Health Canada Santé Canada

Canada

Natural Health Products Fee Proposal

Technical Briefing

May 25, 2023

Purpose

To introduce Health Canada's **proposed fee model** for natural health products (NHPs) and provide an **overview of proposed improvements** to the NHP program

"Overall, Health Canada's oversight of natural health products available for sale in Canada **fell short of ensuring that products were safe and effective**"

Report 2 | Reports of the Commissioner of the Environment and Sustainable Development (2021)

The audit identified the following gaps:

Quality
Increase oversight of the quality of NHPs, reduce reliance on attestations

Labelling and advertising
Greater monitoring of labels and advertising, product labels can be read by consumers

Monitoring and compliance
Risk-based inspections, new tools to deter and address non-compliance for serious health risks

In response...

- Health Canada has committed throughout the development of the Self-Care Framework, and in its response to the Commissioner of the Environment and Sustainable Development (CESD)'s audit of the NHP program, that expanding cost recovery to NHPs is critical to strengthening the program to meet the needs of Canadians and support its long-term sustainability

- To strengthen the NHP program, Health Canada publicly committed to improvements that fall under four main categories: **quality**, **labelling and advertising**, and **monitoring and compliance**

Cost recovery is an established practice

- Cost recovery is the practice of establishing and collecting fees. Health Canada has been charging fees to recover all or part of the costs incurred to deliver services related to drugs and medical devices since 1995. Many international regulators also charge fees for health product licensing and regulatory activities.
    - These services include the **scientific evaluation** of products before they are authorized for sale, the **monitoring** of these products once made available to Canadians and **verifying compliance** and acting on non-compliance using tools such as inspections.

- Revenues from fees cover all or part of the costs incurred to deliver those services, offsetting the burden to taxpayers.

- Health Canada has the authority under the ***Food and Drugs Act*** **(FDA)** to set fees for services and activities related to the regulation of health products, including pharmaceuticals, biologic drugs, medical devices, veterinary drugs and NHPs.

Cost Recovery – Guiding Principles

Accountability & Transparency

- Transparent fee setting and costing methodology
- Meaningful and inclusive stakeholder engagement
- Ongoing stakeholder communication
- Meaningful and measurable performance standards
- Accessible and constructive complaint resolution and dispute management process

Predictability & Sustainability

- Accurate and accessible fee schedules
- Consistent application of costing methodologies
- Clear and accessible remission policies
- Established processes for regularly reviewing and updating fees
- Routine assessment of new business lines for potential fee regimes

Stewardship & Fairness

- Appropriate fee-setting ratios, with fees that do not exceed full cost
- Consideration of fee mitigation measures, where appropriate
- Ongoing promotion of cost recovery business improvements
- Delivery of service in accordance with established service standards
- Ongoing cost monitoring and identification of cost containment measures
- Reimbursement in accordance with the remission policy

Current regulatory activities for product licensing

- ✓ Initial administrative and regulatory **screening**
- ✓ Assessing **safety and efficacy**
- ✓ Issuing **Information Request Notices** for deficiencies and omissions
- ✓ Issuing **regulatory decisions**
- ✓ Processing **notifications and amendments**
- ✓ Updating **monographs**
- ✓ Performing **product classification**

Current regulatory activities for site licensing

- ✓ Initial administrative and regulatory **screening**
- ✓ Assessing evidence of **compliance with Good Manufacturing Practices**
- ✓ Issuing **Information Request Notices** for deficiencies and omissions
- ✓ Issuing **regulatory decisions**
- ✓ Processing **notifications and amendments**
- ✓ Issuing **Foreign Site Reference Numbers**
- ✓ Assessing and processing **site licence renewals**

Proposed program improvements are designed to fill current gaps

Pre-market: Improved product quality oversight

Program improvements include:

- Reduced reliance on attestations
- Automated review of finished product specifications for some monographs
- Auditing to review quality evidence
- Updating critical guidance elements

Proposed program improvements are designed to fill current gaps

Compliance and enforcement: Increased effectiveness

Current State	Future State
Reactive, limited regulatory powers	**Deter and address non-compliance with increased oversight, timeliness, agility, enhanced tools**

Program improvements include:

