

Just like them, we want to support the health of Canadians by ensuring the products sold across the country are safe and effective.

Health Canada knows that many NHP companies are small businesses and is committed to supporting them. The Department is considering measures to help alleviate the impact of fees on businesses. This includes fee reductions for small



businesses of 25% to 50% and a full waiver of pre-market evaluation fees for small businesses marketing their first product.

Health Canada is actively reviewing thousands of comments received on its fee proposal, including the fee reduction for small businesses, as part of an open and transparent consultation process with Canadians and businesses.

This is not about limiting the production of NHPs or consumers' access to them. This is about making sure the products people use are safe and of high quality.

In an effort to help you communicate with your constituents about these changes, we have attached a number of products for you to use, including:

- Key messages;
- Fact sheet;
- Frequently asked questions;
- Sample email or letter to constituents / content for a house mailer; and
- NHP safety information.

These products can be found at the following link.

I hope you find this information useful.

Natural Health Products Key Messages

General

- Our number one priority is to keep Canadians healthy and safe.
- We know how important natural health products (NHPs), such as vitamins and minerals, herbal remedies, and sunscreens, are in our daily routines.
- Yet, Health Canada has seen serious non-compliance that could potentially be harmful to consumers, such as product contamination and the presence of ingredients not listed on the label.
- This is why we are making changes to improve the safety of products.
- The Government has already introduced new labelling regulations to support consumers in making informed choices and new legislation allowing Health Canada to take action when serious safety issues arise, such as ordering a recall.
- Health Canada is now proposing fees for industry that would allow it to expand its oversight of NHPs to create an even safer marketplace for consumers. This will let us support industry in complying with standards through education and guidance, and do more site inspections.

If pressed on why

- These regulatory and legislative changes will create a safer marketplace and will help everyone make more informed choices about the products that we value.
- Health Canada recently conducted a pilot inspection program. The findings support the need to educate industry about its regulatory obligations as well as to increase oversight of the NHP industry.
- Right now, unlike with all other health products, NHP sites do not have a regular cycle of inspections to ensure that companies adhere to quality standards.
- The fees will provide Health Canada with the resources to conduct the necessary oversight of the NHP industry to ensure that the products we use and trust are in fact safe and high quality.



If pressed on small business

- Small- and medium-sized businesses are the backbone of our economy, and we know they care for the wellbeing of all Canadians.
- Just like them, we want to support the health of Canadians by ensuring the products sold across the country are safe and effective.
- Health Canada knows that many NHP companies are small businesses and is committed to supporting them. The Department is considering measures to help alleviate the impact of fees on businesses. This includes fee reductions for small businesses of 25% to 50% and a full waiver of pre-market evaluation fees for small businesses marketing their first product.
- Health Canada is actively reviewing thousands of comments received on its fee proposal, including the fee reduction for small businesses, as part of an open and transparent consultation process with Canadians and businesses.

NATURAL HEALTH PRODUCTS

Frequently Asked Questions

Will the new natural health product (NHP) regulations and legislative changes increase prices for businesses and consumers?

- Health Canada is committed to making sure natural health products (NHPs) in Canada are safe and of high quality.
- Health Canada's changes will create a safer marketplace for consumers.
- Canadians want safe and accessible natural health products, and that's what these changes will achieve.

Labelling regulations

- Better labelling will help Canadians know what's inside their natural health products so they can use them safely.
- To reduce costs for new labelling, in consultation with industry, Health Canada established a multi-year (up to six years) transition period for new labels.

Legislative powers

- Legislation passed by the Government of Canada now means Health Canada can also take faster action when a serious health risk is identified with an NHP so Canadians can be safer and healthier.
- This change doesn't affect companies already following the rules, whether they are small or large businesses.

Proposed fees

- The Government of Canada recognizes the importance of the NHP industry, which employs more than 50,000 people and generates billions in domestic sales and exports.
 - Small- and medium-sized businesses are the backbone of our economy, and we know they care for the wellbeing of all Canadians.
 - Just like them, we want to support the health of Canadians by ensuring the products sold across the country are safe and effective.
 - Health Canada knows that many NHP companies are small businesses and is committed to supporting them. The Department is considering measures to help alleviate the impact of fees on businesses. This includes fee reductions for small businesses of 25% to 50% and a full waiver of pre-market evaluation fees for small businesses marketing their first product.
 - Health Canada is actively reviewing thousands of comments received on its fee proposal as part of an open and transparent consultation process. Health Canada will determine a way forward that protects Canadians and supports businesses.
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Will the new and significant fees to import, manufacture and sell NHPs cause small- and medium-sized businesses to shut down their Canadian operations?

