

Health Canada Cost Recovery for Regulatory Services

Stakeholder Information Session - February 25, 2022

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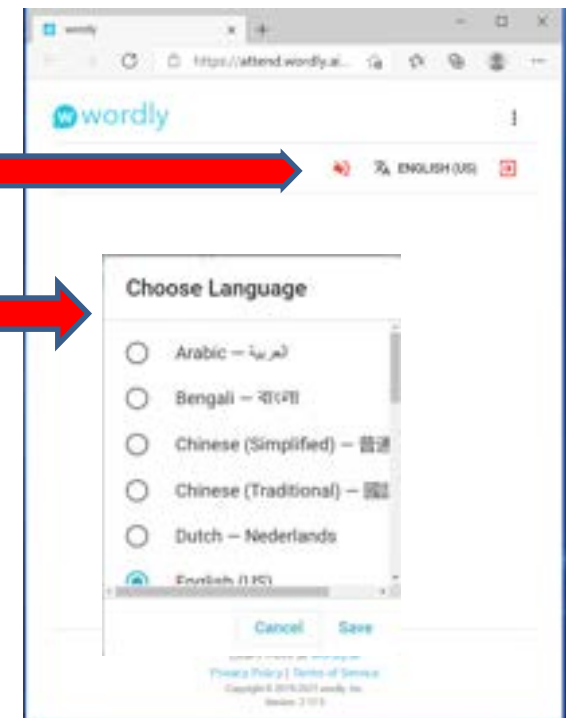
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Utilisation de Wordly.ai

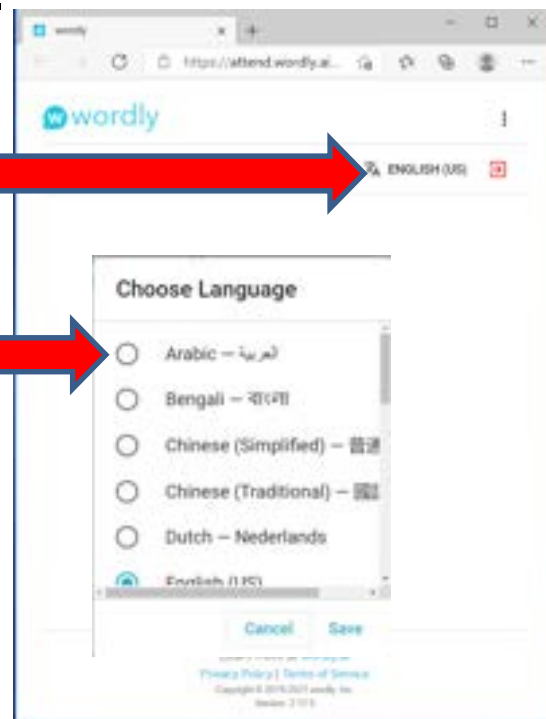
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Purpose

- To introduce stakeholders to Health Canada's approach to cost recovery for regulatory services, including the established fee model for drugs and medical devices.
- To outline the approach to introducing cost recovery for natural health products.

Overview



- Health Canada has been charging fees to industry for its regulatory services related to drugs and medical devices since the mid-90s, consistent with international practices.
- 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 part or all of the costs incurred to deliver those services.
- Since 2017, 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 natural health products.



- In 2020, fees for drugs and medical devices were updated and mitigation measures for small businesses were introduced using this authority.

COST RECOVERY FOR DRUGS AND MEDICAL DEVICES

Drug and Device Fee Types

There are three types of fees:

Pre-Market Evaluation (EVAL)

Before a drug or medical device is authorized for sale in Canada, Health Canada reviews it to assess its safety, efficacy and quality.

PRODUCT LICENCE

Establishment Licences (EL)

The licence confers the right to undertake regulated activities such as the manufacturing of drugs and medical devices. Health Canada provides compliance and enforcement oversight to ensure facilities comply with regulatory requirements.

SITE LICENCE

Right to Sell (RTS)

Health Canada monitors products on the Canadian market through post-market surveillance and compliance and enforcement activities.

- The webpage [Funding and Fees](#) lists all the current fees and guidance documents for drugs and medical devices, as well as links to previous consultation documents.

Cost recovery follows established principles

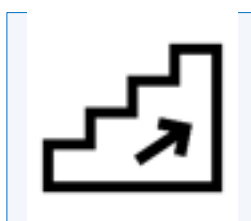
Health Canada has been charging fees for drugs and devices for **over 20 years**. Fees were last updated (in 2020) using the below guiding principles.



Be
Reasonable &
Fair



Minimize
Impact on
Small
Business



Make fees
Gradual &
Predictable



Apply
Appropriate
Mitigation



Ensure
Accountability

- The Department currently recovers three (3) fee categories for all other health products:
 - Scientific review to verify safety, efficacy and quality of products prior to authorization decision;
 - Review of site / establishment licence application (e.g. fabrication, importation), including inspections; and
 - Annual Right to Sell fees to monitor products through post-market surveillance, compliance, and enforcement activities.