- Permanent risk-based GMP inspection program
- Expanded regulatory powers to address non-compliance

Proposed program improvements are designed to fill current gaps

Post-market: Strengthened oversight of online advertising

Current State	**Future State**
Reactive monitoring, manual web scanning	**Proactive & risk-based monitoring, including automated web scanning**

Program improvements include:

- Proactive advertising monitoring - including expanding online advertising monitoring
- Ensuring labels more readable for consumers

Proposed fee types

The proposed fees fall into **three categories** – the same general categories currently used for other health products

Pre-Market Evaluation (EVAL)	Site Licences (SL)	Right to Sell (RTS)
For the assessment and licencing of new products entering the Canadian market, or amendments to existing products	For the assessment and licencing of facilities that manufacture, import, label, or package health products	For the ability to sell a product or products in Canada

Fee framework for NHPs

Fee setting ratios (cost %)

- **Pre-Market Evaluation fees** based on **75%** fee setting ratio
- **Site Licensing fees** based on **100%** fee setting ratio
- **Right to Sell fees** based on **67%** fee setting ratio

Performance Standards and Penalties

- Every fee has an associated performance standard
- In situations where the performance standard is not met, the applicant or licence holder will receive a rebate of **25%** of the fee paid
  - **Pause-the-Clock** provisions that allow for the count (in days) of a performance standard to be paused may apply under specified circumstances

Annual Adjustment

- Fees will increase annually by an amount equivalent to the Consumer Price Index (CPI) (rounded to the nearest dollar) from the previous year to ensure that fees continue to keep pace with the impact of inflation on costs

Non-payment of fees

- If fees are not paid, Health Canada can withhold or withdraw services or rights & privileges

Proposed fee mitigation

- Fee mitigation for **small businesses** was implemented as part of the April 1, 2020, fee update for drugs and medical devices. This is being extended to NHPs in the fee proposal.

- Qualifying small businesses (fewer than 100 employees **or** between $30,000 and $5 million in gross annual revenue including all its affiliates), are entitled to the following:

  - **50%** fee reduction for **pre-market evaluation fees**, with **100%** of the fee waived for **first NHP pre-market evaluation submission**
  - **25%** fee reduction for annual **Right to Sell** fees
  - **25%** fee reduction for **site licence fees**

- Fees are not applied to **publicly funded health care institutions** (licensed, approved or designated by a province/territory in accordance with the laws of the jurisdiction to provide care or treatment to persons or animals suffering from any form of disease or illness) or **branches or agencies of the Government of Canada or of the government of a province or territory.**

Costing model for current costs

- Costing is activity-based, as per Treasury Board Secretariat (TBS)'s Guide to Cost Estimating, and was also used in developing fees for drugs and medical devices

- The Guide requires that **all Departmental costs be included when determining the upper limit of a fee** (e.g., the direct cost of application review, RTS processing, inspections and all related overhead costs)

- Data for the costing model is taken from a Departmental **time tracking system**, which tracks salary costs, and financial systems that track other operating costs (e.g., outside contractors, training budgets, travel expenses)

- Health Canada uses a costing model for health products that begins with the **direct costs of delivering services**, and adds **all other costs that support service delivery**, wherein we:
    - Assign **direct** program costs to fee lines based on activities
    - Allocate **indirect** program costs proportionally based on size of direct activities
    - Add **corporate** costs as percentages of direct and indirect costs
    - Attribute **capital** costs proportionally
    - Adjusted to reflect new **collective agreements** and **workload**

Costing model components

Program Costs

Direct: All costs directly related to application review (EVAL), post market surveillance (RTS), compliance and enforcement (SL), and Direct Service Support.