- Our government understands the importance of small businesses to our economy and that is why the fee proposal includes significant cost reductions for small businesses.
- Cost recovery will help offset the costs incurred by the Government in providing NHP program services to industry. These costs are currently fully funded by Canadian taxpayers.
- Health Canada knows that many NHP companies are small businesses and is committed to supporting them. The Department is considering measures to help alleviate the impact of fees on businesses. This includes fee reductions for small businesses of 25% to 50% and a full waiver of pre-market evaluation fees for small businesses marketing their first product.
- Health Canada is actively reviewing thousands of comments received on its fee proposal as part of an open and transparent consultation process. Health Canada will determine a way forward that protects Canadians and supports businesses.

Why is the Government unnecessarily adding to inflation on health and wellness products, when Canadians are already financially stretched to the max?

- Canadians want safe and accessible natural health products, and that's what these changes will achieve.
- While NHPs are generally lower risk, that does not mean they are without risk.
- Between 2021 and 2023, there were 100 voluntary recalls of licensed NHPs for safety issues, including bacterial contamination and the presence of foreign matter in a product.
- A pilot inspection program conducted between March 2021 and March 2022 to assess whether NHP manufacturers and importers were following regulatory requirements for good manufacturing practices found that all of the sites had compliance issues, ranging in severity, with some requiring immediate action.
- We want Canadians to have safer natural health products.

Why are we asking companies (who may go out of business) to pay for Health Canada's services?

- Health Canada currently relies solely on public funding to support its regulatory activities relating to NHPs. Regulatory services for other health products are funded through a mix of service fees and public funding.
- Health Canada is proposing fees for industry to allow the Department to recover some of the costs of the services it provides to industry, and expand its oversight of natural health products to create an even safer marketplace for consumers.
- This will allow the Department to support industry in complying with regulations through education and guidance, and to conduct inspections to ensure that NHPs are manufactured, imported, labelled and packaged in accordance with regulations.

Why are we asking companies (who may go out of business) to pay for Health Canada's services? *(Continued)*

- The Department has consulted with stakeholders on the proposed cost recovery fees, including measures to alleviate the impact to small businesses.
 - Health Canada's proposed fees would be generally around \$1,100 to \$2,800 for the majority of submissions or \$550 to \$1,400 for qualifying small businesses. Health Canada is proposing a 25% to 50% fee reduction for small businesses and a full waiver of the pre-market evaluation for small businesses marketing their first product.
 - The new fees would be accompanied by new standards for timelines, such as product and site licensing review timelines, holding Health Canada accountable and providing industry with greater predictability of the Department's services.
 - Health Canada's proposed fees were calculated using sound costing methodologies. They are tailored to NHPs and are different from those for higher-risk health products, like prescription drugs.
 - Health Canada has been working extensively with industry in the last several years to understand the potential costs and impacts on small businesses and to minimize disruptions in Canadians' access to safe natural health products.
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Since the majority of NHPs are safe, why are we asking a large credible industry to pay for five bad actors?

- While natural health products are generally safe, they are not without risk.
 - Between 2021 and 2023, there were 100 voluntary recalls of licensed NHPs for safety issues, including bacterial contamination and the presence of foreign matter.
 - In 2021, the Commissioner of the Environment and Sustainable Development completed an audit of the NHP program, which found both strengths and areas for improvement. The Department committed to undertaking a number of activities to improve the safety of these products.
 - Health Canada conducted a pilot inspection program between March 2021 and March 2022 to assess whether 36 manufacturers and importers were following regulatory requirements for good manufacturing practices. All of the inspections identified compliance issues ranging in severity.
 - The revenue generated by the proposed fees will allow Health Canada to establish a new, permanent NHP Good Manufacturing Practice inspection program to educate industry on its obligations and to verify industry compliance with regulatory requirements.
 - The Department has consulted extensively and will continue to engage industry on all of these initiatives and to support small and medium-sized businesses.
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How do other countries regulate NHPs?