Guiding principles (cont'd)

Health Canada's established guiding principles for OTC products can be easily extended to NHPs



Be Reasonable & Fair

- Recognizing that industry needs to pay its fair share and reduce burden on taxpayers, fees will be set reasonably, and they will not exceed costs.
- Fees will be based on costs of delivering the program that meets the commitments made in response to the NHP Program audit.
- Fee setting ratios applied to other health products will be applied to NHPs.
- International fee benchmarks are considered when setting fees to ensure the competitiveness of the Canadian market (e.g. Canada vs. European Union).



Minimize Impact on Small Business

- Fees should not deter small businesses from doing business in Canada, nor from developing new products, so mitigation measures will be put in place. (*see next slide for mitigations*).

Guiding principles (cont'd)



Make fees Gradual & Predictable

- Some fees could be phased-in to limit immediate impact on industry.



Apply Appropriate Mitigation

- Fees should be reduced or waived in explicit circumstances to support small businesses, the health care system and/or other public institutions.
 - 50% reduction for submission fees, with 100% fees waived for 1st submission;
 - 25% reduction for annual Right to Sell fees;
 - 25% reduction for site licence fees.



Ensure Accountability

- Fees will be established after consultations with stakeholders.
- All fee-related annual reporting/engagement on costs, revenues and performance results will be maintained and expanded to include NHPs.
- Each fee will have an associated performance standard, and a 25% penalty will be applied to any submission that misses the standard.
- Annual review and reporting requirements are built into the process, this allows Health Canada to commit to continuous improvements.

Drug and Device Fee Framework



Fee setting ratios (cost %)

- Evaluation fees based on 75% fee setting ratio.
- Right to Sell fees based on 67% fee setting ratio.
- Establishment Licensing fees based on 100% fee setting ratio.

Performance Standards and Penalties

- Every fee has an associated performance standard.
- An individual submission/application that exceeds the performance standard. receives a rebate of 25% of the fee paid.



Annual Adjustment

- All annual fee adjustments are tied to the Consumer Price Index (CPI) of previous year, rounded to nearest dollar.

Withholding of service

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

Drug and Device Fee Mitigation and Waivers



Small Business mitigation measures

- Mitigation for small businesses was implemented in the April 1, 2020, fee update for drugs (including disinfectants) and medical devices. Qualifying small businesses (fewer than 100 employees **or** between \$30,000 and \$5 million in gross annual revenue), are entitled to the following:
 - No charge for a business's first qualifying pre-market submission review.
 - All subsequent pre-market submissions receive a 50% remission.
 - 25% remission on annual Right to Sell fee or Establishment Licence fee.

Urgent Public Health Need

- Fees are waived for products on the [list of drugs for an urgent public health care need](#) as per the *Access to Drugs in Exceptional Circumstances Regulations*.

Publicly funded health care institutions / other Canadian government branches or agencies

- 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.

Consultation and Transparency



- The *Food and Drugs Act* requires consulting before fees can be set.
- Fees and supporting guidance documents are posted on the Health Canada website.
- Treasury Board Secretariat requires tabling of [Health Canada: Fees Report](#) every year, including costs, revenues and performance results.
- Health Canada has committed to meeting annually with drug and device stakeholders to discuss cost recovery.

COST RECOVERY FOR NATURAL HEALTH PRODUCTS

Fees for Natural Health Products



- NHP regulatory activities, including licensing, are currently 100% funded by taxpayers, unlike all other health products, including non-prescription drugs.
- The Commissioner of the Environment and Sustainable Development (CESD) NHP audit made recommendations regarding the Department's oversight of NHP quality, monitoring of labels and advertising, and compliance and enforcement of marketed NHPs.
- In response to the 2021 NHP audit, and to offset the costs of program improvements, the Department committed to taking steps to introduce fees for NHPs.
- Health Canada would not be the first or only country to charge fees for the regulatory oversight of natural health products.
- In introducing fees for NHPs, Health Canada intends to apply its established costing model (see Annex) and its existing fee framework already in place for drugs and devices.

Next Steps

- Develop and publish Fee Proposal for stakeholder consultation
- Continue regular engagement with stakeholders



Existing Costing Model and Methodology

- Activity-based costing, as per Treasury Board Secretariat's [Guide to Costing](#)
- Develop costing model, using data from financial systems and time tracking to determine fee line and unit costs
 - Assign **direct program** costs to fee lines based on activities
 - Allocate **indirect program** costs proportionally based on size of direct activities
 - **Corporate** and **capital** costs attributed proportionally
 - Adjustments made to reflect collective agreements and workload
- Costs reflect service delivery against proposed performance standards

Program Costs

Direct: All costs related to

- submission / application review

- post market surveillance
- compliance and enforcement

Indirect: All costs specific to program overhead

Corporate Costs

All costs related to:

- human resources
- IM/IT
- financial management
- accommodation
- legal services

Capital Costs

All costs related to:

- laboratory equipment
- core regulatory IM/IT systems
- billing and payment systems
- fleet costs for inspectors