



Health Canada

2017 to 2018 Report on Fees



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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Contents

MINISTER'S MESSAGE	5
GENERAL FEES INFORMATION	7
GENERAL AND FINANCIAL INFORMATION BY FEE CATEGORY	7
FINANCIAL TOTALS FOR ALL FEE CATEGORIES	33
FEES UNDER THE DEPARTMENT'S AUTHORITY	34
FEES SET BY MINISTERIAL AUTHORITY TO ENTER INTO CONTRACT	47

Minister's message

As the Minister of Health, I am pleased to present the Health Canada 2017 to 2018 Report on Fees, which sets out detailed information on fees in the Department. These fees support the sustainability of Health Canada's regulatory programs and activities, which protect the health and safety of Canadians. On June 22, 2017, the Service Fees Act received Royal Assent, thereby repealing the User Fees Act. The Service Fees Act introduces a modern legislative framework that enables costeffective delivery of services and, through enhanced reporting to Parliament, improved transparency and oversight. The Act provides for:



- a streamlined approach to consultation and the approval of new or modified fees;
- a requirement for services to have service standards and reporting against these standards, along with a policy to remit fees to fee payers when standards are not met;
- an automatic annual fee adjustment by the Consumer Price Index (CPI) to ensure that fees keep pace with inflation; and
- annual detailed reporting to Parliament in order to increase transparency.

This 2017-18 Fees Report is the first report to be prepared by Health Canada under the Service Fees Act. The report includes new information, such as a detailed listing of all fees along with future-year fee amounts. Additional fee information will be included starting next fiscal year, once Health Canada fully transitions to the Service Fees Act regime. Health Canada's fee portfolio changed in the following ways, as reflected in the 2017-18 report:

- On April 1, 2017, Health Canada's Pest Management Regulatory Agency implemented a revised fee regime, its first update since 1997.
- Health Canada will undergo further changes to its fee portfolio in 2018-19, as a set of fees was introduced to support the legalization, strict regulation and restriction on access to cannabis under the Cannabis Act.
- In addition, Health Canada held official consultations on the Fee Proposal for Drugs and Medical Devices, which aimed to update regulatory fees related to human drugs, medical devices and veterinary drugs to reflect the current costs of regulatory activities. Work is ongoing to finalize these updates and as such, fees contained within this report do not reflect proposed changes.

I welcome the increased transparency and oversight that the Service Fees Act's reporting regime embodies, and I am fully committed to transitioning my department to this modern framework. I look forward to continuing to advance my key mandate priorities through collaboration and evidence-based decision-making that will maintain and improve the health and safety of all Canadians.

The Honourable Ginette Petitpas Taylor, P.C., M.P. Minister of Health

General fees information

The tables that follow provide information on each category of fees, including:

- the name of the fee category
- the date that the fee (or fee category) was introduced and last amended (if applicable)
- service standards
- performance results against these standards
- financial information regarding total costs, total revenues and remissions

In addition to the information presented by fee category, there is a summary of the financial information for all fees as well as a listing of fees under the department's authority. This listing includes the existing dollar amounts and the adjusted dollar fee amount for a future year.

General and financial information by fee category

General information

Fee category: Fees for Right to Sell Drugs

Fee-setting authority: Financial Administration Act

Year introduced: 1995 Year last amended: 2011

Service standard: 120 calendar days to update the Drug Product Database following notification

Performance results: 100% within 120 calendar days

Other information: N/A

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions†
12,015,179	12,200,583	63,830,126	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: Fee for Right to Sell a Licensed Class II, III or IV Medical Device

Fee-setting authority: Financial Administration Act

Year introduced: 1999 Year last amended: 2011

Service standard: 20 calendar days from deadline for receipt of annual notification to update the Medical

Devices License Listing (MDALL) database

Performance results: 99.1% within 20 calendar days

Other information: N/A

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
8,412,791	8,955,877	15,713,214	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: Fees for the Examination of a Drug Submission (Pharmaceuticals and Biologic Products)

Fee-setting authority: Financial Administration Act

Year introduced: 1995 Year last amended: 2011

Service Standards - Pharmaceuticals		
Fee Name	Submission Type	Service Standard - Review 1 (average time in calendar days)
New Active Substance	New Drug Submission	300
Clinical/ Chemistry & Manufacturing	New Drug Submission	300
Manufacturing	Supplement to a New Drug Submission	300
Clinical Only	New Drug Submission	300
	Supplement to a New Drug Submission	300
	Drug Identification Number Application - Pharmaceutical	210
Comparative Studies / Chemistry & Manufacturing	Abbreviated New Drug Submission	180
	New Drug Submission	180
	Supplement to an Abbreviated New Drug Submission	180
	Supplement to a New Drug Submission	180
	Drug Identification Number Application - Pharmaceutical	210
Chemistry & Manufacturing	Abbreviated New Drug Submission	180
	New Drug Submission	180
	Supplement to an Abbreviated New Drug Submission	180
	Supplement to a New Drug Submission	180
	Drug Identification Number Application - Pharmaceutical	210
Published Data	Supplement to a New Drug Submission	300

	Supplement to an Abbreviated New Drug Submission	300
	Drug Identification Number Application - Pharmaceutical	210
Switch from Prescription to Over the Counter	New Drug Submission	180
the Counter	Supplement to a New Drug Submission	180
Disinfectant	New Drug Submission	300
	Supplement to a New Drug Submission	300
	Drug Identification Number Application – Disinfectant 210	210
	Drug Identification Number Application – Disinfectant 180	180
Labelling Only	New Drug Submission	60
	Supplement to a New Drug Submission	60
	Abbreviated New Drug Submission	60
	Supplement to an Abbreviated New Drug Submission	60
	Drug Identification Number Application - Pharmaceutical	180
Label Standard	Drug Identification Number Application - Pharmaceutical	45
	Drug Identification Number Application – Disinfectant	45
	Drug Identification Number Application – Category IV	45
Administrative	Abbreviated New Drug Submission	45
	New Drug Submission	45
	Supplement to a New Drug Submission	45
	Supplement to an Abbreviated New Drug Submission	45
	Drug Identification Number Application - Pharmaceutical	45

Drug Identification Number Application – Disinfectant	45
Drug Identification Number Application – Category IV	45