- It is difficult to make international comparisons given the differences in how health services are funded in different countries, how each country defines NHPs and the cost-recovery approach they use.
- In Canada, we define NHPs as substances that are naturally occurring and are used to restore or maintain good health. Other countries use various definitions, and may include or exclude certain ingredients, products or usages.
- In Australia, therapeutic products are classified based on level of risk, so NHPs may be subject to the same regulatory requirements as non-prescription drugs depending on their risk categorization. Australia recovers 100% of its costs through industry fees.
- In the European Union (EU), most herbal medicines are considered to be drugs, though they are not centrally authorized. Many herbal medicines have been in use since before the European Medicines Agency was created and would have been authorized at the national level by each EU country.
- Companies seeking market access for traditional herbal medicines in EU member states need to follow national procedures and pay any applicable fees in those jurisdictions, although they may submit a request for scientific opinion and pay a fee through the centralized process. Fees may also vary depending on the claims made or the type of marketing authorization chosen.
- Overall, compared to other jurisdictions where NHPs may be considered a drug, the fees proposed by Health Canada are lower.

Are NHPs purchased by Canadians from U.S.-based websites subject to the same rules and regulations as Canadian products?

- All companies that sell NHP products online, whether domestic or international, must comply with Canadian regulations to keep people in Canada safe.
- Canadian residents and visitors can import a 90-day supply or single course of treatment of an NHP, or any other health product, for personal use without requiring specific licences.
- However, when possible, Canadians are encouraged to buy licensed health products in Canada that have been assessed by Health Canada to be safe and effective if used according to their directions for use.
- Health Canada is responsible for health product compliance monitoring and enforcement activities to verify that regulatory requirements are being applied appropriately.
- Health Canada works in partnership with the Canada Border Services Agency to assess the compliance of health products that have been referred at the border, regardless of whether the products are entering by mail/courier or on a person.
- Collecting fees for NHPs will let us support industry in complying with standards through education and guidance and do more inspections so that consumers can use NHPs without worry.

Why is HC discriminating against Canadian products and jobs?

- Health Canada is not stopping or limiting the sale of NHPs. Health Canada has been working to introduce important improvements within the NHP Program to ensure that Canadians have continued access to a wide range of safe and high quality NHPs.
 - Product availability is not expected to change. However, unsafe NHPs could be removed more quickly from the market.
 - Products sold in Canada must meet Canadian requirements, whether imported or produced domestically.
 - This is not about limiting the production of NHPs or consumers' access to them. This is about making sure the products people use are safe and of high quality.
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Why should ultra-safe NHPs be regulated?

- The *Natural Health Products Regulations* came into force in 2004 following the 1998 recommendations of the Standing Committee on Health, to provide a pathway to market NHPs with risk-based regulatory oversight.
 - While natural health products are lower risk, they are not without risk. For example, there can be serious adverse reactions (though they are rare), and the use of these products can affect how a person's prescription medications work.
 - Our number one priority is to keep Canadians healthy and safe.
 - We know how important NHPs, such as vitamins and minerals, herbal remedies, and sunscreens, are for our daily routines. Yet, Health Canada has seen serious non-compliance that could be harmful to consumers, such as product contamination and the presence of ingredients not listed on the label.
 - This is why we are making changes to improve the safety of products.
 - The Government has already introduced new labelling regulations to support consumers in making informed choices and new legislation allowing Health Canada to take action when serious safety issues arise, such as ordering a recall.
 - Health Canada is now proposing fees for industry which would allow it to better protect Canadians by doing more inspections and support industry in complying with standards through education and guidance.
 - Canadians should be able to trust that the products on store shelves are safe, that they contain what they say they contain, and that all the information about their safe use is available on the label.
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Is there any evidence to support regulating the NHP industry?

- The Standing Committee on Health undertook a study of NHPs and published a report in 1998 called “Natural Health Product: A New Vision,” that includes 53 recommendations regarding the legislative and regulatory regime for NHPs. This report was used to inform the initial creation of the *Natural Health Products Regulations*, which came into force in 2004.
 - To this day, NHPs continue to be regulated in a manner appropriate for the lower-risk nature of these products under the *Natural Health Products Regulations*, which is a separate and distinct regulatory framework from prescription drugs.
 - While natural health products are lower risk, they are not without risk.
 - For a two-year period beginning in 2021, Health Canada received reports of 1,019 adverse reactions in which NHP use had a suspected role, of which 772 were serious (e.g., required hospitalization or were life threatening). And these are only the reports Health Canada received. Adverse reactions are significantly underreported both in Canada and internationally. It is important to note, adverse reaction reports are suspected associations and it is often not possible to determine if an adverse reaction is a result of using a specific health product.
 - Between 2021 and 2023, there were 100 voluntary recalls of licensed NHPs for safety issues, including bacterial contamination and the presence of foreign matter.
 - In 2021, the Commissioner of the Environment and Sustainable Development completed an audit of the NHP program, which found both strengths and areas for improvement. The Department committed to undertaking a number of activities to improve the safety of these products, including introducing user fees that take small businesses into consideration.
 - Health Canada conducted a pilot inspection program between March 2021 and March 2022 to assess whether 36 manufacturers and importers were following regulatory requirements for good manufacturing practices. All of the inspections identified compliance issues ranging in severity.
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How effective was the consultation on the fee proposal, which was only 90 days and ran during the summer months, when many people are on vacation?

