Health Canada Santé Canada

Proposed fees for natural health products

For consultation

May 2023

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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Overview

Introduction

Health Canada is the federal department responsible for helping people in Canada maintain and improve their health. One of the roles we play in carrying out this mandate is that of a regulator. As a regulator, we evaluate products before they are authorized for sale, monitor these products once they are on the market, and oversee compliance and enforcement.

These regulatory activities incur costs to the federal government and provide benefits to the regulated industry. Health Canada charges industry fees to cover a portion of these costs. This practice of establishing fees is referred to as cost recovery and has been in place for certain health product lines since the 1990s. By pursuing cost recovery, we make sure that our activities do not rely solely on public funding (taxpayers).

Health Canada's authority to set and charge health product fees comes from the *Food and Drugs Act* (FDA). Currently, we have cost recovery in place for various regulatory programs, including those related to human and veterinary drugs, and medical devices.

To promote transparency and accountability when setting fees, we consult and engage with industry stakeholders. When proposing a new set of fees, we establish a fee proposal for their review and comment.

To accurately set fees and develop a robust cost-recovery program, Health Canada:

- calculates the costs of regulated activities
- establishes corresponding fee amounts and performance standards
- for example, the time for us to evaluate a new product application
- puts in place appropriate fee mitigation and remission measures

Once fees are implemented, industry stakeholders will pay to receive specified regulatory services, regulatory oversight and maintain access to the Canadian market.

Background

Natural health products

Health Canada defines natural health products (NHPs) as naturally occurring substances that are used to restore or maintain good health. They are often made from ingredients such as plants, animals, microorganisms and marine sources. They come in a wide variety of forms like tablets, capsules, tinctures, solutions, creams, ointments and drops.

NHPs include:

- vitamins and minerals
- herbal remedies
- homeopathic medicines
- traditional medicines like Chinese and Ayurvedic (East Indian) medicines
- probiotics
- other products like amino acids and essential fatty acids

Many everyday products used by consumers, such as certain toothpastes, antiperspirants, shampoos, facial products and sunscreens, are also classified as NHPs in Canada.

In Canada, oversight of NHPs falls under the *Natural Health Products Regulations* (NHPR) of the FDA. These regulations came into effect on January 1, 2004, after we consulted extensively with stakeholders and the public to determine an appropriate regulatory framework for NHPs. The regulations help people in Canada access a wide range of NHPs that are safe, effective and of high quality.

To be legally sold in Canada, NHPs must have a product licence and the Canadian sites that manufacture, package, label and import these products must have a site licence (SL). To obtain product and site licences, labelling and packaging requirements must be met, good manufacturing practices must be followed, and proper safety and efficacy evidence must be provided.

According to the 2011 Functional Foods and Natural Health Products Survey, the NHP industry in Canada had annual sales of $5 billion CAD. While a similar survey has not been conducted since 2011, there is further indication that the industry continues to grow. As of 2022, Health Canada had licensed about 120,000 NHPs (although about half of these do not appear on the Canadian market). Every year, we receive an average of 10,000 applications for product licences.

Framework

Introduction

Health Canada relies solely on public funding to fund our regulatory activities relating to natural health products (NHPs). Regulatory services for other health products are funded through a mix of service fees and public funding.

We have been charging fees for other health products such as drugs and medical devices since the 1990s. The fee structure has 3 main categories:

- **Pre-market evaluation (EVAL)** fees to assess and license new products entering the Canadian market or to amend existing products
- **Site licence (SL)** fees to assess and license facilities that manufacture, import, label or package health products
- referred to as establishment licences in the regulation of drugs and medical devices (the framework upon which NHP fees are based)
- **Right to sell (RTS)** fees to allow companies to sell their products in Canada and help recover some of the costs for post-market surveillance and regulatory compliance and enforcement activities

In 2017, the Government of Canada introduced the *Service Fees Act* (SFA), which replaced the 2004 *User Fees Act*. The SFA established a requirement for an annual fee report to be tabled in Parliament and introduced mandatory fee remissions, annual fee adjustments and fee performance standards. This act also increased transparency, accountability and predictability for the fees charged by the federal government.

At the same time, the Minister of Health was granted authority to fix fees under the FDA. These fees are exempt from the SFA, but mirror many of its provisions. In 2020, the Minister exercised this authority to update most fees for drugs and medical devices.

The current fee proposal expands on that fee framework to include NHPs. This is the only health product line for which we do not charge fees.

Cost recovery for natural health products

Health Canada is proposing fees for NHP regulatory activities to recover a portion of the costs of our regulatory activities and to support improvements to the NHP program. These improvements include:

- limiting applications for hypothetical NHPs
- for instance, those that are unlikely to be marketed
- increasing predictability of regulatory services for industry

Health Canada will be accountable via fee remissions for unmet performance standards.

The fee revenues will allow us to strengthen our oversight of NHPs, monitor labelling and advertising, and put in place a permanent inspection program. The increased resources provided by fees will also help us improve our ability to:

- detect and respond to quality issues
- address issues of non-compliance for unlicensed products
- prevent harmful products from making their way into the marketplace

CESD report on natural health products

In 2021, the Commissioner of the Environment and Sustainable Development (CESD) tabled an audit on Health Canada's NHP program. The audit focused on whether NHPs available for sale in Canada are safe, effective and represented accurately to consumers. The audit's recommendations in Annex A validated key gaps that Health Canada had identified and worked to address in recent years. The study report issued by the Standing Committee on Public Accounts in 2022 also reinforced these findings.

Health Canada is committed to addressing all the audit's recommendations and to strengthening the NHP program by:

- improving labelling
- increasing oversight of the quality of NHPs
- increasing monitoring of labels and advertising, including online advertising
- strengthening compliance and enforcement activities, such as:
- an inspection program
- new tools to protect the health and safety of people in Canada when serious health risks arise

We are also looking at introducing fees to regulate NHPs, make program improvements and strengthen regulatory oversight.

Natural health product regulatory program

The NHP regulatory program consists of pre-market (product and site licensing) and post-market (monitoring, compliance and enforcement) activities.

> Note: The licensing requirements of the *Natural Health Products Regulations* apply to any person or company that manufactures packages, labels and/or imports NHPs for commercial sale in Canada. They do not apply to health care practitioners who compound products for their own patients or to retailers of NHPs.

Pre-market activities

Product licensing

To sell NHPs in Canada, a company must apply for and obtain a product licence from Health Canada. Applicants must give detailed information about their product, including medicinal and non-medicinal ingredients, manufacturing processes, sourcing, dosage, potency and recommended usage.

The safety, quality and efficacy of NHPs and their health claims requires appropriate evidence so that Health Canada and consumers know that the products are safe and effective. Evidence may include clinical trial data or references to published studies, journals, pharmacopoeias and traditional resources. The type and amount of supporting evidence required depends on the proposed health claim and the product's overall risks.