Service Standards - Biologics		
Fee Name	Submission Type	Service Standard - Review 1 (average time in calendar days)
New Active Substance	New Drug Submission	300
Clinical/ Chemistry &	New Drug Submission	300
Manufacturing	Supplement to a New Drug Submission	300
	Drug Identification Number Application - Biologics	210
Clinical Only	New Drug Submission	300
	Supplement to a New Drug Submission	300
Comparative Studies/ Chemistry	Abbreviated New Drug Submission	180
& Manufacturing	Supplement to a New Drug Submission	180
	Drug Identification Number Application - Biologics	210
Chemistry & Manufacturing	Abbreviated New Drug Submission	180
	Supplement to an Abbreviated New Drug Submission	180
	Supplement to a New Drug Submission	180
	Drug Identification Number Application - Biologics	210
Labelling Only	New Drug Submission	60
	Supplement to a New Drug Submission	60
	Drug Identification Number Application - Biologics	180
Published Data	Supplement to a New Drug Submission	300

Administrative	New Drug Submission	45
	Drug Identification Number Application - Biologics	45

Performance Results - Pharmaceuticals		
Fee Name	Submission Type	Results - Review 1 (average time in calendar days)
New Active Substance	New Drug Submission	269
Clinical/ Chemistry & Manufacturing	New Drug Submission	300
Manufacturing	Supplement to a New Drug Submission	270
Clinical Only	New Drug Submission	N/A
	Supplement to a New Drug Submission	269
	Drug Identification Number Application - Pharmaceutical	204
Comparative Studies / Chemistry	Abbreviated New Drug Submission	164
& Manufacturing	New Drug Submission	180
	Supplement to an Abbreviated New Drug Submission	171
	Supplement to a New Drug Submission	155
	Drug Identification Number Application - Pharmaceutical	200
Chemistry & Manufacturing	Abbreviated New Drug Submission	167
	New Drug Submission	N/A
	Supplement to an Abbreviated New Drug Submission	149
	Supplement to a New Drug Submission	167
	Drug Identification Number Application - Pharmaceutical	191
Published Data	Supplement to a New Drug Submission	269

	Supplement to an Abbreviated New Drug Submission	276
	Drug Identification Number Application - Pharmaceutical	206
Switch from Prescription to Over the Counter	New Drug Submission	N/A
the Counter	Supplement to a New Drug Submission	N/A
Disinfectant	New Drug Submission	299
	Supplement to a New Drug Submission	N/A
	Drug Identification Number Application – Disinfectant 210	208
	Drug Identification Number Application – Disinfectant 180	171
Labelling Only	New Drug Submission	52
	Supplement to a New Drug Submission	55
	Abbreviated New Drug Submission	41
	Supplement to an Abbreviated New Drug Submission	46
	Drug Identification Number Application - Pharmaceutical	158
Label Standard	Drug Identification Number Application - Pharmaceutical	39
	Drug Identification Number Application – Disinfectant	38
	Drug Identification Number Application – Category IV	38
Administrative	Abbreviated New Drug Submission	26
	New Drug Submission	33
	Supplement to a New Drug Submission	27
	Supplement to an Abbreviated New Drug Submission	31
	Drug Identification Number Application - Pharmaceutical	29

Drug Identification Number Application – Disinfectant	38
Drug Identification Number Application – Category IV	34

Performance Results - Biologics		
Fee Name	Submission Type	Results - Review 1 (average time in calendar days)
New Active Substance	New Drug Submission	260
Clinical/ Chemistry &	New Drug Submission	292
Manufacturing	Supplement to a New Drug Submission	293
	Drug Identification Number Application - Biologics	N/A
Clinical Only	New Drug Submission	N/A
	Supplement to a New Drug Submission	277
Comparative Studies/ Chemistry & Manufacturing	Abbreviated New Drug Submission	177
	Supplement to a New Drug Submission	179
	Drug Identification Number Application - Biologics	177
Chemistry & Manufacturing	Abbreviated New Drug Submission	177
	Supplement to an Abbreviated New Drug Submission	N/A
	Supplement to a New Drug Submission	136
	Drug Identification Number Application - Biologics	176
Labelling Only	New Drug Submission	60
	Supplement to a New Drug Submission	57
	Drug Identification Number Application - Bioligics	164
Published Data	Supplement to a New Drug Submission	270

Administrative	New Drug Submission	28
	Drug Identification Number Application - Biologics	42

Other information:

Review 1= Drug Submission Reviews

N/A: At time of reporting either no submissions of that type were received or no reviews of that submission type were completed, therefore no performance information available.

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions†
43,609,604	47,998,937	102,956,423	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: Certificate of Supplementary Protection Application Fees

Fee-setting authority: Patent Act

Year introduced: 2017 Year last amended: N/A

Service standard: 60 calendar days Performance results: 43 calendar days

Other information: N/A

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
N/A	117,143	155,181	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: Fees for the Examination of Medical Device License Applications

Fee-setting authority: Financial Administration Act

Year introduced: 1998 Year last amended: 2011

Service standards:

Fee Name	Service Standard - Review 1 (average time in calendar days)
Class II Licence Application	15
Class III Licence Application	60
Class III Licence Application (Near Patient In Vitro Diagnostic Devices)	60
Class III Changes in Manufacturing	60
Class III Significant Changes	60
Class IV Licence Application	75
Class IV Licence Application (Devices that contain Human-Animal Tissue)	75
Class IV Licence Application (Near Patient In Vitro Diagnostic Devices)	75
Class IV Changes in Manufacturing	75
Class IV Significant Changes	75

Performance results

Fee Name	Results - Review 1 (average time in calendar days)
Class II Licence Application	12
Class III Licence Application	52
Class III Licence Application (Near Patient In Vitro Diagnostic Devices)	56
Class III Changes in Manufacturing	54

Class III Significant Changes	51
Class IV Licence Application	68
Class IV Licence Application (Devices that contain Human-Animal Tissue)	64
Class IV Licence Application (Near Patient In Vitro Diagnostic Devices)	N/A
Class IV Changes in Manufacturing	51
Class IV Significant Changes	59

Other information:

N/A: At time of reporting either no submissions of that type were received or no reviews of that submission type were completed, therefore no performance information available.

