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Performance Standards for the Fees in Respect of Drugs and Medical Devices Order

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Canada

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Normes de rendement pour l'Arrêté sur les prix à payer à l'égard des drogues et instruments médicaux

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Performance Standards for the Fees in Respect of Drugs and Medical Devices Order

This document provides the performance standards to be used to determine whether a remission should be granted, under the *Fees in Respect of Drugs and Medical Devices Order (Order),* to a person who must pay a fee under that Order.

The *Guideline on Service Standards* developed by the Treasury Board of Canada Secretariat defines a service standard as follows: a service standard is a public commitment to a measurable level of performance that clients can expect under normal circumstances.

Further to consultations from October 2017 to June 2018, Health Canada has established the following performance standards in relation to fees that are payable under the Order. The standards appropriately reflect the department's ability to deliver its service(s) within a set timeframe.

This document was originally published on November 22, 2018. The following updates have been made:

- November 1, 2022, to reflect changes to the fee category definitions in the Order
- September 11, 2023, to reflect changes to the fee category descriptions in the Order
- February 16, 2024, to reflect the introduction of biocides fees to the Order

For the *Fees in Respect of Drugs and Medical Devices Order*, the following performance standards apply to fees for drugs, biocides and medical devices.

Fees for examination of a submission – Drugs for human use

	Submission Class	Description	Performance Standard
1	New active substance	Submissions in support of a drug, other than a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph	300 calendar days to complete Review 1*
2	Clinical or nonclinical data and chemistry and manufacturing data	Submissions based on clinical or nonclinical data and chemistry and manufacturing data for a drug that does not include a new active substance	For drugs under Division 1 of the *Food and Drug Regulations*: 210 calendar days to complete Review 1* For drugs under Division 8 of the *Food and Drug Regulations*: 300 calendar days to complete Review 1*

3	Clinical or nonclinical data only	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance	For drugs under Division 1 of the *Food and Drug Regulations*: 210 calendar days to complete Review 1* For drugs under Division 8 of *Food and Drug Regulations*: 300 calendar days to complete Review 1*
4	Comparative studies	Submissions based on comparative studies (e.g., clinical or non-clinical data, bioavailability data and data on the pharmacokinetics and pharmacodynamics of the drug) with or without chemistry and manufacturing data for a drug that does not include a new active substance	For drugs under Division 1 of the *Food and Drug Regulations*: 210 calendar days to complete Review 1* For drugs under Division 8 of *Food and Drug Regulations*: 180 calendar days to complete Review 1*
5	Chemistry and manufacturing data only	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance	For drugs under Division 1 of the *Food and Drug Regulations*: 210 calendar days to complete Review 1* For drugs under Division 8 of *Food and Drug Regulations*: 180 calendar days to complete Review 1*
6	Clinical or nonclinical data only, in support of safety updates to the labelling	Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance	120 calendar days to complete Review 1*
7	Labelling only	Submissions, other than those described in item 8, 11 or 12, of labelling material, that include data in support of the following: brand name assessment, standardized or published test methods, in vitro or in vivo photostability or applications for a drug identification number in support of changes to brand names of non-prescription drugs (but not including examination of other supporting clinical or non-clinical data,	120 calendar days to complete Review 1*

		comparative data, or chemistry and manufacturing data)	
8	Labelling only (generic drugs)	Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment	120 calendar days to complete Review 1*
9	Administrative submission	Submissions in support of a change in the manufacturer's name or brand name, including the following: changes in ownership of the drug; request for an additional brand name; changes resulting from a licensing agreement being entered into by two manufacturers that do not require an assessment of labelling material or brand name (e.g., post-authorization label changes filed by licensees to remain identical to licensor's drug and post-authorization chemistry and manufacturing updates for drugs listed in Schedule C or D of the *Food and Drugs Act*)	45 calendar days to review
10	Disinfectant — full review	Submissions, other than those described in item 11, that include data in support of a disinfectant	For drugs under Division 1 of the *Food and Drug Regulations*: 180** or 210 calendar days to complete Review 1* For drugs under Division 8 of *Food and Drug Regulations*: 300 calendar days to complete Review 1*
11	Labelling only (disinfectants)	Submissions in support of changes to the labelling of disinfectants that do not require supporting data, submissions in support of safety updates for disinfectants that are new drugs or submissions in support of a change in the manufacturer's name or brand name that requires a review of labelling	90 calendar days to complete Review 1*

		material due to deviations from the previously authorized labelling or drug	
12	Drug identification number application — labelling standards	Applications, including those that pertain to changes to brand names for non-prescription drugs, that include an attestation of compliance with a labelling standard or Category IV Monograph for a drug and that do not include clinical or non-clinical data or chemistry and manufacturing data	60 calendar days to complete Review 1*

*Review 1 is the period from the date of acceptance to the date of the first decision (Notice of Deficiency, Notice of Non-compliance, Notice of Compliance with Conditions or Notice of Compliance).
**The 180 calendar days to complete Review 1 is a Label Only assessment that does not include the submission of data. It relies on bridged / cross-referenced data from other submissions.