NHPs must also meet specific labelling requirements to help consumers make safe and informed choices about the products they use.

Once we assess a product and determine that it is safe, effective and of high quality, we will issue a product licence.

We will also issue an 8-digit natural product number (NPN) or homeopathic medicine number (DIN-HM). This number must appear on the label, as it indicates that Health Canada has reviewed and approved the product.

> Only the company that holds the licence for a product can market that product in Canada and have access to the Canadian market to sell their product and collect revenue. This makes licences a direct and exclusive benefit that is unique to the licence holder.

Site licensing

Companies that manufacture, package, label or import NHPs must follow the good manufacturing practices (GMP) requirements outlined in Part 3 of the *Natural Health Products Regulations* (NHPR). GMP requirements cover the following:

- product specifications
- premises

- equipment
- personnel
- sanitation
- operations
- quality assurance
- stability
- records
- product sterilization
- lot or batch samples
- recall processes and reporting

Companies must provide evidence of compliance with GMPs to be issued a site licence by Health Canada.

Post-market activities

Surveillance, Compliance, and Enforcement

Health Canada also conducts post-market activities, including surveillance and compliance and enforcement oversight activities on NHPs for sale in Canada.

We identify potential product compliance or safety issues by analyzing adverse reaction reports from industry, hospitals, and health professionals and consumers.

> Note that product licence holders must report any serious adverse reactions related to their product to the Canada Vigilance Program and submit summary reports of safety information for NHPs under certain conditions as specified in the NHPR.

We also conduct literature searches, data scans and communications with foreign regulatory agencies.

Compliance verification also includes assessing selected products at the border in collaboration with the Canada Border Services Agency before they are admitted into Canada. Where necessary, laboratory analyses on samples are conducted to assess product safety, quality and/or efficacy.

Complaints from the public, industry, international partners and other sources also inform our compliance verification activities. When a compliance or safety issue is established or where the potential for harm exists, Health Canada takes appropriate risk mitigation steps, including:

- mandating changes in product safety information
- issuing public warnings or advisories
- recalling a product
- requesting that products be withdrawn from the market

Health Canada also oversees and enforces the regulatory requirements related to health product advertising. We assess advertising complaints that we receive and the promotional claims for NHPs against the *Food and Drugs Act*, the NHPR and the terms of the product's authorization. When we find non-compliance, we may take action.

Note that Health Canada has advertising-specific policies and guidance and conducts stakeholder awareness activities to help prevent non-compliant advertising. In 2021-22, we completed an inspection pilot program to promote and verify industry compliance with GMPs. The results from this pilot are being used to help us transition to a permanent risk-based inspection program.

Fees and fee policy

Introduction

Fees are set based on corresponding regulatory costs incurred by Health Canada, in accordance with Treasury Board Secretariat's Guide to Cost Estimating. The portion of the costs recovered by fees (the fee-setting ratio) is determined by analyzing several factors, including the public-private benefit. The goal is to determine the degree to which an activity or service provides private benefit to industry versus the benefit received by the public. Multiple factors are considered, such as financial or competitive advantage, market access and innovation development in Canada, as well as the potential disincentives for regulatory compliance.

To ensure alignment across health products, Health Canada is proposing a fee structure for natural health products (NHPs) similar to that for human drugs and medical devices, as implemented April 1, 2020. The 3 categories are:

- **100%** of total costs for site licences
- **75%** of total costs related to pre-market evaluation
- **67%** of total costs related to the right to sell

Fee details and mitigation and accountability measures (for example, fee remissions) are described in this section.

Small business mitigation

Health Canada is proposing small business fee reduction measures to minimize the impact of fees on small businesses. These are the same as those in place for drugs and medical devices. Applying the same practice to NHPs will help align cost-recovery principles and practices across health products.

To qualify as a small business, a company, including its affiliates, must either have fewer than 100 employees or between $30,000 and $5 million CAD in annual revenue. Qualifying businesses are eligible for the following fee remissions:

- **100%** for pre-market evaluation fees for the business's first-ever NHP product submission
- **50%** for pre-market evaluation fees for all subsequent product submissions
- **25%** for site licence fees and the annual right to sell fee

Mitigation for publicly funded health care institutions

As is the case for drugs and medical devices, fees for NHPs will not be applied to health care institutions that receive public funding. This applies to institutions that are licensed, approved or designated by a province or territory in accordance with its laws to provide care or treatment to persons or animals suffering from disease or illness. This provision also applies to branches or agencies of the federal, provincial or territorial government.

Performance accountability

It is important that Health Canada provides timely, efficient and effective service. This fee proposal outlines updated performance standards (timelines) for each type of regulatory activity for which a fee is charged. These performance standards will help keep us accountable. They include financial mechanisms (such as fee remissions) for when a performance target is missed.

The approach to NHP performance standards and remissions for missed standards is modelled on the structure in place for drugs and medical devices.

Health Canada will remit **25%** of the fee paid if the published performance standard is not met. Note that we may use this provision in conjunction with our established approach for other health products, known as pause-the-clock. This would allow for the count (in days) of a performance standard to be paused under specified circumstances.

Pause-the-Clock allows for a performance standard to be paused if Health Canada is unable to process the file within the timeline due to circumstances beyond Health Canada's control. A company can request a pause-the-clock if it needs more time to respond with required information, such as when an information request notice (IRN) has been issued. (IRNs provide applicants the opportunity to address non-administrative deficiencies or information omissions, as per sections 15 and 37 of the NHPR.) Additional guidance will be published outlining the conditions and processes for the pause-the-clock mechanism.

Fees and performance standards

The NHP fee structure will consist of fees that fall under the 3 categories previously specified:

1. Pre-market evaluation (EVAL)
    - A fee will be charged for applications for new NHP products or applications to amend existing products.
2. Site licences (SL)
    - A fee will be charged to assess new NHP site licence applications or amendments to site licences.
    - An annual site licence fee will be charged to each facility that manufactures, imports, labels and/or packages NHPs to support site licence renewal and post-market compliance and enforcement activities. For sites conducting multiple regulated activities, one fee associated with the most expensive activity undertaken at that site will be charged.
3. Right to sell (RTS)
    - An annual fee will be charged to allow companies the exclusive right to sell their NHPs in Canada.

Table 1 details each activity category for which fees are being proposed, along with corresponding performance standards (existing or proposed standards, whichever applies). For a summary of the costing methodology used to calculate the full costs used to establish these fees, refer to Annex B.

In some cases, a new performance standard is longer than the existing one. This reflects the reality of assessing increasingly complex applications within those categories of activities. Note that the processing or reviewing of applications and the associated performance standard will not begin until the fee has been paid and the screening is complete (where applicable). Non-payment of fees could lead to the withdrawal or withholding of the applicable product, site licence or update to an existing licence (in the case of an amendment request).