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
6,261,776	6,116,671	20,979,592	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: Veterinary Drug Evaluation Fee

Fee-setting authority: Financial Administration Act

Year introduced: 1996 Year last amended: N/A

Service standards:

Fee Name	Service Standard - Review 1 (average time in calendar days)
New Drug Submission	300
Abbreviated New Drug Submission	300
Supplement to a New Drug Submission	240
Supplement to an Abbreviated New Drug Submission	240
Administrative	90
Drug Identification Number (including changes)	120
Notifiable Change	90
Experimental Studies Certificate	60
Labels (No longer reviewed)	45
Emergency Drug Release	2

Performance Results:

Fee Name	Results - Review 1 (average time in calendar days)
New Drug Submission	310
Abbreviated New Drug Submission	287
Supplement to a New Drug Submission	225
Supplement to an Abbreviated New Drug Submission	204
Administrative	11
Drug Identification Number (including changes)	110
Notifiable Change	71

Experimental Studies Certificate	57
Labels (No longer reviewed)	N/A
Emergency Drug Release	2

Other information:

Review 1= Drug Submission Reviews

N/A: No longer reviewed.

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
833,874	1,114,183	6,110,102	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: Drug Establishment Licensing Fees Fee-setting authority: Financial Administration Act

Year introduced: 1998 Year last amended: 2011

Service standard: 250 calendar days to issue / renew license

Performance results: Average of 122 calendar days

Other information: N/A

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
16,766,144	16,593,274	22,472,562	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: Medical Device Establishment Licensing Fees

Fee-setting authority: Financial Administration Act

Year introduced: 2000 Year last amended: 2011

Service standard: 120 calendar days to issue / renew license

Performance results: Average of 22 calendar days

Other information: N/A

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
10,655,054	10,134,538	9,336,613	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: Fees to be Paid for the Examination of an Application in Respect of a Pest Control

Product

Fee-setting authority: Pest Control Products Act

Year introduced: 1997 Year last amended: 2017

Service standard: The performance standard is 90% of applications are to be processed within the

applicable review timelines.

	Description	Service Standards
Category A	New active ingredients or integrated system products, their related end-use products, and manufacturing-use products; Major new use of registered pest control products (defined as the addition of a new use-site category to the use pattern for a specific registered active ingredient); Specification of import Maximum Residue Limits (MRLs) for an unregistered active ingredient.	285 to 655 days
Category B	New pest control products containing registered active ingredients; Amendment to existing pest control products (for example, product chemistry, labelling); Emergency registration' the addition of import MRLs for previously assessed active ingredients.	158 to 425 days
Category C	Product registrations and amendments with no data requirements. These applications involve minor label or formulation reviews, such as product registration based on registered precedent products.	180 to 240 days
Category D	Submissions within particular programs including:	10 to 244 days
	Import for Manufacture and Export Program (IMEP),	
	Own Use Import (OUI), Grower Requested Own Use (GROU) Equivalency and import permits, Master Copies, Private Labels, Registration Renewal, and Discontinuations.	
Category E	Research authorizations for new active ingredients and new use(s) of registered active ingredients; Research notification for research carried out in Canada.	30 to 159 days
Category F	Registration and amendments to registered pest control products via notification	45 days
Category L	Submissions to register or amend products including new sources of technical grade active ingredient, manufacturing concentrates and end use products where the applicant wishes to use or rely upon data provided by another registrant; Requests to extend the exclusive use protection period based upon minor uses.	45 to 425 days

Performance results

	Description	Results
Category A	New active ingredients or integrated system products, their related end-use products, and manufacturing-use products; Major new use of registered pest control products (defined as the addition of a new use-site category to the use pattern for a specific registered active ingredient); Specification of import MRLs for an unregistered active ingredient.	88% within 285 to 655 days
Category B	New pest control products containing registered active ingredients; Amendment to existing pest control products (for example, product chemistry, labelling); Emergency registration' the addition of import MRLs for previously assessed active ingredients.	92% within 158 to 425 days
Category C	Product registrations and amendments with no data requirements. These applications involve minor label or formulation reviews, such as product registration based on registered precedent products.	97% within 180 to 240 days
Category D	Submissions within particular programs including: Import for Manufacture and Export Program (IMEP), Own Use Import (OUI), Grower Requested Own Use (GROU) Equivalency and import permits, Master Copies, Private Labels, Registration Renewal, and Discontinuations.	99% within 10 to 244 days
Category E	Research authorizations for new active ingredients and new use(s) of registered active ingredients; Research notification for research carried out in Canada.	31% within 30 to 159 days
Category F	Registration and amendments to registered pest control products via notification	92% within 45 days
Category L	Submissions to register or amend products including new sources of technical grade active ingredient, manufacturing concentrates and end use products where the applicant wishes to use or rely upon data provided by another registrant; Requests to extend the exclusive use protection period based upon minor uses.	93% within 45 to 425 days

Other information:

Service standards are defined in Regulatory Directive DIR2017-01 Management of Submissions Policy (MOSP), March 8, 2017

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
2,590,800	5,218,518	33,159,373	N/A

^{*} Starting in 2017 the Pesticides Program revised the methodology to calculate costs for reporting. In previous years the Pesticides Program used direct expenditures, for 2017/18 the Pesticide Program has utilized the activity time tracking system with a full program costing methodology, consistent with other Programs in Health Canada.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: Annual Charge (for a registered Pest Control Product)

Fee-setting authority: Pest Control Products Act

Year introduced: 1997 Year last amended: 2017

Service standard: 100% of all invoices were issued by April 30, 2017

Performance results: 100%

Other information:

Annual Charge fees are identified in the Pest Control Products Fees and Charges Regulations (PCPFCR - April 1, 2017), in Part 2 - Annual Charge

Under the Service Fees Act, this fee is subject to Section 17(1) Annual Adjustment - Consumer Price Index, which will occur on April 1 of each year, commencing April 1, 2019.

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
5,304,300	8,174,445	24,084,509	N/A

^{*} Starting in 2017 the Pesticides Program revised the methodology to calculate costs for reporting. In previous years the Pesticides Program used direct expenditures, for 2017/18 the Pesticide Program has utilized the activity time tracking system with a full program costing methodology, consistent with other Programs in Health Canada.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: Fees charged for filing a claim for exemption under the Hazardous Materials Information

Review Act

Fee-setting authority:

Hazardous Materials Information Review Act, section 48 and Hazardous Materials Information Review Regulations, sections 4, 5, and 7

Year introduced: 1988 Year last amended: 2002

Service standard: The Workplace Hazardous Materials Bureau commits to a service delivery standard of 7 calendar days from the date of the receipt of a complete application, for the issuance of a registry number on an application for a claim for exemption for Confidential Business Information (CBI).

