Health Canada Santé Canada

Canada

Cost Recovery: Fees in Respect of Drugs and Medical Devices

CAPRA Annual Education Day
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YOUR HEALTH AND SAFETY... OUR PRIORITY.

Purpose

- To provide an overview of Cost Recovery for drugs and medical devices and the revised fees for drugs and medical devices that are scheduled to come into force on April 1, 2020
  - **Part 1:** Overview of Health Canada and Cost Recovery
  - **Part 2:** Revised Fees for Drugs and Medical Devices
  - **Part 3:** Next Steps

Part 1: Overview of Health Canada

Health Canada is responsible for helping Canadians maintain and improve their health

- Health Canada via the Health Products and Food Branch and the Regulatory, Operations and Enforcement Branch is responsible for:
  - Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food
  - Reviewing health products (human and veterinary drugs and medical devices) to **assess the risks and benefits** prior to market authorization
  - **Compliance and enforcement** for all products under the mandate of the Branch except food (for which Canadian Food Inspection Agency performs compliance and enforcement activities)
  - Coordinate **post-market surveillance** of health products and assessment of safety signals and trends
  - Share **new safety information** about health products with Canadians
  - Regulate pharmaceuticals, medical devices, biologics and genetic therapies, veterinary drugs, natural health products and food

Part 1: Overview of Cost Recovery

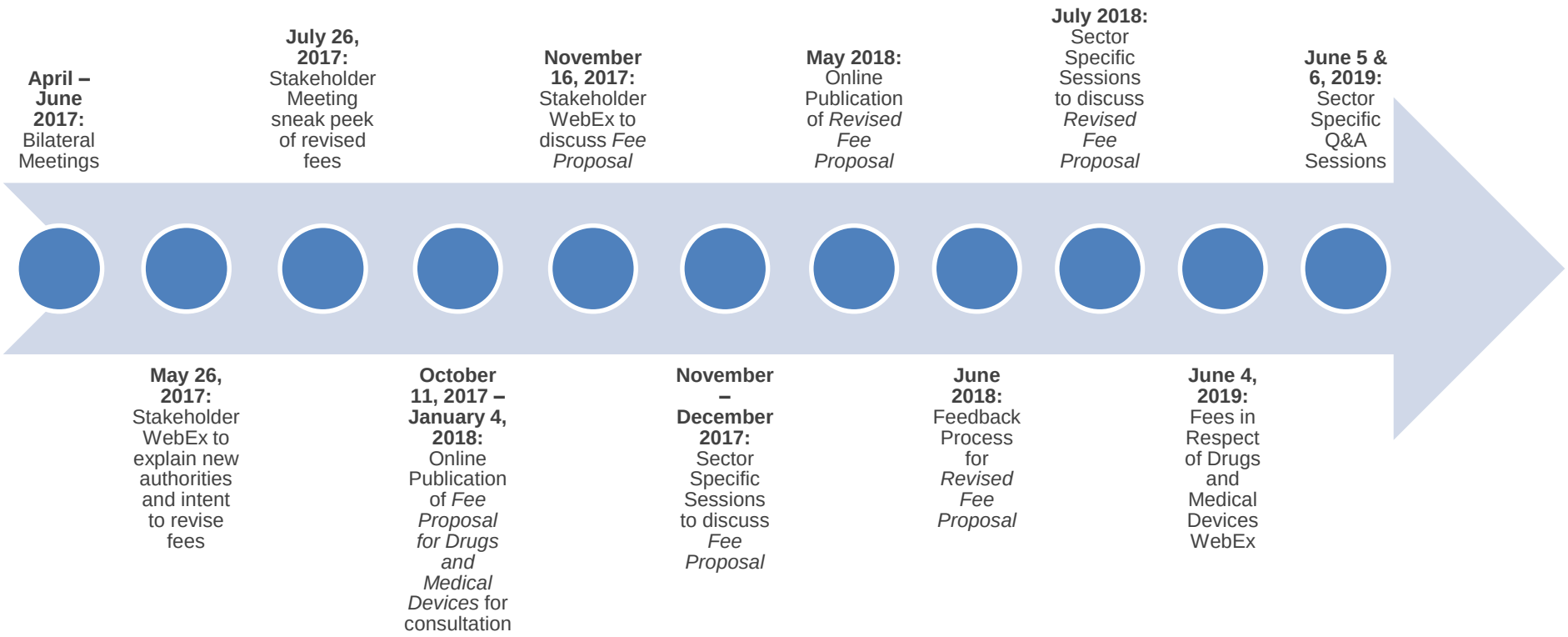
Cost Recovery is the practice of establishing and collecting fees associated to regulatory activities