Fees for examination of a submission – Drugs for veterinary use only***

	Type of submission	Description	Performance Standard
1	Application for drug identification number	Components included in an application as set out in Schedule 2 of the *Fees in Respect of Drugs and Medical Devices Order*	120 calendar days to complete Review 1*
2	Notification — veterinary health product	Information contained in a notification filed under subsection C.01.615 (1) of the *Food and Drug Regulations* in respect of a veterinary health product	30 calendar days to process notification
3	New drug submission	Components included in a submission as set out in Schedule 2 of the *Fees in Respect of Drugs and Medical Devices Order*	300 calendar days to complete Review 1*
4	Supplement to a new drug submission	Components included in a submission as set out in Schedule 2 of the *Fees in Respect of Drugs and Medical Devices Order*	240 calendar days to complete Review 1*
5	Abbreviated new drug submission	Components included in a submission as set out in Schedule 2 of the *Fees in*	300 calendar days to complete Review 1*

		Respect of Drugs and Medical Devices Order	
6	Supplement to an abbreviated new drug submission	Components included in a submission as set out in Schedule 2 of the *Fees in Respect of Drugs and Medical Devices Order*	240 calendar days to complete Review 1*
7	Preclinical submission	Components included in a submission as set out in Schedule 2 of the *Fees in Respect of Drugs and Medical Devices Order*	60 calendar days to review application
8	Sale of new drug for emergency treatment	Information and material to support the sale of a drug to be used in the emergency treatment of a food or non-food-producing-animal	2 business days to review application
9	Experimental studies certificate	Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a food or non-food-producing-animal	60 calendar days to review application
10	Notifiable change	Information and material to support an application for a notifiable change	90 calendar days to review application
11	Protocol	A protocol that is filed with the Minister and may support a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or abbreviated new drug submission, a preclinical submission or information and material that is filed for the purpose of obtaining an experimental studies certificate	90 calendar days to review package

*Review 1 is the period from the date of acceptance to the date of the first decision (Notice of Deficiency, Notice of Non-compliance, Notice of Compliance with Conditions or Notice of Compliance).
*** While there are individual fees for each component and a submission / application can be made up of more than one component, the submission / application is reviewed as one package.

Fees for examination of an application – Biocides

Class		Description	Performance Standard
1	Biocide full review - novel biocide	An application for a market authorization or for a notice of acceptance in respect of a major change, other than an application based on a comparison referred to in item 7, if the biocide has a novel active ingredient, a novel combination of active ingredients, or a novel physical form, use, purpose or method of application.	300 calendar days to complete Review 1*
2	Biocide full review – tier I	An application for a market authorization or for a notice of acceptance in respect of a major change, other than an application referred to in item 1, that contains 25 or fewer reports of tests and studies with respect to efficacy data.	180 calendar days to complete Review 1*
3	Biocide full review – tier II	An application for a market authorization or for a notice of acceptance in respect of a major change, other than an application referred to in item 1, that contains 26 to 50 reports of tests and studies with respect to efficacy data.	195 calendar days to complete Review 1*
4	Biocide full review – tier III	An application for a market authorization or for a notice of acceptance in respect of a major change, other than an application referred to in item 1, that contains at least 51 reports of tests and studies with respect to efficacy data.	210 calendar days to complete Review 1*
5	Biocide comparison — labelling only	An application for a market authorization or for a notice of acceptance in respect of a major change that is based on a comparison and requires a review of labelling.	90 calendar days to complete Review 1*
6	Biocide comparison — administrative application	An application for a market authorization or for a notice of acceptance in respect of a major change that is based on a comparison between the biocide and another biocide that is the subject of a	45 calendar days to review

		market authorization in cases where only the brand name of the biocide, the name of the applicant or the name of the holder of the market authorization, or any combination thereof, differs from the corresponding information in respect of the other biocide.	
7	Biocide — Use of foreign decisions	An application for a market authorization that is based on a comparison between the biocide and a biocide that is authorized for sale by a foreign regulatory authority or an application for a notice of acceptance in respect of a major change to the biocide that is the subject of such a market authorization.	90 calendar days to complete Review 1*
8	Biocide monograph	An application for a market authorization or for a notice of acceptance in respect of a major change that includes an attestation of compliance with a biocide monograph prepared by the Minister and requires supporting information for aspects of the biocide that are outside the parameters of the monograph.	60 calendar days to review
9	Biocide major change — monograph	An application for a notice of acceptance in respect of a major change that includes an attestation of compliance with a biocide monograph prepared by the Minister and that does not require supporting information because the aspects of the biocide that are impacted by the change are within the parameters of the monograph.	30 calendar days to review
10	Biocide major change – quality and risks	An application for a notice of acceptance in respect of a major change that does not include reports of tests and studies with respect to efficacy data.	60 calendar days to review

11	Biocide minor change	The examination of a written description of a minor change.	30 calendar days to review
Review 1 is the period from the date of acceptance to the date of the first decision (Notice of Deficiency, Notice of Non-compliance, Notice of Compliance with Conditions or Notice of Compliance).			