Table 1: Proposed NHP fees and performance standards (existing standards included where applicable)

Fee line/category	Proposed fee amount (2025) ($ CAD)	Existing performance standard (calendar days)	Proposed performance standard (calendar days)
Pre-market evaluation *(EVAL)*			
Class I application or amendment	$1,124	60	60 to review application/amendment
Class II application or amendment	$2,761	90	120 to review application/amendment
Class III application or amendment	$7,209	210	210 to review application/amendment
Class III novel application	$58,332	210 (if treated as a Class III)	300 to review application
Class III novel safety and efficacy amendment	$23,333	210 (if treated as a Class III)	210 to review amendment
Class III novel quality amendment	$8,750	210 (if treated as a Class III)	210 to review amendment
NHP site licences (SL)			
SL applications or amendments	$4,784	30 to 90	180 to review application/amendment
Annual SL - manufacturing - sterile dosage form	$40,071	30 to 90 (for renewals)	90 to review licence renewal application or confirm licence information
Annual SL - manufacturing - non-sterile dosage form	$23,071		
Annual SL - importation	$20,035		
Annual SL - packaging	$7,650		
Annual SL - labelling	$6,921		
NHP right to sell (RTS)			
NHP RTS (per NPN or DIN-HM)	$542	N/A	60 to update licensed NHP database

Note: Unit costs were adjusted to cover the time between when the costing data was collected/calculated and when the fees will be implemented: 3.4% for 2021-22 and 2% for each of 2022-23, 2023-24 and 2024-25.

The proposed performance standards reflect the level of effort and time required to review and process. Each standard has a unique set of activities:

- The pre-market evaluation (EVAL) standards consider the time it takes Health Canada to review the submission package. This does not include the time it takes to conduct the initial screening.
- The site licence (SL) standards consider:
- for SL applications or amendments, the time it takes to review the data submitted with the corresponding application
- for annual SLs, the time it takes to review the information submitted with the renewal package or to confirm with the licence holder the existing licence information, should a licence not be up for renewal during a particular year
- While sites are renewed every 1 to 3 years as per section 36 of the NHPR, the fee proposed here is payable annually (the associated performance standard applies regardless of whether it is a renewal year or not).
- The RTS standard considers the time it takes Health Canada to update the Licensed Natural Health Product Database with information on products on the market.

Performance, revenue and costs for each fee line will be reported in the annual Report on Fees. As is the current approach to fees for drugs and medical devices, fees for NHPs will be adjusted annually after implementation, according to the consumer price index (CPI) from the previous year, to factor in inflation. (Fees are rounded to the nearest dollar.)

Pre-market evaluation (EVAL) fees

To sell NHPs in Canada, a company must hold a valid product licence. Under this fee proposal, there will be 3 classes of NHPs in Canada for which product licences can be obtained. These classes are differentiated by their level of adherence to pre-cleared information (product monographs).

Fees for product evaluation allow for Health Canada to review product safety, efficacy, quality and specific conditions of use. We will charge the same fee for applications or amendments, as the level of effort to review these is comparable. We will not charge a fee for notifications, which are changes to NHPs that do not have a significant impact on the product's safety, efficacy and/or quality, as per section 12 of the NHPR).

As per the NHP Management of Applications Policy, classes of NHPs are as follows:

- **Class I**: Applications that must comply with all of the parameters of an individual Natural and Non-prescription Health Products Directorate (NNHPD) monograph (exactly as worded in the monograph) and can only reference 1 NNHPD monograph
- **Class II**: Applications that must be supported entirely by a combination of 2 or more monographs with or without deviations and without combination issues, or 1 monograph with limited deviations
- **Class III**: Applications that require full assessment (not captured in Class I or II), including products with ingredient combination issues and applications partially referencing monograph information but going beyond the parameters established in the relevant monograph(s)

Health Canada is also proposing a new sub-category called **Novel Class III**, to ensure the Class III fee is not skewed by certain exceptional applications. The fee for this new category reflects the cost of reviewing products with novel active ingredients, a novel combination of active ingredients, a novel use or purpose, or a novel physical form. This means that some existing Class III products will be re-profiled into Novel Class III NHPs. However, we expect this new category to apply to just 1% of applications going forward.

Note: The cost of conducting risk management plan (RMP) reviews is not being factored into the proposed fees at this time. However, these costs may be included in the future, at least for the higher-risk Novel Class III category.

Site licence (SL) fees

Site licence application fees will be charged to review applications for new SLs. The same fee will be charged to review amendments to an existing SL as per section 32 of the NHPR, as the level of effort for us to review is the same.

We calculated SL application and amendment fees on a per site basis, rather than per application, as this is how fees will be charged upon implementation. We determined the unit cost for each new SL application or amendment application by dividing the fully loaded cost by the average number of sites listed on applications over the past 3 years. As the fee-setting ratio for SL is 100%, the unit cost is equivalent to the proposed fee. Refer to Annex B for more information.

We will be charging an annual fee to offset the costs of renewing SLs, as well as for compliance and enforcement activities such as inspecting facilities that manufacture, import, package or label NHPs. This fee will offset activities related to verifying that facilities (rather than products) meet regulatory requirements (for example, good manufacturing practices). The annual SL fee will be tiered based on the complexity of the activity or activities being undertaken at each facility. Although the 1- to 3-year licence renewal schedule under the NHPR is the same, we will be charging the annual SL fee every year.

Right to sell (RTS) fees

Industry will be required to pay an annual fee for the right to sell NHPs in Canada. The fee will offset costs incurred by Health Canada to conduct post-market surveillance and compliance and enforcement activities, which together ensure the safety of NHPs being sold in Canada.

Surveillance activities include:

- signal detection and assessment
- reviews of annual or periodic safety summary reports
- oversight and enforcement of regulatory requirements related to NHP advertising
- risk communications

Compliance and enforcement activities include compliance verifications to handle:

- recalls
- safety issues
- complaints
- laboratory analyses
- activities to address illegitimate products at the Canadian border

Summary of fees policy

Table 2 summarizes the fee policy according to its key elements.