- In the 1990s, Health Canada established fees related to regulatory activities for drugs and medical devices. Along with these fees, public funding also supports these programs as Health Canada is not 100% cost recovered
- Cost recovery related to regulatory activities is not unique to Canada. Many other international regulators also charge fees, some up to 100% of their costs
- Fee payers are charged fees for activities related to pre-market regulatory review, compliance and enforcement, and post-market activities related to ongoing surveillance of products once they are on the market

Part 1: Fees

Submission / Application Evaluation (EVAL) Fees	Establishment Licensing (EL) Fees	Right to Sell (RTS) Fees
• Before a drug or medical device is authorized for sale in Canada, Health Canada reviews it to assess its safety, efficacy and quality.	• Health Canada inspects establishments to assess whether they comply with regulatory requirements to conduct regulated activities related to drugs and medical devices.	• Health Canada monitors products on the Canadian market through post-market surveillance and compliance and enforcement activities.

Part 2: Stakeholder Engagement



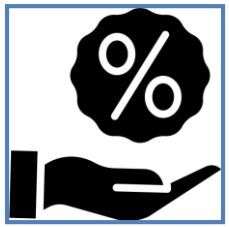
Part 2: Guiding Principles

Be Reasonable and Fair

Recognizing that industry needs to pay its fair share and reduce the burden on taxpayers, fees have been set reasonably and are being phased-in

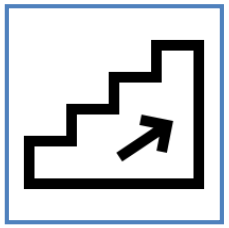
Minimize Impact on Small Business

Fees should not deter small businesses from doing business in Canada



Apply Appropriate Mitigation

Fees should be reduced or exempted in explicit circumstances to support the health care system



Make Fee Increases Gradual and Predictable

Because fees had not been updated in several years, revised fees will be phased-in over multiple years

Ensure Accountability

Remaining transparent and accountable to stakeholders through annual reporting, rigorous performance standards, and annual engagement is key to developing an agile and responsive fee strategy

Part 2: Fees for Drugs and Medical Devices

Fee Setting

Annual Fee Adjustment

Small Business

Mitigation Measures

Performance Standards

Penalty Provision

Timing of Payment

Stakeholder Engagement

Fee Setting

- Fees for Human Drugs and Medical Devices will be phased in over 4 years
- Fees for Veterinary Drugs will be phased in over 7 years
- Evaluation fees for Human Drugs and Medical Devices have been set at 75% of costs
- Evaluation fees for Veterinary Drugs have been set at 50% of costs
- Right to Sell fees have been set at 67% of costs for all products
- 3 tiers for Drug Right to Sell:
  1. Prescription
  2. Non-prescription
  3. Disinfectants
- Establishment Licence fees have been set at 100% of costs

Annual Fee Adjustment

- Fees will be adjusted annually by the Consumer Price Index (CPI) of Canada by the percentage change over 12 months
- Adjusted amount will be published online in the fall with implementation on April 1
- First annual adjustment will be on April 1, 2021

Small Business

- Small businesses that meet the Treasury Board Secretariat's definition of small business (fewer than 100 employees or less than $5 million in gross revenue) and the Competition Act's definition of affiliates are eligible for mitigation
- Measures available are:
  - First Pre-market submission free for new companies
  - 50% mitigation for all subsequent Pre-market Evaluation fees
  - 25% mitigation for all Right to Sell fees
  - 25% mitigation for all Establishment Licence fees

Mitigation Measures

- The following fees will be waived:
  - All fees waived for publicly funded health care institutions, including a Branch of Agency of the Government of Canada or the government of a province or territory
  - First Pre-market drug submission for a drug on the *List of Drugs for an Urgent Public Health Need*
- Drug Establishment Licence (DEL) fee will be pro-rated quarterly for a new DEL application or an amendment to add a new domestic building to an existing DEL

Performance Standards

- All existing performance standards were reviewed and if needed were adjusted to reflect the appropriate level of effort
- All new fee categories have a performance standard
- Performance Standards for the Fees in Respect of Drugs and Medical Devices Order published and posted on the Health Canada website with a Coming into Force on April 1, 2020 https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/performance-fees-drugs-medical-devices.html

Penalty Provision

- Individual submission/application that exceeds the performance standard will receive a rebate of 25% of the fee payable
- Not applicable to:
  - Joint/parallel review submissions
  - Medical Device combination applications

Timing of Payment

- Pre-Market: Found to be complete or incomplete
- Drug Right to Sell: October 1
- Medical Device Right to Sell: December 20
- Establishment Licences: Fee is payable upon notice that the application has been accepted for further examination