Performance results: In 2017-18, the Bureau processed 99% of claims for exemption applications within its service standard. Annual service performance is measured over the course of the fiscal year (e.g., April 1 - March 31).

Other information: N/A

2016–17	2017–18	2017–18	2017–18	
Revenue	Revenue	Cost*	Remissions [†]	
1,283,546	1,056,287	2,673,267	N/A	

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Under the Service Fees Act departments are required to develop policies that determine when fees will be remitted to fee payers should service standards not be met. The requirement for departments to remit is anticipated to come into effect on April 1, 2020.

Fee category: National Dosimetry Services Products, Services and Fees Structure

Fee-setting authority: Ministerial Authority to enter into Contract

Year introduced: 2004 Year last amended: 2017

Service standards:

Provide timely, responsive and reliable dosimetry services:

- Exposures reported within 45 calendar days of receipt Canadian Nuclear Safety Commission (CNSC) regulatory standard:
- ii. Dosimeters shipped 10-13 working days prior to exchange date with clients;
- Dose results for whole body and extremity services reported within internal service standards of iii. 20-30 business days, depending on the dosimetry service;
- Client account information updated within two business days; iv.
- Client voice mails responded to within one business day; and, ٧.
- Client emails responded to within two business days. vi.

Performance results:

National Dosimetry Service (NDS) provided timely, accurate and reliable customer service to workers:

- NDS processed and reported 611,042 dosimeter readings to client groups attaining 100% compliance with the 45 day regulatory (CNSC) standard;
- ii. NDS shipped out 88% of dosimeters 10-13 working days prior to exchange date;
- NDS processed and reported 611,042 readings with 99% reported within the 20-30 business day iii. internal standard, depending on the dosimetry service;
- NDS processed 28,371 changes to client group requests (via Name Lists) with 94% completed iv. within two business days;
- NDS responded to 1,585 Client Services voice mail call backs with 91.1% being addressed within ٧. one business day; and,
- vi. NDS responded to 4,615 emails with 90.1% addressed within two business days.

Other information: N/A

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
5,810,715	6,163,812	6,140,049	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Some fees are exempt, such as those fixed by contract or under the Access to Information Act.

Fee category: Drug Master File Fees

Fee-setting authority: Ministerial Authority to enter into Contract

Year introduced: 1996 Year last amended: 2017

Service standard: 30 calendar days

Performance results: 98% Other information: N/A

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
773,663	993,181	1,469,899	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Some fees are exempt, such as those fixed by contract or under the Access to Information Act.

Fee category: Certificate of Pharmaceutical Product Fees

Fee-setting authority: Ministerial Authority to enter into Contract

Year introduced: 1996 Year last amended: N/A

Service standard: 10 calendar days to issue certificate Performance results: Average of eight calendar days

Other information: N/A

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
274,449	258,731	287,637	N/A

^{*} The amount includes direct and indirect costs, where such costs are identifiable and material.

[†] A remission is a partial or full return of a fee paid as a result of a missed performance standard. Some fees are exempt, such as those fixed by contract or under the Access to Information Act.

Fee category: Fees for processing requests filed under the Access to Information Act

Fee-setting authority: Access to Information Act

Year introduced: 1988 Year last amended: 1992

Service standard: A response is provided within 30 days following receipt of a request; the response time may be extended under section 9 of the Access to Information Act.

Performance results: Health Canada achieved a compliance rate* of 59.5% for fiscal 2017-18. Public Health Agency of Canada achieved a compliance rate* of 77.2% for fiscal 2017-18.

* Includes cases where a Notice of Extension is sent to the requester within 30 days of receipt of the request.

Other information:

The Act authorizes fees for certain aspects of processing formal requests and the fee structure is prescribed in the Access to Information (ATI) Regulations. However, Treasury Board Secretariat in May 2016 issued the Interim Directive on the Administration of the Access to Information Act which imposed a requirement to waive all fees chargeable other than the \$5 application fee, regardless of the size and scope of the request or burden on the Department to process. Based on requests received in 2017-18, Health Canada collected \$7,655 in application fees, and Public Health Agency of Canada collected \$515 in application fees. Health Canada waived \$2,788 in fees while Public Health Agency of Canada waived \$313 in fees.

Financial information (dollars)

2016–17	2017–18	2017–18	2017–18
Revenue	Revenue	Cost*	Remissions [†]
6,928	8,170	10,960,057	N/A

^{*} The amount includes direct and indirect costs. Due to the Shared Services Partnership whereby Health Canada provides Access to Information (ATI) services on behalf of Public Health Agency of Canada, the Fiscal Year 2017-18 total costs detailed between the 2 departments are as follows:

- Health Canada Access to Information (ATI) \$10,304,134
- Public Health Agency of Canada Access to Information (ATI) \$655,923

† A remission is a partial or full return of a fee paid as a result of a missed performance standard. Some fees are exempt, such as those fixed by contract or under the Access to Information Act.

Financial totals for all fee categories

Total revenues, cost and remissions (dollars)

2016–17	2017–18	2017–18	2017–18
Total revenue	Total revenue	Total cost	Total remissions
114,598,823	125,104,350	320,328,604	N/A

Note: the totals are the sums of the revenues, costs and remissions reported for all fee categories in the "Financial information" tables.

The 2016-17 total revenue as published in the 2016-17 Departmental Results Report did not include Fees set by Ministerial Authority to enter into Contract (\$6,858,828).

Fees under the department's authority

Fee amounts for 2017–18 and 2019–20 and for a future fiscal year, as applicable (dollars).

The 2019-20 adjusted fee amounts reflect either:

- the 2018 April All-items Consumer Price Index for Canada (2.2%) on current fees;
- the yearly adjustment, to current fees, at a predetermined rate (e.g. 2%), in accordance with legislation or regulation; or

Future fee amount and fiscal year would be the new amount of the fee, in a future fiscal year other than 2019 to 2020, adjusted by a predetermined rate in accordance with the authority in legislation or regulation. This is not applicable for any Health Canada fees.

Note: Health Canada held official consultations on the Fee Proposal for Drugs and Medical Devices, which aimed to update regulatory fees related to human drugs, medical devices and veterinary drugs to reflect the current costs of regulatory activities. Work is ongoing to finalize these updates and as such, fees contained within this report do not reflect proposed changes.