Table 2: Breakdown of proposed fee policies for NHPs

Fee-setting ratios (ratios that are applied to the full costs to determine what the fee should be)	Fee-setting ratios proposed for NHPs are the same as the established ratios for human drugs and medical devices: • **100%** for SL fees • **75%** for EVAL fees • **67%** for RTS fees
Annual fee adjustments	Annual fee adjustments will be tied to the CPI of the previous year, rounded up to the nearest dollar.
Small business mitigation	Fee-reduction measures that have been established for cost recovery for drugs and medical devices will also be applied for NHPs. Companies must meet our small business definition (fewer than 100 employees **or** between $30,000 and $5 million in gross annual revenue, including affiliates). Registered small businesses will be eligible for the following fee remissions: • **100%** for first-ever NHP EVAL product submission • **50%** for all subsequent EVAL submissions • **25%** for SL and RTS fees
Performance standard	Each fee category has a corresponding performance standard, as per **Table 1**.
Penalty provision(through remission)	Applicants will receive a **25%** fee remission when we are unable to meet a performance standard (note that the pause-the-clock mechanism may be applied).
Pre-market evaluation (EVAL) fees	The applicable Class I, II, III or III novel fee will be charged for: • a product licence application • an amendment of an application
Site licensing (SL) fees	There are 2 types: • fee per application for new SL application and amendment to an existing SL (per site) • annual fee per site listed on the SL (a tiered fee based on the complexity of regulated activities conducted at the site)
Right to sell (RTS) fees	Annual fee for each individual NPN or DIN-HM held by a company

International analysis

Health Canada's regulatory regime is not directly comparable to those of other countries. However, it is important for us to be aware of and understand how other regulators treat natural health products (NHPs) when setting up a cost-recovery regime in Canada.

Health Canada looked at 4 regulators:

- European Medicines Agency (EMA) (English only)
- Australia's Therapeutic Goods Administration (TGA) (English only)
- United States' Food and Drug Administration (U.S. FDA) (English only)
- United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) (English only)

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.

For example, in the U.S., most herbal medicines are considered dietary supplements and are not evaluated before being marketed. There are also no U.S. FDA-approved products labelled as homeopathic. The FDA published a draft guidance on complementary and alternative medicines (English only) in 2007 (last updated in May 2020) outlining how it regulates various products.

In Australia, therapeutic products are classified based on level of risk, so NHPs may be subject to the same requirements as non-prescription drugs depending on their risk categorization.

In the European Union (EU), most herbal medicines are considered to be drugs, though they are not centrally authorized. Typically, herbal medicines have been in use before the EMA was created (central authorization is only for new medicines) and would have been authorized at the national level for 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:

- market authorization (English only)
- classification as drugs (English only)

Fees may also vary depending on the claims made or the type of marketing authorization chosen.

For example, in Australia, "listed medicines" are not eligible to make any health claims. However, a claim to prevent, alleviate or cure a serious form of a disease, ailment, defect or injury will automatically incur a high-risk categorization regardless of ingredients:

- differences among listed/assessed listed/registered medicines (English only)
- listed medicines are defined as not required to be TGA-assessed before being sold in the market
- thus, they are not eligible for any health claims
- health claims (English only)

In EU member states, different fees apply depending on whether the company is seeking to market the product on a national level or in other partner countries as well:

- Guide to fees for human products (refer to section 1.9) (English only)
- applying the codes in the Guide to the associated excel file returns the application prices of new homeopathic products

Fees for site licensing also vary due to other factors. However, for our international comparison, we focused on fees for manufacturing sites, as this information was readily available.

Overall, compared to other jurisdictions where a given NHP is considered a drug, the fees proposed by Health Canada are lower. Where a given NHP is not regulated as a health product or is unregulated, the fees proposed by Health Canada are higher. For example, the European Commission considers most herbal products to be drugs and has correspondingly higher levels of oversight and fees. Several other jurisdictions also have measures to support small businesses. For example, in the United Kingdom, companies meeting their small business definition qualify for 25% to 50% fee reductions and payment deferrals (English only).

The EMA also waives some fees for micro businesses:

- Article 70 of Regulation (EC) No 726/2004 of the European Parliament and of the Council (English only)

Table 3 summarizes regulatory frameworks and fee ranges across jurisdictions (conversion rate as of December 7, 2022. For a more detailed comparison, consult Annex C.

Table 3: Comparing Canada's NHP regulatory regime to other foreign regulators

	Health Canada (proposed)	Australia/TGA	United Kingdom/MHRA	European Union/EMA	United States/FDA
Product classification	Class I, II, III Separate from drugs or foods	From listed (low risk), assessed listed, to registered (high risk) medicines[1]	From dietary supplement to prescription medicine	From food supplement, herbal medicine, to drug	From dietary supplement to drug
Product licensing fee	$1,124 to $58,332	Listed and assessed listed products: $1,229 CAD ($893 + $451 AUD) Registered products: $38,433 CAD ($3,047 + $38,988 AUD)	$856 CAD (£517) to $8,290 CAD (£5,006) (homeopathic to new drug application)	$0 to $449,520 CAD (€313,200) (marketing authorization application)	$0 (up to $823,706 CAD or $633,620 USD for comparable products[2])
Annual product fee	$542	$1,094 CAD ($1,200 AUD) to $1,440 CAD (1,580 AUD)	$126 CAD (£76) to $4,021 CAD (£2,428) based on product classification (periodic homeopathic/herbal to standard)	$0 to $161,035 CAD (€112,200) based on product classification (maintenance of a marketing authorisation)	N/A
SL fee	$4,784	Initial fee of $766 CAD ($841 AUD) + variable inspection cost (manufacturing licences)	$303 CAD (£183) to $5,205 CAD (£3,143) (NOP[3] to standard licence application)	$34,015 CAD (€23,700) + variable inspection cost	$21,921 to $32,880 CAD ($16,119 to $24,178 USD) (monograph

	Health Canada (proposed)	Australia/TGA	United Kingdom/MHRA	European Union/EMA	United States/FDA
Annual site fee	$6,921 to $40,071	$4,507 CAD ($4,945 AUD) (annual charges for manufacturing licences)	$775 CAD, (£468) (periodic manufacturing licence)	Up to $31,575 CAD (€22,000) (from Ireland) (annual fee major site)	drug facility fee)[4]
Fee reduction	First NHP product application free for small business, 25% to 50% reduction thereafter 25% to 50% reduction also applies to SL applications and amendments and right to sell	Annual product fee deferred until product sold on market 50% annual licence fee reduction for small businesses[5]	25% to 50% fee reduction for small business and payment deferrals[6]	40% to 100% fee reduction for micro and small businesses,[7] orphan drug fee reductions and payment deferrals for inspection and marketing authorization[8]	N/A

[1] Products are defined by 3 levels of risk. Listed medicines are the lowest categorization a product could receive. If the product refers to the prevention, cure or alleviation of a non-serious form of a disease, ailment, defect or injury, it is a medium-risk product and must comply with the requirements and fees for assessed listed medicines. If the product refers to prevention, alleviation or cure of a serious form of a disease, ailment, defect or injury, it is a high-risk product and must comply with the requirements and fees for registered medicines.

[2] Some products that are considered NHPs in Canada are considered drugs in the U.S. (for example, homeopathics, alcohol-based sanitizers, essential oils/aromatherapies). They therefore have a product fee associated with them.