- Over the past seven years, Health Canada has consulted extensively with a broad range of stakeholders on proposals to improve the safety of NHPs and to respond to an evolving and growing marketplace, continually signalling its intention to pursue cost recovery for all NHPs.
 - Since 2021, Health Canada has been more explicitly communicating this intention, as introducing cost recovery is part of the Department's response to the recommendations of the Commissioner of the Environment and Sustainable Development Audit of the NHP program.
 - The Department has also reiterated its intention at every multilateral and bilateral meeting with key industry associations, and at every external stakeholder conference.
 - The Department held a public consultation on its fee proposal from May 12 to August 10, 2023, as well as industry information sessions to explain the proposal and respond to questions to ensure that industry was well-positioned to provide fulsome comments.
 - The consultation was initially intended to last 75 days. This duration is consistent with past consultations relating to cost recovery for prescription drugs and aligns with Treasury Board Secretariat guidance. Following feedback from some stakeholders requesting an extension, the consultation period was amended to 90 days, ending on August 10, 2023.
 - The Department received over 4,700 comments from industry stakeholders and the public, and is now actively reviewing those comments to determine a way forward that both protects Canadians and supports businesses.
 - The Department will continue to engage industry on all these initiatives and to support small and medium-sized businesses to provide Canadians with access to a variety of safe and high quality products.
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Sample email or letter to constituent / content for a house mailer

Dear constituent,

Access to a variety of health care products is vital to our health and wellbeing, and this includes natural health products. These products, like vitamins and minerals, herbal remedies, as well as many sunscreens and toothpastes, are an important part of our daily routines.

Because so many of us use natural health products every day to care for ourselves and our families, it is important that they be safe and properly made.

While natural health products are generally lower risk than drugs, safety issues can and do occur. In a two-year period, beginning in 2021, Health Canada received 1,019 reports of adverse reactions associated with, though not necessarily proven to be caused by, natural health products. Of these reports, 772 were serious (e.g., required hospitalization or were life threatening). During this period, there were also 100 voluntary recalls of licensed natural health products for various reasons, including bacterial and chemical contamination.

In an effort to make the natural health product market safer for consumers and help them make more informed choices, Health Canada recently introduced two important regulatory and legislative changes:

- In July 2022, Health Canada introduced new regulatory requirements to make natural health product labels easier for Canadians to read and understand. This includes, for example, increased font size and improved colour contrast.
- In June 2023, the Government passed legislation allowing Health Canada to take more action if a serious risk to health is identified with a natural health product. This legislation allows Health Canada to order recalls or add warnings to labels, if necessary, which it couldn't do before.

Now, Health Canada is proposing fees for industry to allow the Department to create an even safer marketplace for consumers — one that helps them worry less about the products that they value. The revenues generated by the proposed fees would allow Health Canada to establish a new, natural health product inspection program to educate industry, including manufacturers and suppliers, about Health Canada's health and safety requirements, and to increase Health Canada's inspection capacity to ensure industry is following those important requirements.

Our government values the natural health product industry, which employs more than 50,000 people and generates billions in domestic sales and exports. Health Canada knows that many natural health product companies are small businesses and is committed to supporting them. The Department is considering measures to help alleviate the impact of fees on businesses. This includes fee reductions for small businesses of 25% to 50% and a full waiver of pre-market evaluation fees for small businesses marketing their first product.

Health Canada is actively reviewing thousands of comments received on its fee proposal, including the fee reduction for small businesses, as part of an open and transparent consultation process with Canadians and businesses.

This is not about limiting the production of NHPs or consumers' access to them. This is about making sure the products we all use every day are safe and of high quality.