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
RIGHT TO SELL DRUGS FEE 1			
Human drugs	1,152	1,200	Not applicable
Vet Drugs	250	255.50	Not applicable
FEE FOR RIGHT TO SELL A LICENSED MEDICAL I	DEVICE 1		
Medical Device Right to Sell (if annual gross revenue medical device sales is less than \$20,000)	61	65	Not applicable
Medical Device Right to Sell (in any other cases)	375	391	Not applicable
DRUG SUBMISSION EVALUATION FEES (PHARMA	CEUTICALS AN	D BIOLOGIC PRO	DDUCTS) ¹
New active substance	341,770	355,579	Not applicable
Clinical or non-clinical data and chemistry and manufacturing data	173,106	180,101	Not applicable
Clinical or non-clinical data only	80,794	84,059	Not applicable
Comparative studies	48,834	50,808	Not applicable

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year	
Chemistry and manufacturing data only	23,089	24,023	Not applicable	
Published data only	19,147	19,921	Not applicable	
Switch from prescription to non-prescription status	46,491	48,370	Not applicable	
Labelling only	3,111	3,238	Not applicable	
Administrative Submission	324	338	Not applicable	
Disinfectants	4,305	4,480	Not applicable	
Drug identification number application – labelling standards	1,726	1,797	Not applicable	
Remission Processing Fee	566	590	Not applicable	
CERTIFICATE OF SUPPLEMENTARY PROTECTION APPLICATION FEES				
Certificate of Supplementary Protection	9,011	9,376	Not applicable	
MEDICAL DEVICE LICENSE APPLICATION FEES ¹	T			
Class II - Licence Application	397	414	Not applicable	
Class III - Licence Application	5,691	5,922	Not applicable	
Class III - Licence Application (Near patient In Vitro Diagnostic Devices)	9,687	10,079	Not applicable	
Class III – Changes in Manufacturing	1,433	1,492	Not applicable	
Class III – Significant Changes	5,330	5,546	Not applicable	
Class IV - Licence Application	13,235	13,770	Not applicable	
Class IV - Licence Application (Devices that contain Human- Animal Tissue)	12,347	12,846	Not applicable	
Class IV - Licence Application (Near patient In Vitro Diagnostic Device)	22,560	23,473	Not applicable	
Class IV - Changes in Manufacturing	1,433	1,492	Not applicable	
Class IV - Significant Changes	6,073	6,319	Not applicable	
Remission Processing Fee	61	65	Not applicable	
VETERINARY DRUG EVALUATION FEES ¹				
New Drug Submission:				

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in one animal species. (In the case of an antiparasitic drug, several indications in one food animal species.)	15,980	16,331.56	Not applicable
Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species.	9,680	9,892.96	Not applicable
Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in two animal species, or a single route of administration, dosage form and two indications in one animal species.	23,240	23,751.28	Not applicable
Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species.	31,470	32,162.34	Not applicable
Comparative (pharmacodynamics, clinical or bioavailability) data to support an additional route of administration	2,900	2,963.80	Not applicable
Comparative (pharmacodynamics, clinical or bioavailability) data to support each additional strength.	480	490.56	Not applicable
For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species.	21,790	22,269.38	Not applicable
For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species.	29,050	29,689.10	Not applicable
For food-producing animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route of administration.	2,900	2,963.80	Not applicable

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in an additional species.	14,520	14,839.44	Not applicable
Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug.	4,840	4,946.48	Not applicable
Chemistry and manufacturing data to support one strength of a single dosage form.	4,840	4,946.48	Not applicable
Chemistry and manufacturing data to support an additional strength of a single dosage form submitted at the same time as the above item.	2,420	2,473.24	Not applicable
Documentation to support a change of manufacturer.	250	255.50	Not applicable
Supplement to a New Drug Submission:			
Efficacy data to support an additional indication in one animal species.	12,590	12,866.98	Not applicable
Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species.	9,680	9,892.96	Not applicable
Efficacy and safety data (in the intended species) to support an indication in another animal species.	15,980	16,331.56	Not applicable
Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in two animal species, or a single route of administration and dosage form and two indications in one animal species.	23,240	23,751.28	Not applicable
Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species.	31,470	32,162.34	Not applicable
Efficacy and safety data (in the intended species) to support the concurrent use of two drugs approved for the same animal species.	7,740	7,910.28	Not applicable
Comparative (pharmacodynamics, clinical or bioavailability) data to support an additional route of administration.	2,900	2,963.80	Not applicable
Comparative (pharmacodynamics, clinical or bioavailability) data to support each additional strength.	480	490.56	Not applicable

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year	
For food-producing animals, residue depletion studies to establish a new withdrawal period for a change in the dosage or route of administration of an approved dosage form in one species.	2,900	2,963.80	Not applicable	
For food-producing animals, metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage and route of administration of an approved dosage form in an additional species.	14,520	14,839.44	Not applicable	
For food-producing animals, toxicity studies to support a change of an established acceptable daily intake, maximum residue limit and withdrawal period.	7,260	7,419.72	Not applicable	
For the concurrent use of two drugs in a species of food-producing animals, residue depletion studies to determine if an extension to existing withdrawal periods is required.	5,810	5,937.82	Not applicable	
Chemistry and manufacturing data to support a change in the source of a medicinal ingredient or its manufacturing process.	4,840	4,946.48	Not applicable	
Chemistry and manufacturing data to support a change in formulation or dosage form.	2,420	2,473.24	Not applicable	
Chemistry and manufacturing data to support a change in packaging or in the sterilization process.	1,930	1,972.46	Not applicable	
Chemistry and manufacturing data to support an extension of the expiry dating.	1,450	1,481.90	Not applicable	
Chemistry and manufacturing data to support the concurrent use of two drugs.	1,450	1,481.90	Not applicable	
Chemistry and manufacturing data to support a change in the manufacturing site for parenteral dosage forms.	480	490.56	Not applicable	
Documentation to support a change to the name of a manufacturer or the brand name of a drug.	250	255.50	Not applicable	
Abbreviated New Drug Submission and Supplement to an Abbreviated New Drug Submission:				
Comparative (pharmacodynamics, clinical or bioavailability) data to support a single route of administration and dosage form.	2,900	2,963.80	Not applicable	
For food-producing animals, residue depletion studies to confirm that the withdrawal period(s) for each species falls within the conditions of use for the Canadian reference product.	2,900	2,963.80	Not applicable	