- Examples: Pre-market submission review, screening, processing, and approval; post-market signal detection and review; inspections

Indirect: All costs specific to program overhead

- Examples: Management and management support; program audits; communications; policy; planning & reporting

Corporate Costs

All costs related to:

- Departmental corporate services (e.g., human resources; IM/IT financial management; legal services; material management) - 22.2% of all program costs
- Accommodations - 13% of all salary costs
- Employee benefits – 27% of all salary costs
- Shared Services Canada (GOC digital services) - 4% of all salary costs

Capital Costs

All costs related to:

- Laboratory equipment
- Core regulatory IM/IT systems
- Fleet costs for inspectors

Prospective costing for program improvements and increased regulatory oversight

Fee line	Costing includes
Pre-Market (EVAL)	• Development of an automated validation system for lower-risk product applications • Implementing quality review for product submissions
Site Licence (SL)	• Ensuring capacity for current and future IT developments to improve site licence processing • Establishing a permanent risk-based inspection program
Right to Sell (RTS)	• Increasing capacity to allow for more timely processing of notifications • Increasing support for educating Canadians and stakeholders about NHPs • Strengthening the oversight of advertising for products making non-compliant health claims • Taking a proactive risk-based approach to higher risk products, as well as a quality audit function • NHP post-market safety surveillance and assessment (including adverse reaction reports associated with NHPs)

Prospective costing for process improvements

- In addition to the resources needed for the program improvements identified earlier, further resources across all fee lines will be necessary to:
  - Ensure capacity to be able to **meet updated service standards**
    - Convert student costs to full-time equivalents (FTEs)
  - Implement **modernized IT systems**
    - For example: Conversion of submission tracking systems to reflect new submission categories
  - Apply **continuous business improvements**
  - Establish **invoicing functions**

Calculating total costs

Costing was done in **3 stages**:

1. The **current cost** for Health Canada to deliver services related to NHPs was calculated using the health products costing model as demonstrated in the earlier slide. This is how much regulatory activities would cost if no changes were made.

2. The **prospective costs** of the NHP program were then calculated, using estimates of additional resources needed for full implementation, and then adding corporate costs in the same way as for current costs.

3. The current and prospective costs were added together to arrive at the **total cost**.

Calculating unit costs

- **Pre-market (Classes I-III)**
  - Divided total cost for each fee by total hours spent on submissions used to calculate the fee (from time tracking database) to obtain **hourly rate**
  - Multiplied the hourly rate by average time to complete a submission for each fee to calculate the **unit cost**

- **Pre-market (Class III Novel)**
  - Unit cost of Class III Novel applications was calculated using **subset of historical applications** which would be considered Class III Novel under the new framework
  - Unit cost of Class III Novel amendments determined based on estimated **proportion of effort** compared to full review of Class III Novel application

- **Post-market (RTS)**
  - Divided total cost for post-market activities by estimated number of **authorized and marketed NHPs** following implementation of fees (50,000)

Calculating unit costs (cont.)

- **Application/amendment for site licence**
  - Calculated total annual cost to review site licence applications and site amendment applications, and divided by total number of sites listed in NHP site applications/amendments

- **Annual site licence fee**
  - Calculated an hourly rate for licence review and inspection costs and allocated costs based on the complexity of regulated activities conducted at each type of site

Cost estimates – EVAL, RTS

Activity	Average Annual Existing Costs	Average Annual Volume	Average Level of Effort (hours)	Existing Unit Cost	Estimated Annual Prospective Costs	Prospective Unit Cost	Overall Unit Cost
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**

Activity	Average Annual Existing Costs	Estimated Annual Prospective Costs	Total Costs	Estimated Volume	Unit Cost
Right to Sell (RTS)	$20,478,528	$16,357,357	$36,835,885	50,000	**$737**

Cost estimates – SL applications, SL annual fee

Activity	Average Annual Existing Costs	Average Annual Volume	Existing Unit Cost	Estimated Annual Prospective Costs	Total Annual Costs	Unit Cost
SL Application or Amendment	$2,359,973	1,261	$1,871	$3,139,730	$5,499,703	**$4,360**

Activity	Average Annual Existing Costs	Estimated Annual Prospective Costs	Total Annual Costs
SL Annual Fee	$1,623,618	$14,194,368	**$15,817,986**

Site's 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**
Importation			38.50	**$18,259**
Packaging			14.70	**$6,972**
Labelling			13.30	**$6,308**