Fees for Examination of an application for an establishment licence – Drugs for human use and / or veterinary use only

Fee name	Description	Performance Standard
Drug Establishment Licence	Application for new licence, annual review of licence, or amendment to a licence to add a new building in Canada	250 calendar days to issue decision
Activity		
Fabrication — sterile dosage form		
Importation		
Fabrication — nonsterile dosage form		
Distribution		
Wholesaling		
Packaging/labelling		
Testing		

Fees for right to sell drugs for human use

Fee name	Description	Performance Standard
Right to Sell Drugs for Human Use	The annual fee for the right to sell a drug (Disinfectant, Non-prescription drug, or a Drug other than one referred to earlier) for which a drug identification number has been assigned under section C.01.014.2 (1) of the *Food and Drug Regulations*	20 calendar days to update Drug Product Database following receipt of a complete Annual Notification Package

Fees for right to sell drugs for veterinary use only

Fee name	Description	Performance Standard
Right to Sell Drugs for Veterinary Use Only	The annual fee for the right to sell a drug for veterinary use only for which a drug identification number has been assigned under section C.01.014.2 (1) of the *Food and Drug Regulations*	20 calendar days to update Drug Product Database following receipt of a complete Annual Notification Package

Fees for right to sell biocides

Fee Name	Description	Performance Standard
Right to Sell Biocide	The annual fee that is payable for the right to sell a biocide for which a market authorization has been issued under section 11 of the *Biocides Regulations*	20 calendar days to update biocides database following receipt of annual notification of sale

Fees for examination of an application for licence, amendment application for a licence or application to amend authorization – Medical devices

	Category	Description	Performance Standard
1	Applications for Class II licence	Applications for Class II medical device licence other than those referred to in item 10	15 calendar days to review

2	Applications for Class II licence amendment or applications to amend Class II authorization	Applications for amendment of Class II medical device licence or applications to amend authorization filed under section 68.14 of the *Medical Devices Regulations* for a Class II medical device that is not a UPHN medical device, other than applications referred to in item 10	15 calendar days to review
3	Applications for Class III licence	Applications for Class III medical device licence other than those referred to in item 4 or 10	60 calendar days to complete Review 1*
4	Applications for Class III licence (near patient)	Applications for Class III medical device licence for a near patient in vitro diagnostic device	60 calendar days to complete Review 1*
5	Applications for Class III licence amendment or applications to amend Class III authorization — changes in manufacturing	Applications for amendment of Class III medical device licence or applications to amend authorization filed under section 68.14 of the *Medical Devices Regulations* for a Class III medical device that is not a UPHN medical device — changes in manufacturing process, facility or equipment or manufacturing quality control procedures	60 calendar days to complete Review 1*
6	Applications for Class III licence amendment or applications to amend Class III authorization — significant changes not related to manufacturing	Applications for amendment of Class III medical device licence or applications to amend authorization filed under section 68.14 of the *Medical Devices Regulations* for a Class III medical device that is not a UPHN medical device — significant changes other than those referred to in item 5	60 calendar days to complete Review 1*
7	Applications for Class IV licence	Applications for Class IV medical device licence other than those referred to in item 10	75 calendar days to complete Review 1*

8	Applications for Class IV licence amendment or applications to amend Class IV authorization — changes in manufacturing	Applications for amendment of Class IV medical device licence or applications to amend authorization filed under section 68.14 of the *Medical Devices Regulations* for a Class IV medical device that is not a UPHN medical device — changes referred to in paragraph 34(a) or 68.13 (a) of the *Medical Devices Regulations* that relate to manufacturing	75 calendar days to complete Review 1*
9	Applications for Class IV licence amendment or applications to amend Class IV authorization — significant changes not related to manufacturing	Applications for amendment of Class IV medical device licence or applications to amend authorization filed under section 68.14 of the *Medical Devices Regulations* for Class IV medical device that is not a UPHN medical device — any other changes referred to in paragraph 34(a) or (b) or 68.13 (a) or (b) of the *Medical Devices Regulations*	75 calendar days to complete Review 1*
10	Applications for Class II, III or Class IV licence, applications to amend such a license or applications to amend Class II, III OR Class IV authorization — private label medical device	Applications for Class II, III or IV medical device licence, applications to amend Class II, III or IV license or applications to amend authorization filed under section 68.14 of the *Medical Devices Regulations* for a Class II, III or Class IV medical device that is not a UPHN medical device— private label medical device	15 calendar days to review

*Review 1 is the period from the date of acceptance of an administratively complete application to the date of the first decision (for Class II and Private Label Applications: Licence, Screening Deficiency Letter, Rejection Letter, Withdrawal; for Class III and IV: Licence, Additional Information Request, Refusal Letter, or Withdrawal).

Fees for examination of an application for a medical device establishment licence

Fee Name	Description	Performance Standard
Medical Device Establishment Licence	Applications for new licence and annual review of licence	120 calendar days to issue decision

Fees for Right to sell Licensed or authorized Class II, III or IV medical devices

Fee name	Description	Performance Standard
Right to Sell Medical Device	The annual fee for the right to sell a licensed Class II, III or IV medical device or an authorized Class II, III or IV medical device that is not a UPHN medical device.	20 days to update Medical Device Licence Listing database following receipt of a complete Annual Notification Package