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
Chemistry and manufacturing data for a non- compendial medicinal ingredient of a drug.	4,840	4,946.48	Not applicable
Chemistry and manufacturing data to support a single dosage form.	4,840	4,946.48	Not applicable
Documentation to support (a) a change of manufacturer, in the case of an abbreviated new drug submission; or (b) a change to the name of a manufacturer or the brand name of a drug, in the case of a supplement to an abbreviated new drug submission.	250	255.50	Not applicable
Drug Identification Number Application:			
Information, other than that referred to in item 2, to support an application for a number, including the submission of labelling material for a second review, if required.	720	735.84	Not applicable
Published references or other data.	500	511.00	Not applicable
Documentation to support a change of manufacturer, a change to the name of a manufacturer or a change to the brand name of a drug.	250	255.50	Not applicable
Preclinical New Drug Submission:			
Efficacy and safety data (in the intended species) and protocol to support the conduct of clinical studies relative to a single dosage form, route of administration and indication in one species.	4,840	4,946.48	Not applicable
Efficacy data and protocol to support the conduct of clinical studies relative to a single route of administration and indication with a dosage form for which a notice of compliance has been issued for use in the species to be treated.	3,870	3,955.14	Not applicable
For food-producing animals, toxicity, metabolism and residue depletion studies to establish a temporary acceptable daily intake, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species.	14,520	14,839.44	Not applicable
For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species.	21,790	22,269.38	Not applicable

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species.	29,050	29,689.10	Not applicable
For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism studies to establish a withdrawal period for a single dosage form, dosage and route of administration in an additional species.	7,260	7,419.72	Not applicable
Chemistry and manufacturing data to support a single dosage form containing a non-compendial medicinal ingredient.	4,840	4,946.48	Not applicable
Chemistry and manufacturing data to support a single dosage form containing a compendial medicinal ingredient.	2,420	2,473.24	Not applicable
Notifiable Change or Protocol Review:			
Information and material to support an application for Notifiable Change	1,300	1,300	Not applicable
Request for review of scientific information outside of a regular drug submission (i.e. review of a proposed trial protocol)	1,300	1,300	Not applicable
Experimental Studies Certificate:			
Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a non-food-producing animal.	960	981.12	Not applicable
Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that for a previously authorized experimental studies certificate for a drug to be administered to a non-food-producing animal.	480	490.56	Not applicable
Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a food-producing animal.	2,900	2,963.80	Not applicable

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that for a previously authorized experimental studies certificate for a drug to be administered to a food-producing animal.	480	490.56	Not applicable
Emergency Drug Sale:			
Information and material to support the sale of a drug to be used in the emergency treatment of a non-food-producing animal.	50	51.10	Not applicable
Information and material to support the sale of a drug to be used in the emergency treatment of a food-producing animal.	100	102.20	Not applicable
HUMAN DRUG ESTABLISHMENT LICENCE FEES 1			
Good Manufacturing Practices Component:			
A. Fabrication			
Basic Fee	17,402	18,107	Not applicable
Each Additional Category	4,361	4,538	Not applicable
Dosage Form Classes:			
Two classes	8,708	9,061	Not applicable
Three classes	17,402	18,107	Not applicable
Four classes	21,762	22,642	Not applicable
Five classes	26,106	27,162	Not applicable
Six classes	30,454	31,686	Not applicable
Each additional class	1,748	1,819	Not applicable
Sterile dosage forms	8,708	9,061	Not applicable
B. Packaging/Labelling			
Basic Fee	11,636	12,107	Not applicable
Each Additional Category	2,907	3,026	Not applicable
Dosage Form Classes:			
Two classes	5,803	6,039	Not applicable

