Health Canada Santé Canada

# Guidance Document

## Management of Applications for Medical Device Licences

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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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## Document change log

| Date | Change | Location (section, paragraph) | Nature of and/or reason for change |
|---|---|---|---|
| April 1, 2020 | 7 | Full document | As of April 1, 2020, new fees along with a revised fee policy will come into force requiring significant changes to the guidance document. |
| November 4, 2019 | 6 | Full document | Formatting revisions |
| January 11, 2019 | 5 | Full document | Rewritten to add clarity and conform to Good Guidance Practices |
| | 4 | Full document | Removed information pertaining to Investigational Testing Authorizations as this information is now published in a separate guidance, Applications for Medical Device Investigational Testing Authorizations Guidance Document - Summary |
| | 3 | Full document | Addition of information pertaining to New and Amendment Private Label Licence Applications |
| | 2 | Full document | Updated text of 'Fee Status' sections throughout document for clarity and consistency |
| | 1 | Section 2.11 | Included information resulting from "Pause the Clock" consultation |

## Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

## Table of Contents

# 1. Introduction

## 1.1 Purpose/Overview

This document outlines the way in which Health Canada manages applications for medical device licences.

## 1.2 Scope and Application

This guidance document applies to the following application types:

- Licence Applications for Class II, III and IV medical devices;
- Licence Amendments for Class II medical devices, and Licence Amendments (significant changes)[1] for Class III and IV medical devices;
- Licence Amendment Minor Changes[2] (Faxbacks) for Class II, III and IV medical devices;
- New and Amendment Medical Device Licence Applications for Private Labels

For guidance on a specific device, please contact the Medical Devices Directorate to schedule a pre-submission meeting by email at hc.devicelicensing-homologationinstruments.sc@canada.ca.

## 1.3 Policy objectives

To provide a transparent outline of the processes Health Canada operates to manage medical device licence applications, in accordance with the Medical Devices Regulations.

## 1.4 Policy statements

The management principles outlined herein will be applied consistently to all medical device applications.

All applications will be examined for completeness and suitability for review and all subsequent solicited information will be subjected to a screening process.

All information and data submitted in support of a medical device licence application or application remains the property of Health Canada.

# 2. Guidance for implementation

## 2.1 Filing of Medical Device Licence Applications

Manufacturers are requested to send all original applications, application amendments and responses to Additional Information Letters to:

Bureau of Device Licensing Services
Medical Devices Directorate, Health Canada
11 Holland Avenue, Address Locator: 3002A
OTTAWA, Ontario K1A 0K9
Email: hc.devicelicensing-homologationinstruments.sc@canada.ca

## 2.2 Tools, Guidance Documents, Policies, and Application Forms

Health Canada has published numerous tools, guidelines, policies, and application forms to assist manufacturers in the preparation and filing of medical device licence applications. Manufacturers submitting medical device licence applications should refer to the Health Canada web site for tools, guidelines, policies, and forms relating to medical devices.

- Guidance Documents on Medical Devices (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents.html)
- Policy Documents on Medical Devices (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/policies.html)
- Medical Device Licence Application Forms (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/forms.html)
- Device Advice: e-Learning tool (https://training-formation.phac-aspc.gc.ca/course/index.php?categoryid=42&lang=en)

## 2.3 Target Performance Standards in Calendar Days

| | New and Amendment Class II MDL Applications | New and Amendment (Significant Change) Class III MDL Applications | New and Amendment (Significant Change) Class IV MDL Applications | Licence Amendment Minor Change Applications | New and Amendment Private Label MDL Applications |
|---|---|---|---|---|---|
| Administrative Screening | 4 | 4 | 4 | 4 | 4 |
| Screening Period | | | | | |
| Regulatory Screening | 12* | 5 | 5 | 4 | 12* |
| Technical Screening | --* | 7 | 7 | -- | --* |
| Administrative Processing | 3* | 3 | 3 | 3 | 3* |
| Target Performance Standard** | 15 | -- | -- | -- | 15 |

| | New and Amendment Class II MDL Applications | New and Amendment (Significant Change) Class III MDL Applications | New and Amendment (Significant Change) Class IV MDL Applications | Licence Amendment Minor Change Applications | New and Amendment Private Label MDL Applications |
|---|---|---|---|---|---|
| Review Period | | | | | |
| Review 1 | -- | 57* | 72* | -- | -- |
| Administrative Processing | -- | 3* | 3* | -- | -- |
| Review 2 | -- | 42 | 42 | -- | -- |
| Administrative Processing | -- | 3 | 3 | -- | -- |
| Target Performance Standard** | -- | 60 | 75 | -- | -- |

* Cells highlighted in green denote the Target Performance Standard of the respective application(s).

** The Target Performance Standard for each of the respective applications is the number of days to first decision tracked individually.

## 2.4 Administrative Screening

All application types will be validated for administrative completeness e.g., completed fee form, the folder structure of an application submission, the file naming convention used for an application submission, the file formats used for an application submission and the transmission of electronic data for the submission of an application as outlined, in detail, in the "Guidance on How to Complete the Application for a New Medical Device Licence". The Directorate will target to complete this examination within four (4) calendar days of receipt.

### 2.4.1 Acceptable Applications

You will receive a notification via email once your application is considered to have met administrative requirements and has been forwarded for subsequent application screening.

### 2.4.2 Incomplete Applications

Applications that are deficient with respect to administrative content will result in the issuance of a request for outstanding information. The manufacturer will be given ten (10) calendar days to provide the requested information. Failure to provide the requested information within the specified time-frame or provision of deficient or incomplete information will result in the issuance of a Rejection Letter.

Fee status: No fees will be levied as a result of application rejection at the administrative screening stage.