I encourage you to visit [Health Canada's website](#) for more details.

Safety Issues - Natural Health Products

Since introducing the regulatory framework for natural health products (NHPs) in 2004, Health Canada has seen potential cases of safety issues and evidence of low regulatory compliance across the NHP industry.

Product recalls

For a two-year period beginning in 2021, 100 voluntary recalls of licensed NHPs have been conducted.

Example: There were approximately 53 voluntary recalls of licensed hand sanitizers due to improper labelling, unacceptable or dangerous ingredients, or lack of product testing over a span of two years. For example, some products were found to contain benzene, which is classified as a human carcinogen.

Adverse reactions

For a two-year period beginning in 2021, Health Canada received 1,019 reports of adverse reactions in which NHPs had a suspected role, of which 772 were serious (e.g., required hospitalization or were life threatening). And these are only the reports Health Canada received. Adverse reactions are significantly underreported both in Canada and internationally.

It is important to note, adverse reaction reports are suspected associations; they often don't include enough information for Health Canada to determine if the reaction was the result of using a specific health product.

Example: In 2016, Health Canada received a report of a 17-year-old who developed liver and kidney injury after using a [green tea extract](#) product for weight management for five days. Health Canada later strengthened product labelling to warn about the risk of liver injury and recommended that green tea extract products be used by adults only.

Product contamination

While NHPs are generally lower risk than drugs, even lower-risk health products can pose serious risks to health if there are quality concerns, such as contamination with foreign matter, mold, mildew, lead, arsenic, salmonella or E. coli.

Example: In 2022, there was a recall of one lot of an antacid that was found to contain fragments of fibreglass and other materials, including paper and aluminum foil. Elderly people and people with narrow areas in their intestines because of disease or surgery may have been at risk of injury.

Labelling issues

Mislabeled products and products with incomplete labelling information can lead to safety issues and health risks.

Example: In 2021, the Commissioner of the Environment and Sustainable Development examined a sample of 75 licensed products for sale on Canadian websites. A total of 88% of products examined were advertised with misleading product information and 56% were marketed with misleading label information, such as unauthorized health claims and missing information about risks..

Safety issues identified during site inspections

During the NHP pilot inspection program that occurred between 2021 and 2022, high levels of non-compliance with Good Manufacturing Practices (GMP) were observed. Issues were identified at all 36 NHP importers and manufacturers inspected, ranging in severity.

[A report](#) summarizing the results of the pilot was published, providing an opportunity to educate the public and encourage compliance within industry.

An interim inspection program is ongoing and the same trends noted above continue to be observed.

NATURAL HEALTH PRODUCTS

Frequently Asked Questions



<p>TRUE: Right now, unlike with all other health products, natural health products (NHP) companies—including manufacturing, importing, packaging and labelling sites—do not have a regular cycle of inspections to ensure that they follow quality standards.</p>	<p>FALSE: Enhanced regulation will lead to a decrease in the types and numbers of NHPs on the market, reducing choice for consumers.</p>
<p>TRUE: Since extending Vanessa’s Law to NHPs in June 2023, the Department now has the ability to recall unsafe products and to add label warnings when necessary to make NHPs safer.</p>	<p>FALSE: The current NHP regulations are sufficient.</p>
<p>TRUE: In two years, Health Canada received 1,019 reports of adverse reactions in which NHP use had a suspected role, of which 772 were serious (e.g., required hospitalization or were life threatening).</p>	<p>FALSE: There is no data to support the need for the changes the Government is making to the NHP program.</p>
<p>TRUE: A recent audit found that 88% of sampled NHPs were advertised with false and misleading product information, and 56% with misleading label information.</p>	<p>FALSE: There is no data to support the need for the changes the Government is making to the NHP program.</p>
<p>TRUE: Health Canada consulted Canadians and businesses on its fee proposal for the program and received thousands of submissions which it is actively reviewing.</p>	<p>FALSE: Health Canada did not consult Canadians or small- and medium-sized businesses.</p>
<p>TRUE: Health Canada is proposing to support small- and medium-sized businesses by reducing or waiving their fees.</p>	<p>FALSE: These changes will shut down businesses and reduce access to NHPs.</p>
<p>TRUE: Regulating natural health products protects small- and medium-sized business by providing education and guidance to make sure the products they sell are safe.</p>	<p>FALSE: Changes to the NHP program will kill small- and medium-sized businesses.</p>
<p>TRUE: All companies that sell NHP products online, both domestically and internationally, or at retail outlets in Canada must comply with Canadian regulations to keep people in Canada safe.</p>	<p>FALSE: American and international companies won’t be impacted by changes to the NHP program. They only impact Canadian companies.</p>

SUPPORTING DETAILS

FACT

While most natural health products (NHPs) are lower risk than drugs, they are not without risk. If an NHP is contaminated or used improperly, it could potentially cause serious health risks.