[3] The U.K.'s SL fee varies based on type of applications. NOP = non-orthodox practitioners/ wholesaler licences/manufacturer licences. Consult the Guidance to apply for manufacturer or wholesaler of medicines licences (English only).

[4] Consult the Over-The-Counter Monograph Drug User Fee Program (English only).

[5] Consult Part 7 – 43AAJ, *Therapeutic Goods Regulations (1990)* (English only).

[6] Consult the Statutory guidance on payment easements and waivers for small and medium companies (English only).

[7] Consult Table 5.1.2 (English only).

[8] Refer to page 40 of the Explanatory note on general fees payable to the European Medicines Agency (English only).

Consultation process

Health Canada is committed to meaningful consultation.

For this fee proposal, the consultation will run for 75 days, starting on May 12, 2023.

Stakeholders will have an opportunity to provide feedback and identify concerns about this fee proposal through an online comment form. This form will be available throughout the consultation period.

We will also be offering additional engagement opportunities to support participation in this consultation.

Once the consultation period ends, Health Canada will:

- collect and review the comments before finalizing the fee structure
- publish the feedback, along with our response, at a later date

Conclusion

Following an audit of the natural health products (NHP) program by the Commissioner of the Environment and Sustainable Development, CESD issued its findings and recommendations.

Based on this audit, Health Canada is committed to pursuing cost recovery for NHPs, both to ensure program sustainability and to strengthen the program's key activities.

The fees described in this proposal factor in our costs to provide industry with regulatory services and oversight. They will also help shift the burden of NHP regulation away from taxpayers.

We hope to start charging fees on April 1, 2025. We are offering fee remissions for registered small businesses and for missed performance standards. This will ensure that applicants are compensated in the event that standards are not met.

A cost-recovery regime for NHPs is a key step forward to ensuring that Health Canada continues to:

- provide reliable regulatory oversight to the NHP industry
- promote access to safe, effective, and high-quality NHPs for people in Canada

Annex A, CESD report

The Commissioner of the Environment and Sustainable Development (CESD) looked at natural health products (NHPs) and published a report with its recommendations in 2021. Health Canada committed to implementing the recommendations. To finance the changes that will result from addressing the CESD recommendations, we will be charging fees. This new fee structure will help to reduce the need for public funds.

Read the CESD 2021 report on natural health products.

Recommendation 2.26

Health Canada should obtain sufficient evidence to verify that licensed sites follow good manufacturing practices before products are released on the market and obtain information about which NHPs are available on the market.

Health Canada response

Health Canada notes its limited regulatory authorities to compel companies to provide information on quality as part of the product licence submission process. Applicants are required to provide only an attestation that their product will meet the prescribed quality requirements. To improve its pre-market quality oversight of natural health products, the department has been using information gathered through 2 compliance monitoring projects and a paper-based audit of good manufacturing practices at several manufacturing sites. The department also acknowledges that natural health products are the only line of health products for which all regulatory activities are funded by the public. The absence of a stable funding framework combined with the limited regulatory authorities for quality has placed significant pressure on the department to perform its regulatory activities and efficiently respond to the increasingly high number and scientific complexity of product submissions. In response to this recommendation, the department will: establish fully costed options for a risk-based approach to quality oversight prior to the issuance or renewal of licences and determine the full regulatory and operational implications of these options; explore mechanisms to obtain information about which products are available on the market; and take steps to propose user fees to natural health products to offset the costs of licensing and post-market activities.

Recommendation 2.47

Health Canada should develop a risk-based monitoring and inspection program that establishes the scope and frequency of inspections and that considers risks related to products, sites, and problems raised from its follow-up activities.

Health Canada response

Health Canada recognizes that natural health products are the only line of health products for which there is no ability to mandate a recall or to impose terms and conditions to mitigate safety risks associated with these products. The department has completed several compliance monitoring projects to gather information on quality oversight of natural health products and recognizes the need to expand its activities into a more robust inspection program. The department will: implement a pilot program for inspecting the good manufacturing practices of natural health products to promote and verify compliance of the natural health product industry through inspections of licence holders across Canada and take further actions on the basis of the outcome of this pilot; take steps to propose new tools to strengthen the department's ability to deter and address non-compliance, which include moving forward with a proposal to extend to natural health products the use of powers under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law); establish fully costed options for a risk-based approach to inspections; and take steps to propose the expansion of user fees to natural health products to offset the costs of post-market activities.

Recommendation 2.56

Health Canada should, in cases of products suspected of causing serious health risk, obtain the information it needs to verify and ensure that these products are not available for sale to consumers in Canada.

Health Canada response

In addition to the immediate steps Health Canada already takes to protect the health and safety of Canadians when a serious risk to health is identified, the department will: take steps to propose new tools to strengthen its ability to deter and address non-compliance, which include moving forward with a proposal to extend to natural health products the use of powers under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law); and take steps to propose the expansion of user fees to natural health products to offset the costs of licensing and post-market activities.

Annex B, Costing data and tables

Costing methodology

Health Canada's approach to costing for activities relating to health products is based on the Treasury Board Secretariat's Guide to Cost Estimating. This guide sets out the Government of Canada's concepts and principles for costing. Our approach was used to update the fees for drugs and medical devices in 2020 and to develop the fee proposal for biocides in 2022.

Health Canada has a program-wide time tracking system (the Cross-Application Timesheet – Project System, or CATS-PS) for health products. We use this system to collect level of effort by activity, including tracking the time spent reviewing individual applications. Costs are calculated by applying employee salaries to this level of effort, based on the highest pay level for the employee's classification and the most recent rates of pay. This system allows both direct program costs and indirect program costs to be assigned to activities based on their use of resources.

We also developed and implemented a tool that defines key health product activities and thus enables us to allocate costs across programs and product lines.

The information from both tools is aligned with the data in our financial system (SAP), which allows for more accurate cost mapping.

We also have methodologies in place to allocate internal and corporate services and capital costs.

The information from these structures and systems was used to establish and validate the proposed fees.

Existing costs

We determined the costs of current NHP activities by totalling all applicable costs (program direct and indirect costs, corporate costs and capital costs). We developed a costing model that makes it possible to link costs to specific activities within a branch and to calculate total costs by fee line. We used 3 fiscal years of data (2018-19, 2019-20 and 2020-21) from the time tracking system and made adjustments where necessary.

The total costs include both the direct costs to support product and site licence applications as well as indirect costs. Costs were allocated proportionally as follows:

- direct service support costs (for screening, managerial review and approval, and oversight of individual reviews) to all activities within the associated fee
- indirect costs to all activities within the program
- corporate costs to all activities across all programs

Costs by type are summarized in Table 4.

