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



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

The purpose of this document is to provide 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.

For the purposes of the *Fees in Respect of Drugs and Medical Devices Order*, to come into force on April 1, 2020, below are the performance standards applicable to fees for drugs 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 non-clinical data and chemistry and manufacturing data	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance	For drugs under Division 1 of the <i>Food and Drug Regulations</i> : 210 calendar days to complete Review 1* For drugs under Division 8 of the <i>Food and Drug Regulations</i> : 300 calendar days to complete Review 1*
3	Clinical or non-clinical 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 <i>Food and Drug Regulations</i> : 210 calendar days to complete Review 1* For drugs under Division 8 of <i>Food and Drug Regulations</i> : 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 <i>Food and Drug Regulations</i> : 210 calendar days to complete Review 1* For drugs under Division 8 of <i>Food and Drug Regulations</i> : 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 <i>Food and Drug Regulations</i> : 210 calendar days to complete Review 1* For drugs under Division 8 of <i>Food and Drug Regulations</i> : 180 calendar days to complete Review 1*
6	Clinical or non-clinical 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, comparative data, or chemistry and manufacturing data)	120 calendar days to complete Review 1*
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 <i>Food and Drugs Act</i>)	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 <i>Food and Drug Regulations</i> : 180** or 210 calendar days to complete Review 1*

			For drugs under Division 8 of <i>Food and Drug Regulations</i> : 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 material due to deviations from the previously authorized labelling or drug	90 calendar days to complete Review 1*
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*

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 <i>Fees in Respect of Drugs and Medical Devices Order</i>	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 <i>Food and Drug Regulations</i> 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 <i>Fees in Respect of Drugs and Medical Devices Order</i>	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 <i>Fees in Respect of Drugs and Medical Devices Order</i>	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 <i>Fees in Respect of Drugs and Medical Devices Order</i>	300 calendar days to complete Review 1*
6	Supplement to an abbreviated new drug submission	Components included in a submission as set out in Schedule 2 of the <i>Fees in Respect of Drugs and Medical Devices Order</i>	240 calendar days to complete Review 1*
7	Preclinical submission	Components included in a submission as set out in Schedule 2 of the <i>Fees in Respect of Drugs and Medical Devices Order</i>	60 calendar days to review application

		<i>Order</i>	
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).

**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.

*** 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 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 <i>Food and Drug Regulations</i>	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 <i>Food and Drug Regulations</i>	20 calendar days to update Drug Product Database following receipt of a complete Annual Notification Package

Fees for Examination of an Application for a Medical Device Licence

Category	Description	Performance Standard
1	Applications for Class II licence	15 calendar days to review
2	Applications for Class II licence amendment	15 calendar days to review
3	Applications for Class III licence	60 calendar days to complete Review 1*
4	Applications for Class III licence (near patient)	60 calendar days to complete Review 1*
5	Applications for Class III licence amendment — changes in manufacturing	60 calendar days to complete Review 1*
6	Applications for Class III licence amendment — significant changes not related to manufacturing	60 calendar days to complete Review 1*
7	Applications for Class IV licence	75 calendar days to complete Review 1*
8	Applications for Class IV licence amendment — changes in	75 calendar days to complete Review 1*

	manufacturing	to manufacturing	
9	Applications for Class IV licence amendment — significant changes not related to manufacturing	Applications for amendment of Class IV medical device licence — any other changes referred to in paragraph 34(a) or (b) of the <i>Medical Devices Regulations</i>	75 calendar days to complete Review 1*
10	Applications for Class II, III or Class IV licence or licence amendment — private label medical device	Applications for Class II, III or IV medical device licence or applications for amendment of such a licence — 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 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	20 days to update Medical Device Licence Listing database following receipt of a complete Annual Notification Package