For example, for a two-year period beginning in 2021, Health Canada received reports of 1,019 adverse reactions in which NHP use had a suspected role, of which 772 were serious (e.g., required hospitalization or were life threatening). And these are only the reports Health Canada received. Adverse reactions are significantly underreported both in Canada and internationally.

It is important to note, adverse reaction reports are suspected associations; they often don't include enough information for Health Canada to determine if the reaction was the result of using a specific health product.

FACT

Health Canada supports access to safe and high-quality NHPs for Canadians. To achieve this, Health Canada regulates NHPs under the *Natural Health Products Regulations*, which is a separate and distinct regulatory framework from prescription drugs.

The Government recently passed legislative changes that provide Health Canada with additional abilities, such as to remove unsafe products from the market or to require warnings on a product label to support their safe use. Health Canada will only use these authorities if a company refuses to take voluntary actions to address a risk.

FACT

Health Canada is proposing fees to begin recouping a portion of the costs of providing services to industry so that it can expand its oversight of these products and create a safer marketplace for consumers. This will provide continued access to safe and high-quality products that Canadians can rely on.

Health Canada knows that many NHP companies are small businesses and is committed to supporting them. The Department is considering measures to help alleviate the impact of fees on businesses. This includes fee reductions for small businesses of 25% to 50% and a full waiver of pre-market evaluation fees for small businesses marketing their first product.

Health Canada is actively reviewing thousands of comments received on its fee proposal as part of an open and transparent consultation process. Health Canada will determine a way forward that protects Canadians and supports businesses.



 **FACT**

Health Canada consults the public, including industry, on proposed regulatory changes.

Over the past seven years, Health Canada has consulted extensively with a broad range of stakeholders on proposals to improve the safety of NHPs and respond to an evolving and growing marketplace.

For improved NHP labelling, Health Canada engaged in extensive consultations, including with industry, from 2018 to 2022, and used feedback to make adjustments to both the regulations and guidance, as well as the transition period to update labels, prior to their final publication.

The Department continues to engage broadly to ensure stakeholders have opportunities to share their perspectives and inform Health Canada's work.

 **FACT**

Health Canada's legislative and regulatory amendments will support the availability of safe and high quality NHPs. NHPs are important to Canadians to help support and maintain their health and Health Canada is committed to ensuring their continued availability.

These important improvements within the NHP program will help protect the health and safety of consumers. New requirements were introduced to support more consistent and prominent labelling of key information, such as allergens, and to support Canadians in selecting and safely using these products.

NHPs are the only line of health products in Canada for which all regulatory activities are funded exclusively by taxpayers. The proposal includes measures to reduce or waive fees for small businesses to help ensure that a variety of products continue to be made available.


 **FACT**

Health Canada's proposed fees were calculated using sound costing methodologies. They are tailored to NHPs and are different from those for higher-risk health products, like prescription drugs.

The proposed fees reflect the costs associated with performing regulatory activities for NHPs. Three types of fees are proposed:

- Fees to evaluate applications for new NHPs or to amend existing NHPs (starting as low as \$562 for qualifying small businesses on the simplest applications to \$58,332 for the most complex applications, which are expected to be very rare);
- Fees to assess new NHP site licence applications or amendments to existing site licences (\$3,588 for qualifying small businesses and \$4,784 for larger businesses), and an annual site licence fee to support site licence renewal and compliance and enforcement activities for products that are already on the market (ranging from \$5,191 for qualifying small business labelling facilities to \$40,071 for larger business sterile manufacturing facilities); and
- Annual “right” to sell fees to allow companies the right to sell their NHPs in Canada (\$406.50 for qualifying small businesses and \$542 for larger businesses annually).

All fees are based on the Government's cost to provide services and were calculated using the methodology prescribed by the Treasury Board *Guide to Costing*.

Health Canada would review and update fees on a regular basis, which is already done for fees for all other health products, to ensure that they remain accurate and reflect the current level of effort to regulate NHPs.