Three or more classes 8,708 9,061 Not applicable C. Importation/Distribution Basic Fee 7,256 7,551 Not applicable Each Additional Category 1,816 1,891 Not applicable Dosage Form Classes: Two classes 3,630 3,778 Not applicable Each fabricator 1,748 1,819 Not applicable Each additional dosage form class for each fabricator 881 917 Not applicable Each additional dosage form class for each fabricator 881 917 Not applicable Each additional mad Wholesaling Distribution and Wholesaling Ee 4,361 4,538 Not applicable E. Testing Testing Fee 2,907 3,026 Not applicable Drug Analysis Component² Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components Drugs for human use that are prescription drugs, controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been assigned Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 A. Fabrication Basic Fee 6,000 6,132 Not applicable	Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
Basic Fee 7,256 7,551 Not applicable Each Additional Category 1,816 1,891 Not applicable Dosage Form Classes: Two classes 3,630 3,778 Not applicable Three or more classes 7,256 7,551 Not applicable Each fabricator 1,748 1,819 Not applicable Each additional dosage form class for each fabricator D. Distribution and Wholesaling Distribution and Wholesaling Fee 4,361 4,538 Not applicable E. Testing Testing Fee 2,907 3,026 Not applicable Drug Analysis Component² Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components Drugs for human use that are prescription drugs, controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been assigned Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	Three or more classes	8,708	9,061	Not applicable
Each Additional Category 1,816 1,891 Not applicable Dosage Form Classes: Two classes 3,630 3,778 Not applicable Three or more classes 7,256 7,551 Not applicable Each fabricator 1,748 1,819 Not applicable Each additional dosage form class for each fabricator D. Distribution and Wholesaling Distribution and Wholesaling Fee 4,361 4,538 Not applicable E. Testing Testing Fee 2,907 3,026 Not applicable Drug Analysis Component* Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components Drugs for human use that are prescription drugs, controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been assigned Dealer's Licence* Dealer's Licence* Scod Manufacturing Practices Component A. Fabrication	C. Importation/Distribution			
Dosage Form Classes: Two classes 3,630 3,778 Not applicable Three or more classes 7,256 7,551 Not applicable Each fabricator 1,748 1,819 Not applicable Each additional dosage form class for each fabricator D. Distribution and Wholesaling Distribution and Wholesaling Fee 4,361 E. Testing Testing Fee 2,907 3,026 Not applicable Drug Analysis Component² Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components 11,603 12,073 Not applicable Drugs for human use that are prescription drugs, controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been assigned Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	Basic Fee	7,256	7,551	Not applicable
Two classes 3,630 3,778 Not applicable Three or more classes 7,256 7,551 Not applicable Each fabricator 1,748 1,819 Not applicable Each additional dosage form class for each fabricator 881 917 Not applicable Each additional dosage form class for each fabricator 881 917 Not applicable D. Distribution and Wholesaling Distribution and Wholesaling Fee 4,361 4,538 Not applicable E. Testing Testing Fee 2,907 3,026 Not applicable Drug Analysis Component² Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components Drugs for human use that are prescription drugs, controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been assigned Dealer's Licence³ Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	Each Additional Category	1,816	1,891	Not applicable
Three or more classes 7,256 7,551 Not applicable Each fabricator 1,748 1,819 Not applicable Each fabricator 881 917 Not applicable D. Distribution and Wholesaling Distribution and Wholesaling Fee 4,361 4,538 Not applicable E. Testing Testing Fee 2,907 3,026 Not applicable Drug Analysis Component² Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components Drugs for human use that are prescription drugs, controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been 4,361 4,538 Not applicable Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	Dosage Form Classes:			
Each fabricator 1,748 1,819 Not applicable Each additional dosage form class for each fabricator 881 917 Not applicable D. Distribution and Wholesaling Distribution and Wholesaling Fee 4,361 4,538 Not applicable E. Testing Testing Fee 2,907 3,026 Not applicable Drug Analysis Component² Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components Drugs for human use that are prescription drugs, controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been 4,361 4,538 Not applicable Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	Two classes	3,630	3,778	Not applicable
Each additional dosage form class for each fabricator D. Distribution and Wholesaling Distribution and Wholesaling Fee	Three or more classes	7,256	7,551	Not applicable
fabricator D. Distribution and Wholesaling Distribution and Wholesaling Fee	Each fabricator	1,748	1,819	Not applicable
Distribution and Wholesaling Fee 4,361 4,538 Not applicable E. Testing Testing Fee 2,907 3,026 Not applicable Drug Analysis Component² Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components 11,603 12,073 Not applicable Drugs for human use that are prescription drugs, controlled drugs or narcotics 8,708 9,061 Not applicable Drugs for human use, not included in any other item, for which a drug identification number has been assigned 4,361 4,538 Not applicable Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication		881	917	Not applicable
E. Testing Fee 2,907 3,026 Not applicable Drug Analysis Component² Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components 11,603 12,073 Not applicable Drugs for human use that are prescription drugs, controlled drugs or narcotics 8,708 9,061 Not applicable Drugs for human use, not included in any other item, for which a drug identification number has been assigned 4,361 4,538 Not applicable Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	D. Distribution and Wholesaling			
Testing Fee 2,907 3,026 Not applicable Drug Analysis Component² Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components Drugs for human use that are prescription drugs, controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been assigned Dealer's Licence3 Dealer's Licence S,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	Distribution and Wholesaling Fee	4,361	4,538	Not applicable
Drug Analysis Component2 Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components 11,603 12,073 Not applicable Drugs for human use that are prescription drugs, controlled drugs or narcotics Prugs for human use, not included in any other item, for which a drug identification number has been assigned Dealer's Licence Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	E. Testing			
Vaccines 29,001 30,174 Not applicable Schedule D Drugs which are not vaccines or whole blood and its components 11,603 12,073 Not applicable Drugs for human use that are prescription drugs, controlled drugs or narcotics 8,708 9,061 Not applicable Drugs for human use, not included in any other item, for which a drug identification number has been assigned 4,361 4,538 Not applicable Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	Testing Fee	2,907	3,026	Not applicable
Schedule D Drugs which are not vaccines or whole blood and its components Drugs for human use that are prescription drugs, controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been assigned Dealer's Licence Dealer's Licence S,082 S,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	Drug Analysis Component ²			
blood and its components Drugs for human use that are prescription drugs, controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been assigned Dealer's Licence Dealer's Licence VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	Vaccines	29,001	30,174	Not applicable
Controlled drugs or narcotics Drugs for human use, not included in any other item, for which a drug identification number has been assigned Dealer's Licence ³ Dealer's Licence VETERINARY DRUG ESTABLISHMENT LICENCE FEES ^{1&4} Good Manufacturing Practices Component A. Fabrication		11,603	12,073	Not applicable
for which a drug identification number has been assigned A,361		8,708	9,061	Not applicable
Dealer's Licence 5,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	for which a drug identification number has been	4,361	4,538	Not applicable
S,082 5,288 Not applicable VETERINARY DRUG ESTABLISHMENT LICENCE FEES 184 Good Manufacturing Practices Component A. Fabrication	Dealer's Licence ³			
Good Manufacturing Practices Component A. Fabrication	Dealer's Licence	5,082	5,288	Not applicable
Good Manufacturing Practices Component A. Fabrication	VETEDIN	ADV DDIIG ESTA	BI ISHMENT LIC	ENCE FEES 184
A. Fabrication	VETERINA	ART DRUG ESTA	EDEIOTHVIENT LIC	LHOL I LEG
A. Fabrication	Good Manufacturing Practices Component			
	Basic Fee	6,000	6,132	Not applicable

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
Each Additional Category	1,500	1,533	Not applicable
Dosage Form Classes:			
Two classes	3,000	3,066	Not applicable
Three classes	6,000	6,132	Not applicable
Four classes	7,500	7,665	Not applicable
Five classes	9,000	9,198	Not applicable
Six classes	10,500	10,731	Not applicable
Each additional class	600	613.20	Not applicable
Sterile dosage forms	3,000	3,066	Not applicable
B. Packaging/Labelling			
Basic Fee	4,000	4,088	Not applicable
Each Additional Category	1,000	1,022	Not applicable
Dosage Form Classes:			
Two classes	2,000	2,044	Not applicable
Three or more classes	3,000	3,066	Not applicable
C. Importation/Distribution			
Basic Fee	2,500	2,555	Not applicable
Each Additional Category	625	638.75	Not applicable
Dosage Form Classes:			
Two classes	1,250	1277.50	Not applicable
Three or more classes	2,500	2,555	Not applicable
Each fabricator	600	613.20	Not applicable
Each additional dosage form class for each fabricator	300	306.60	Not applicable
D. Distribution and Wholesaling			
Distribution and Wholesaling Fee	1,500	1,533	Not applicable
E. Testing			
Testing Fee	1,000	1,022	Not applicable
Drug Analysis Component			
Drug Identification Numbers for Veterinary Use Dealer's Licence ³	250	255.50	Not applicable