Table 4: NHP costs by type

Program costs	**Direct:** Includes costs for submission review, compliance and enforcement, and post-market surveillance Includes salary for NHP application reviewers and inspectors, costs associated with laboratory analysis, and operating and maintenance costs **Direct service support:** Includes costs for activities that support individual activities, such as screening, reviewing and approval processes of individual submissions/inspections or the oversight of direct activities **Indirect:** Includes costs for program overhead (such as management, planning and reporting, policy work, and audit and evaluation work)

Capital costs	Includes maintenance, upgrade and investment costs for laboratory equipment, information systems and fleet costs for inspectors
Corporate costs	These costs are related to services provided by Health Canada's corporate branches, including: • 22% of total program costs for internal services (such as management and oversight for access to information requests, audits and evaluations, communications, human resources, financial management, information management and technology • 27% of salary costs for the Employees Benefits Program • 13% of salary costs for accommodation • 4% of salary costs for Shared Services Canada

Prospective costs

Health Canada is committed to undertaking new activities to improve the NHP program. Our goal is to:

- establish a risk-based approach to:
- quality oversight before we issue or renew a licence
- inspections to promote and verify compliance of the NHP industry with good manufacturing practices (GMP)
- improve labelling of NHPs
- obtain information about which products are available on the market
- require licence holders to display a Canadian label, including an NPN or DIN-HM, in advertisements targeted to people in Canada
- implement a comprehensive, proactive risk-based monitoring strategy to ensure that advertising of NHPs is consistent with the product licence
- implement a permanent risk-based inspection program
- develop new tools to strengthen our ability to deter and address non-compliance, including a proposal to extend to NHPs the use of powers under the *Protecting Canadians from Unsafe Drugs Act*

To meet the proposed obligations, including establishing a robust fee regime, we need more resources, such as:

- staff for a new inspection program
- more staff to handle new review components within the existing NHP framework and to ensure performance standards are sustainably met
- more management and management support staff to support new reviewers
- invoicing capabilities
- more information technology (IT) resources
- increased operating budgets to support these additional resources

Costs for these prospective resources were added to the existing unit costs, to generate an overall unit cost for each fee. Methodologies to establish costs under each individual fee line are described in the next sections.

Costing for pre-market evaluation (EVAL) activities

This fee line includes activities such as:

- individual product licence application review
- application screening and processing
- application coordination and management
- scientific/technical management

We used the costing method described earlier to determine the hourly rate and the volume and average time spent on applications within each existing fee category. This data was based on all applications completed between April 2018 and March 2021 (the reference period). We then determined the hourly rate for each fee line by dividing the total costs by the calculated total direct hours spent on each fee line. To arrive at the current unit cost for each fee line, we multiplied the hourly rate by the average time required to complete an application in that fee line.

For Class III novel applications, we used the same hourly rate as for Class III applications. The time to complete this new application type was estimated to be 70 hours, which is consistent with time tracking data for the most complex NHP submissions.

For Class III novel amendments, we have set the fee as follows:

- at 40% of the proposed fee for Class III novel application for safety and efficacy amendments
- reflects a projected level of effort
- at 15% of the Class III novel application fee for quality amendments

We have not factored into the current fee structure the costs associated with conducting risk management plan (RMP) reviews. We will, however, be tracking our costs and revising the fee structure in the future as appropriate.

Prospective costs were added for the following:

- more staff to handle the increase in volume (based on historical trends) and to ensure performance standards are met
- risk-based quality reviews for all products, within the existing NHP framework, with implementation of an automated validation system for low-risk submissions
- business improvements to address the CESD audit, such as:
- improving quality assurance
- updating guidance for applicants
- developing tools for removing industry irritants in the application process
- revising monographs to ensure that products can move down to a lower class when sufficient evidence has been received and reviewed by Health Canada to provide assurance of a product's safety
- invoicing capabilities
- IT modernization and ongoing support
- increased operational costs related to new staff and to correct under-resourcing of current staff

Corporate costs were applied to prospective costs in the same way as for existing costs. We then calculated the prospective unit cost by dividing total prospective costs (including corporate costs) by the number of applications received in the reference period. Note the overall unit cost is the sum of the existing and prospective unit costs.

The prospective costs are higher than the existing costs because of required investments to improve the regulatory program and meet the commitments of the CESD audit.

For example, for Class I applications, there are significant system and IT investments to support the automated validation system for single ingredient applications and to support and update various web applications. For Class II and III applications, there is a significant investment of resources to support the implementation of quality review, which is not currently being done.

Additional resources have also been included in the prospective costs for Class III to help ensure performance standards can be met. In addition, all fee lines will require digitization, so those costs have also been added.

Pre-market evaluation costs are summarized in Table 5.

Table 5: Estimated total costs for EVAL fees

Activity or amendment	Average annual existing costs	Average annual volume	Average level of effort (hours)	Existing unit cost	Estimated annual prospective costs	Prospective unit cost	Unit cost[1]
Class I application or amendment	$1,840,975	5,091	0.92	$336	$5,244,156	$1,030	$1,366
Class II application or amendment	$3,186,350	2,086	2.72	$1,415	$4,046,157	$1,940	$3,355
Class III application or amendment	$13,850,581	2,898	9.17	$4,645	$11,925,726	$4,115	$8,759
Class III novel application	$1,276,430	36	70	$35,456	$1,275,267	$35,424	$70,880

[1] Full costing data spreadsheets, including hourly rates (used to generate unit costs for the portion of current, as opposed to prospective, costs) are managed internally by Health Canada. These rates are not included in the fee proposal.

Costing for site licence (SL) activities

This fee line includes activities such as:

- site inspections and related compliance and enforcement activities
- review of applications and amendments for SLs
- processing of SL renewals

We used the same costing method and 3-year timeframe that was used for EVAL fees to calculate existing costs for each SL fee. Each type of fee includes costing as follows:

- direct costs for existing SL applications, amendments and renewals
- costs of activities related to foreign sites and generic site licensing activities

Prospective costs were then added to take into account the following:

- a new inspection program (to annual fee only)
- more staff to handle the forecasted increase in application volumes (based on historical trends) and to ensure performance standards are met
- business improvements to address the CESD audit, such as:
- improving quality assurance
- updating guidance for applicants
- developing tools for removing industry irritants in the application process
- invoicing capabilities
- IT modernization and ongoing support

- additional operational costs related to new staff and to correct historical under-resourcing of current staff

While IT costs are allocated to both SL applications and annual fees, IT projects related to site licensing were more heavily allocated to the licence application costs. This is due to the increased level of effort required compared to renewals.

Corporate costs were applied to prospective costs in the same way as for existing costs.