Stakeholder Engagement

- Health Canada will meet with industry annually to discuss areas of interest (i.e. costs, efficiencies, performance)
- First Annual Meeting scheduled for fall 2020
- Various quarterly and annual performance reports will continue to be available upon request

Fees for Pre-Market Evaluation

Human Drugs

- Eliminated Categories:
  - Published Data Only and Rx Switch
- New Categories:
  - Safety, Labelling Only generic/disinfectant

Medical Devices

- New Fee for Class II Amendments and Private Label applications
- Class IV medical device applications merged into a single fee category

Veterinary Drugs

- New Fee for Veterinary Health Product Notification

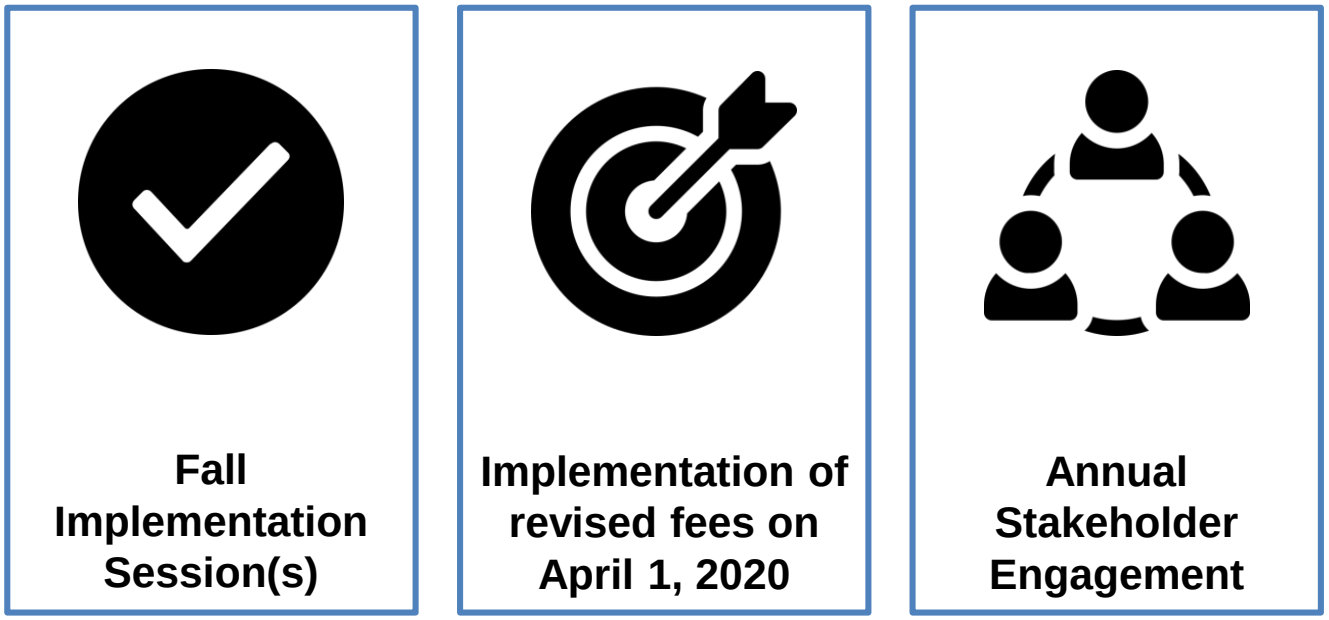
Fees for Right to Sell

- Fee will be charged if drug has been notified as marketed as of its annual renewal date
  - If drug retroactively notifies as marketed, the applicable Right to Sell fee will be charged
  - If product was dormant at any point during 12 months, will not be charged unless it re-enters the market
  - Any drug approved but not notified as marketed will not be charged
  - Any discontinued product will not be charged
- Fee will be charged for active Medical Devices licences

Fees for Establishment Licence

- The Drug Establishment Licence (DEL) fee structure has two components:
  - Domestic building fee – one fee for each building listed on the DEL based on the most upstream activity at that building
  - Foreign building fee – a flat fee for each building outside Canada listed on the DEL at any time during the year
- The DEL fee is payable when:
  - Applying for a new DEL;
  - Applying for an annual licence review;
  - Applying to amend an existing DEL to add a new domestic building
- The Medical Device Establishment Licence (MDEL) fee is a flat fee of $4,590, a decrease from $8,438
- Since the MDEL fee will be reduced from the current fee, there will not be a phase in period for this fee line

Part 3: Next Steps



- If you have questions, please do not hesitate to email the Cost Recovery Email account: hc.cro-brc.sc@canada.ca