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
Dealer's Licence	1,750	1,788.50	Not applicable
MEDICAL DEVICE ESTABLISHMENT LICENCE FEE	1		
Medical Devices Establishment Licence	8,109	8,438	Not applicable
PEST CONTROL PRODUCTS FEES AND CHARGES	3		
Fees for application to register, or to amend the re a semiochemical or Microbial Agent	gistration of, a Po	est Control Prod	uct other than
Product Chemistry – active ingredient	4,873	5,071	Not applicable
Product Chemistry – end-use product or manufacturing concentrate	2,713	2,824	Not applicable
Toxicology data accompanying an application to register a pest control product that contains a new active ingredient	75,807	78,871	Not applicable
Toxicology data accompanying an application to register a pest control product –or to amend a pest control product –that contains an registered active ingredient	15,830	16,470	Not applicable
Toxicology data-acute toxicity studies	2,954	3,075	Not applicable
Exposure data accompanying an application to register a pest control that consists of or that contains a new active ingredient	17,498	18,205	Not applicable
Exposure data accompanying an application to register a pest control product –or to amend the registration of a pest control product –that contains a registered active ingredient, when a new risk assessment is necessary	5,758	5,992	Not applicable
Exposure data-other	5,214	5,426	Not applicable
Metabolism data	28,943	30,113	Not applicable
Residue data	15,838	16,479	Not applicable
Environment fate data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	42,685	44,410	Not applicable
Environmental fate data accompanying an application to register a pest control product ,or to amend the registration of a pest control product, that	23,637	24,593	Not applicable

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
contains a registered active ingredient , when a new risk assessment is necessary			
Environmental fate data-other	11,546	12,013	Not applicable
Environment toxicology data accompanying an application to register a pest control product that consists of or that contains a new active ingredient	37,277	38,784	Not applicable
Environmental toxicology data accompanying an application to register a pest control product ,or to amend the registration of a pest control product, that contains a registered active ingredient , when a new risk assessment is necessary	26,690	24,648	Not applicable
Environmental toxicology data-other	2,465	2,566	Not applicable
Value and effectiveness data for a pest control product	906	944	Not applicable
Identification of compensable data	2,162	2,251	Not applicable
Fees for application in respect of a Pest Control Pr Agent	oduct that is a se	emiochemical or	Microbial
Registration of a new active ingredient – food use	7,236	7,529	Not applicable
Registration of a new active ingredient – non-food use	4,341	4,517	Not applicable
Amendment of registration – new risk assessment necessary-environmental fate data, environmental toxicity data or exposure data	2,894	3,012	Not applicable
Amendment of registration – data required, label changes	1,447	1,506	Not applicable
Amendment of registration – data required, other	1,158	1,206	Not applicable
Amendment of registration – no data required	290	302	Not applicable
Registration of new active ingredient	579	603	Not applicable
Amendment of registration	290	302	Not applicable
Fees for other applications in respect of a Pest Co	ntrol Product		
Research authorization – major crops, other than research authorizations set out in paragraphs (c) and (d)	5,080	5,286	Not applicable
Research authorization – minor use crops, other than research authorizations set out in paragraphs (c) and (d)	5,080	5,286	Not applicable

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
Research authorization – microbial agents, semiochemicals and any substance listed in subparagraph 1(d) (ii) of these regulations.	1,217	1,267	Not applicable
Research authorization – greenhouse crops and non-agricultural uses	1,217	1,267	Not applicable
Research notifications	247	258	Not applicable
Registration of active ingredient to be used in pest control product manufactured only for export	7,827	8,144	Not applicable
Amendment to Registration of active ingredient to be used in pest control product manufactured only for export	1,133	1,180	Not applicable
Specification of maximum residue limit for a previously unexamined pest control product	125,461	130,531	Not applicable
Specification of maximum residue limit for an unregistered use of a previously examined pest control product	15,838	16,479	Not applicable
Applications not mentioned in Schedules	1	1	I
Processing	1,133	1,180	Not applicable
Applications not mentioned in schedules	247	258	Not applicable
Renewal	80	84	Not applicable
Annual Charge	1	l	I
Annual Charge	3,600	3,679	Not applicable
FEES CHARGED FOR FILING A CLAIM FOR EXEM INFORMATION REVIEW ACT	PTION UNDER TI	HE HAZARDOUS	MATERIALS
Original Claim:			
First 15 claims	1,800	1,839.60	Not applicable
Next ten claims	400	408.80	Not applicable
Over 25 claims	200	204.40	Not applicable
Refiled Claim:			
First 15 claims	1,440	1,471.68	Not applicable
Next ten claims	320	327.04	Not applicable
Over 25 claims	160	163.52	Not applicable

Hazardous Materials Information Review Regulations for more information (section 4,5 and 7).

Name of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year
CANNABIS FEES 5			
Licence Application Screening Fee:			
Licence for micro-cultivation	Not in effect	1,638	Not applicable
Licence for standard cultivation	Not in effect	3,277	Not applicable
Licence for a nursery	Not in effect	1,638	Not applicable
Licence for micro-processing	Not in effect	1,638	Not applicable
Licence for standard processing	Not in effect	3,277	Not applicable
Licence for sale for medical purposes	Not in effect	3,277	Not applicable
Application for a security clearance	Not in effect	1,654	Not applicable
Application for import or export permit	Not in effect	610	Not applicable
Annual fee	Not in effect	See <u>Cannabis</u> <u>Fees Order</u>	Not applicable
FEES SET BY MINISTERIAL AUTHORITY TO ENTE	R INTO CONTRA	СТ	
National Dosimetry Products and Services Fees	See National Dosimetry Products and Services Fees	See <u>National</u> <u>Dosimetry</u> <u>Products and</u> <u>Services Fees</u>	Not applicable
Certificate of Pharmaceutical Product Fee	86	90	Not applicable
	1 30	<u> </u>	1.01 3.56.100010
Drug Master File Fees:			
New Master Files (file registration)	1,200	1,248	Not applicable
Drug Master Files - letter of access	170	176	Not applicable
Drug Master Files - Update	520	541	Not applicable

Notes:

- Revised fees with respect to Drugs and Medical Devices were consulted on in 2017 and 2018. These new fees will be published on the Health Canada website in advance of implementation.
- Product laboratory analysis activities based on the risks associated with various broad product types.
- Fees for the examination of dealer's licence application.

Name	of fee	2017-18 Fee Amount	2019-20 Adjusted fee amount	Future fee amount and fiscal year	
4)	4) If an establishment conducts licensable activities that include human and veterinary drugs, or controlled substances and / or narcotics, then the human drug fee supersedes the veterinary drug fee.				
5)	5) Cannabis Fees came into effect on October 17, 2018.				