Costing for SL applications and amendments

To arrive at the unit cost, we added existing and prospective unit costs together and then divided this total by the average annual number of sites in the reference period. Since this is effectively a per-site costing, the associated fee (Table 1) applies to each site listed on the application or amendment.

Site licence costs for applications and amendments are summarized in Table 6.

Table 6: Estimated total costs for SL fees (applications and amendments)

Activity	Average annual existing costs	Average annual volume	Existing unit cost	Estimated annual prospective costs	Total annual costs	Unit cost
NHP SL applications and amendments	$2,359,973	1,261	$1,871	$3,139,730	$5,499,703	$4,360

Costing for annual SL fee activities

To arrive at the total cost under this fee, we added existing and prospective unit costs for licence renewals, prospective costs for the new risk-based inspection program and all applicable support costs. We then divided this total cost by the total number of inspection hours planned in the first year that cost recovery is implemented. This final number is the per hour inspection cost. We then applied this hourly inspection cost to each site (where a site is a unique building listed on a site licence) based on the complexity of the activity.

Since the inspection program will be risk-based, not every site will be inspected on a cyclical basis. The complexity of a site's activities was used to estimate regulatory level of effort. For example, sterile manufacturing has the greatest potential of risk to health and is therefore the most complex regulated activity to oversee. This regulated activity is therefore expected to receive the most hours of oversight from the inspection program compared to other site types.

Site types from most to least expensive to regulate are as follows:

- Manufacturing – sterile dosage form
- Manufacturing – non-sterile dosage form
- Importing
- Packaging
- Labelling

For sites conducting multiple regulated activities, we will charge the fee associated with the most expensive activity undertaken at that site. This single fee will cover all the other less expensive activities undertaken at the same site.

As warehouses are not currently regulated under the *Natural Health Products Regulations*, there is no fee associated with those sites, although they will continue to be listed on site licences.

SL costs for the annual fee are summarized in Table 7.

Table 7: Estimated total costs for SL fees (annual fee)

Activity	Average annual existing costs	Estimated annual prospective costs	Total annual costs
SL annual fee	$1,623,618	$14,194,368	$15,817,986

The good manufacturing practices (GMP) inspection program is a new program created in response to the CESD audit. We calculated costs based on the expected program size in the first year that cost recovery is implemented and have included all support costs.

The costs related to the GMP program and licence renewal are summarized in Table 8.

Table 8: Estimated total costs related to licence renewal and the GMP inspection program

Site most complex activity	Total cost	Cost per inspection hour	Estimated inspection hours each year per site	Unit cost per site
Manufacturing - sterile dosage form	$15,817,986	$474.26	77.00	$36,518
Manufacturing - non-sterile dosage form			44.33	$21,025
Importing			38.50	$18,259
Packaging			14.70	$6,972
Labelling			13.30	$6,308

Costing for right to sell (RTS) activities

The RTS fee line funds activities that identify and address safety issues and uphold regulatory compliance. This includes post-market surveillance activities such as:

- signal detection and assessment
- reviews of annual/periodic safety summary reports
- overseeing and enforcing the regulatory requirements related to NHP advertising and risk communications
- product-specific compliance verification
- Canadian border admission
- laboratory testing activities

We calculated costs for post-market surveillance under the RTS fee using the costing method described earlier and the same 3-year dataset as for EVAL and SL fees. All costs were averaged to produce an annual current cost.

We calculated compliance and enforcement costs under the RTS fee using the same costing method with a 1-year dataset (fiscal year 2020-21), as that year's activities represent the expected level of work moving ahead. No additional annual prospective costs for compliance and enforcement were added to these costs.

Annual prospective costs were then added for the following:

- more staff to handle increases in post-market activities and processing notifications
- risk management and quality audits
- stakeholder engagement
- education for stakeholders and consumers
- invoicing capabilities
- IT modernization and ongoing support

- additional operational costs related to new staff and to correct historical under-resourcing of current staff

Note that corporate costs were applied to prospective costs in the same way as for existing costs.

For example, prospective costs for RTS reflect the following:

- support for compliance and enforcement activities if product non-compliance is found during a site visit
- resources to increase oversight activities
- for example, inspection, quality review, proactive advertising
- quality audit function
- additional resources to support stakeholder engagement and education outreach efforts

We calculated the RTS unit cost by adding the total annual existing and prospective costs and dividing by the estimated number of marketed NHPs. The estimate of 50,000 NHPs, which was used to develop the amendments to the *Natural Health Products Regulations* in 2021, was applied. (Note: Responses provided by an industry association and information provided by stakeholders responding to a survey were used to help develop this estimate.)

RTS costs are summarized in Table 9.

Table 9: Estimates total costs for RTS fees

Activity	Average annual existing costs	Estimated annual prospective costs	Total costs	Estimated volume	Unit cost
RTS	$20,478,528	$16,357,357	$36,835,885	50,000	$737

Annex C, International comparison of NHP regulation

Table 10: Comparison of fees by select NHP type, Canada, and other international regulators

NHP product	Canada (CAD)	Australia (AUD) CAD/AUD 0.91	UK (GBP) CAD/GBP 1.66	EU (EUR) CAD/EUR 1.43	US (USD) CAD/USD 1.36
Herbal remedies	NHP – Class II	Listed medicine	Traditional herbal remedy	Herbal medicinal product	Dietary supplement-drug
	Submission review $2,761	Submission review ($1,129 to $25,240 AUD) approx. $1,027 to $22,968 CAD Standard: 45 to 150 working days	Submission review (£2,423 to £7,269) approx. $4,013 to $12,038 CAD Processing time: 150 days	Scientific opinion (€15,400 to €23,700) approx. $22,103 to $34,105 CAD national level (ex. Ireland) Submission review (€3,370 to €5,495) approx. $4,837 to $7,887 CAD Processing time: 210 days	N/A
	RTS ($542)	Annual charge ($1,200 AUD) approx. $1,097 CAD	Periodic (annual) fee (£76) approx. $126 CAD	Annual fee (€125) approx. $179 CAD	N/A
	SL ($4,784 application, up to $23,071 annual)	Manufacturing licence ($841 AUD initial + $4,945 AUD annual) approx. $769 CAD initial + $4,521 CAD Inspection fee ($1,047 AUD/hour/inspector)	Manufacturer's licence (£183 to £3,143 initial +£468 annual) approx. $303 to $5205 + $775 annual CAD Inspection fee (£295 to £1,615/day) $489 to $2,675 CAD	Manufacturer's authorization (€2,080 initial + €4,500 to €22,000 annual) approx. $2,985 initial + $6,459 to $31,575 CAD Processing time: not available	Facility fee ($0 to $24,178 USD annually), approx. $0 to $32,881 CAD Processing time: not available