Proposed fees and performance standards

Fee line	Description	Proposed Fee	Current standard	New standard
Class I (applications or amendments)	NHP meets one monograph without deviations	**$1,124**	60 days	**60 days**
Class II (applications or amendments)	NHP meets two or more monographs, or meets one or more monographs with acceptable deviations	**$2,761**	90 days	**120 days**
Class III (applications or amendments)	NHP deviates from monograph and requires full assessment	**$7,209**	210 days	**210 days**
Class III Novel (applications)	NHP with novel ingredients, a novel combination of active ingredients, a novel use or purpose, or a novel physical form	**$58,332**	210 days (if treated as a Class III)	**300 days**
Class III Novel (safety & efficacy amendment)	Class III novel amendment related to safety & efficacy	**$23,333**	210 days (if treated as a Class III)	**210 days**
Class III Novel (quality amendment)	Class III novel amendment related to quality	**$8,750**	210 days (if treated as a Class III)	**210 days**

Proposed fees and performance standards (cont.)

Fee line	Description	Proposed Fee Calculated as of 2025 and accounts for inflation	Current standard	New standard
Right to Sell	Payable for each NPN or DIN-HM.	**$542**	N/A	**60 days**
Site (application or amendment)	Payable for each site (location) to be licensed in a new application or amendment.	**$4,784**	30-90 days	**180 days**
Annual site fee	Charged to facilities that meet regulatory requirements to manufacture, import, label and/or package NHPs. Determined by most complex licensable activity conducted at each unique Canadian site.	Sterile Manufacturing: **$40,071** Manufacturing: **$23,071** Importing: **$20,035** Packaging: **$7,650** Labelling: **$6,921**	30-90 days (for renewals)	**90 days**

Benefits of Cost Recovery for NHPs

- Cost recovery for NHPs will provide:
  - Increased **predictability** for industry
  - A**ccountability** through fee remissions for unmet performance standards
  - R**eliable regulatory oversight** to the NHP industry

- Cost recovery will also enable Health Canada to increase its oversight of NHPs - creating a safer marketplace for Canadians - by:
  - Implementing a **risk-based approach** to monitoring labelling and advertising
  - Putting in place a **risk-based inspection program**
  - Better equipping Health Canada to **address issues of non-compliance**
  - Detecting and responding to **quality issues**
  - Further **preventing harmful products** from entering the marketplace

International Comparison

Note: All figures are in CAD	**Canada** *(Proposed)*	**Australia** *CAD/AUD 0.91*	**UK** *CAD/GBP 1.66*	**EU** *CAD/EUR 1.43*	**USA** *CAD/USD 1.36*
Product Classification	Class I, II, III, and Class III Novel - *separate from drugs/foods*	Ranges from listed (low risk), to registered (high risk) medicines	Ranges from dietary supplements to prescription medicines	Ranges from food supplements, herbal medicines, to drugs	Ranges from dietary supplements to drugs
Evaluation Fees (EVAL)	Ranges from $1,124 to $58,332	Ranges from $1,229 to $38,988	Ranges from $856 to $8,290 (homeopathic to new drug application)	Ranges from $0 to $449,520 (for drug)	Ranges from $0 - $823,706 (for comparable products)
Right to Sell Fees (RTS)	$542	Ranges from $1,094 to $1,440 based on product risk	Ranges from $126 to $4,021 based on product classification	Ranges from $0 to $161,035 based on product classification	N/A
Site Licensing Fees (SL)	Application & Amendment Fee: $4,784 (multiplies depending on # of sites) Annual Fee: Ranges from $6,921 to $40,071	Application Fee: $766 + variable inspection cost Annual Fee: $4,507 for manufacturer	Application Fee: Ranges from $303 - $5,205 Annual Fee: $775	Application Fee: Up to $34,015 + variable inspection cost Annual Fee: Up to $31,575	Application Fee: Ranges from $21,921 to $32,880 Annual Fee: N/A

Next Steps

- Comment period on the fee proposal is open now - **closing on July 26, 2023**

- Provide feedback via our Online Comment Form regarding:

  - ✓ Proposed **fee structure** and **fee amounts**

  - ✓ Proposed **performance standards** and **penalties** for missed standards

  - ✓ Proposed **fee mitigation measures**

  - ✓ The proposed **timeline for implementation** (April 1, 2025)

  - ✓ Other comments

- Health Canada will incorporate feedback received into revised Fee Proposal
- A finalized proposal will be published in *Canada Gazette*, Part II prior to implementation

Questions?