NHP product	Canada (CAD)	Australia (AUD) CAD/AUD 0.91	UK (GBP) CAD/GBP 1.66	EU (EUR) CAD/EUR 1.43	US (USD) CAD/USD 1.36
		approx. $957 CAD Processing time: up to 12 months	Processing time: 90 days		
Homeopathic medicines	**NHP Class I**	**Listed medicine**	**Homeopathic medicine**	**Homeopathic medicine**	**Drug**
	Submission review ($1,124) Standard: 60 calendar days	Submission review ($1,129 to $25,240 AUD) approx. $1,027 to $22,968 CAD Standard: 45 to 150 working days	Submission review (£517 to £1,312 depending on if components have already been assessed) approx. $856 to $2,172 CAD Processing time: 150 days	National level (ex. Ireland) Submission review (€510 to €1,685) approx. $732 to $2,291 CAD Processing time: 210 days	Processing time: 10 months
	RTS ($542)	Annual charge ($1,200 AUD) approx. $1,097 CAD	Periodic (annual) fee (£76) approx. $126 CAD	Annual fee (€60) approx. $86 CAD	N/A
	SL ($4,784 application, up to $23,071 annual)	Manufacturer's licence ($841 AUD initial +$4,945 AUD annual) approx. $769 CAD initial + $4,521 CAD Inspection fee ($1,047 AUD/hour/inspector) approx. $957 CAD	Manufacturer's licence (£183 to £3,143 initial +£468 annual) approx. $303 to $5,205 + $775 annual CAD Inspection fee (£968 to £2,655/day) approx. $1,603 to $4,397 CAD Processing time: 90 days	Manufacturer's authorization (€2,080 initial + €1,125 annual) approx. $2,985 initial + $1,615 CAD Processing time: not available	Facility fee ($24,178 USD annually) approx. $32,881 CAD Processing time: not available

NHP product	Canada (CAD)	Australia (AUD) CAD/AUD 0.91	UK (GBP) CAD/GBP 1.66	EU (EUR) CAD/EUR 1.43	US (USD) CAD/USD 1.36
		Processing time: up to 12 months			
Traditional medicines	**NHP Class I**	**Listed medicine**	**Traditional herbal medicine**	**Herbal medicinal product**	**Dietary supplement-Drug**
	Submission review ($1,124) Standard: 60 calendar days	Submission review ($1,129 to $25,240 AUD) approx. $1,027 to $22,968 CAD Standard: 45 – 150 working days	Submission review (£2,423 to £7,269) approx. $4,012 to $12,038 CAD Processing time: 150 days	National level (ex. Ireland) Submission review (€3,370 to €5,495) $4,837 to $7,887 CAD Processing time: not available	N/A
	RTS ($542)	Annual charge ($1,200 AUD) approx. $1,097 CAD	Periodic (annual) fee (£76) approx. $126 CAD	Annual fee (€125) approx. $179 CAD	N/A
	SL ($4,784 application, up to $23,071 annual)	Manufacturer's licence ($841 AUD initial +$4,945 AUD annual) approx. $769 CAD initial + $4,521 CAD Inspection fee ($1,047 AUD/hour/inspector) approx. $957 CAD	Manufacturer's licence (£183 to £3,143 initial +£468 annual) approx. $303 to $5,205 + $775 annual CAD Inspection fee (£295 to £1,615/day) approx. $457 to $2,503 CAD Processing time: 90 days	Manufacturer's authorization (€2,080 initial + €4,500 to €22,000 annual) approx. $2,985 initial + $6,459 to $31,575 CAD Processing time: not available	Facility fee ($0 to $24,178 USD annually) approx. $32,881 CAD Processing time: not available

NHP product	Canada (CAD)	Australia (AUD) CAD/AUD 0.91	UK (GBP) CAD/GBP 1.66	EU (EUR) CAD/EUR 1.43	US (USD) CAD/USD 1.36
		Processing time: up to 12 months			
Sterile Saline Mist	**NHP – Class III**	**Registered medicine**	**Medicine**	**Medicine**	**Dietary supplement - drug**
	Submission review ($7,209) Standard: 180 calendar days	Application and evaluation fees ($585 to $3,047 AUD + $3,355 to $38,988 AUD) approx. $535 to $2,773 CAD + $3,053 to $35,479 CAD Standard: 45 – 210 working days	Submission review (£2,564 to £92,753) approx. $4,246 to $153,607 CAD Processing time: 150 days	Scientific opinion (€15,400 to 23,700) approx. $22,103 to $34,105 CAD National level (ex. Ireland) Authorization (€6,120 to €51,000) approx. $7,895 to $65,790 CAD Processing time: 210 days	N/A
	RTS ($542)	Annual charge ($1,580 AUD) approx. $1,445 CAD	Periodic (annual) fee (£307 to £2,428) approx. $508 to $4,021 CAD	Annual fee (€730) approx. $1,044 CAD	N/A
	SL ($4,784 application, up to $40,071 annual)	Manufacturer's licence ($841 AUD initial + $4,945 AUD annual) approx. $769 CAD initial + $4,521 CAD Inspection fee ($1,047	Manufacturers licence (£183 to £3,143 initial +£468 annual) approx. $303 to $5,205 initial + $775 annual CAD Inspection fee (£968 to	Manufacturer's authorization (€2,080 initial + €4,500 to €22,000 annual) approx. $2,985 initial + $6,459 to $31,575 CAD	Facility fee ($0 to $24,178 USD annually) approx. $32,881 CAD Processing time: not available

NHP product	Canada (CAD)	Australia (AUD) CAD/AUD 0.91	UK (GBP) CAD/GBP 1.66	EU (EUR) CAD/EUR 1.43	US (USD) CAD/USD 1.36
		AUD/hour/inspector) approx. $957 CAD Processing time: up to 12 months	£2,655/day) approx. $1,500 - $4,115 CAD Processing time: 90 days	Processing time: not available	
Vitamins and Minerals	**NHP – Class I**	**Listed medicine**	**Food supplement**	**Food supplements**	**Dietary supplement**
	Submission review $1,124 Standard: 60 calendar days	Submission review ($1,129 to $25,240 AUD) approx. $1,027 to $22,968 CAD Standard: 45 to 150 working days	N/A	N/A	N/A
	RTS $542	Annual charge ($1,200 AUD) approx. $1,097 CAD	N/A	N/A	N/A
	SL $4,784 application, up to $23,071 annual	Manufacturer's licence ($841 AUD initial +$4,945 AUD annual) approx. $769 CAD initial + $4,521 CAD Inspection fee ($1,047 AUD/hour/inspector)	N/A	N/A	N/A

NHP product	Canada (CAD)	Australia (AUD) CAD/AUD 0.91	UK (GBP) CAD/GBP 1.66	EU (EUR) CAD/EUR 1.43	US (USD) CAD/USD 1.36
		approx. $957 CAD Processing time: up to 12 months			