## 2.5 Regulatory Screening

All applications will be subject to an examination for validity of regulatory information for the type of application in question e.g., device risk classification, licence application type, the manufacturer's Quality Management System certification, the device labelling, and the supporting information within an application form (all information other than scientific evidence), as defined in the Medical Devices Regulations and as described in various guidance documents.

### 2.5.1 Acceptable Original Information

#### *2.5.1.1 New Class II Licence Applications, Class II Licence Amendments New Private Label Licence Applications, and Private Label Licence Amendments*

The Directorate will target to have Class II Licence Applications, Class II Licence Amendments, New Private Label Licence Applications, and Private Label Licence Amendments examined for application validity and a Licence issued within fifteen (15) calendar days following receipt of an administratively complete application (this includes a twelve (12) day regulatory screening period, and a three (3) day administrative processing period).

Fee status: In the case of New Class II Licence Applications, Class II Licence Amendments, New Private Label Licence Applications, and Private Label Licence Amendments, 100% of the applicable fee will be levied upon acceptance of an administratively complete application.

#### *2.5.1.2 New Class III and Class IV Licence Applications and Class III and IV Licence Amendments (for Significant Changes)*

Following Administrative Screening, administratively complete applications will then undergo Regulatory Screening followed by Technical Screening, as described under Section 2.6.

#### *2.5.1.3 Licence Amendment Minor Changes (Faxbacks)*

The Directorate will target to have Class II, III, and Class IV Licence Amendment Minor Change Applications examined for application validity and a Licence issued within seven (7) calendar days following receipt of an administratively complete application.

Fee Status: There are no fees associated with this type of application.

### 2.5.2 Incomplete Original Information

#### *2.5.2.1 New Class II Licence Applications, Class II Licence Amendments, New Private Label Licence Applications, and Private Label Licence Amendments*

If deficiencies are identified during the examination for validity of a New Class II Licence Application, a Class II Licence Amendment New Private Label Licence Application, or a Private Label Licence Amendment, a Screening Deficiency Notice will be issued to the manufacturer by email.

The manufacturer will then have ten (10) calendar days from the date of the Screening Deficiency Notice to submit the requested information. A new fifteen (15) calendar day target will commence for New Class II Licence Applications, Class II Licence Amendments, New Private Label Licence Applications, and Private Label Licence Amendments upon receipt of an administratively complete response of the requested information (this includes a three (3) day administrative processing period).

Failure to respond to the Screening Deficiency Notice within the specified time-frame or provision of a deficient or incomplete response will result in the issuance of a Rejection Letter. If the manufacturer wishes to re-submit the application at a future time, it will be processed as a new application.

Fee status: In the case of New Class II Licence Applications, Class II Licence Amendments, New Private Label Licence Applications, and Private Label Licence Amendments, 100% of the applicable fee will be levied upon acceptance of an administratively complete application.

#### *2.5.2.2 New Class III and IV Licence Applications and Class III and IV Licence Amendments (for significant changes)*

If deficiencies are identified during the screening of a New Class III or IV Licence Application or Class III or IV Licence Amendment (for significant changes), a Screening Deficiency Notice will be issued to the manufacturer by email. Class III and Class IV device licence applications will be identified as deficient if the regulatory requirements, as described in the Medical Devices Regulations and associated guidance documents, are not met.

The manufacturer will then have fifteen (15) calendar days from the date of the Screening Deficiency Notice to submit all of the requested information in a question and answer format. The Directorate will acknowledge receipt of the Screening Deficiency response from the applicant by email. The response will then be subject to a new fifteen (15) calendar day screening period upon receipt of a completed and validated response (this includes a five (5) day regulatory screening period, a seven (7) day technical screening period, and a three (3) day administrative processing period). Provided that the application is acceptable for review, a Screening Acceptance Letter will be issued to the manufacturer by the Bureau of Device Licensing Services.

If the risk classification outlined in the application is incorrect and the actual classification according to the Medical Device Regulations is a higher risk classification, a Rejection Letter will be issued to the manufacturer.

If an application is rejected or withdrawn, the manufacturer will be required to submit a new application with all the relevant information and fees.

Fee status: A fee (10% of the applicable fee) will be levied upon issuance of a Rejection or Withdrawal Letter.

#### *2.5.2.3 Licence Amendment Minor Changes (Faxbacks)*

If deficiencies are identified during the examination for validity of a Licence Amendment Minor Change Application, a Screening Deficiency Notice will be issued to the manufacturer by email.

The manufacturer will then have ten (10) calendar days from the date of the Screening Deficiency Notice to submit the requested information. A new seven (7) calendar day target for Licence issuance will commence upon receipt of an administratively complete response to the requested information (this includes a three (3) day administrative processing period).

Failure to respond to the Screening Deficiency Notice within the specified time-frame or provision of a deficient or incomplete response will result in the issuance of a Rejection Letter. If the manufacturer wishes to re-submit the application at a future time, it will be processed as a new application.

Fee Status: There are no fees associated with this type of application.

## 2.6 Technical Screening

All Class III and Class IV Licence Applications, and Class III and Class IV Licence Amendment (for significant changes and manufacturing) applications will be screened for technical completeness to ensure that the requisite scientific evidence in support of the medical device licence application in question, as defined in the Medical Devices Regulations and as described in various guidance documents, has been submitted.

### 2.6.1 Acceptable Original Information

**Class III and Class IV Licence Applications and Class III and Class IV Licence Amendments (for Significant Changes)**

The Directorate will target to have Class III and IV Licence Applications and Class III and IV Licence Amendments (for Significant Changes) screened within fifteen (15) calendar days of receipt in the Directorate of an administratively complete and validated application (this includes a three (3) day administrative processing period).

A Screening Acceptance Letter will be issued by the Bureau of Device Licensing Serviceswhen the information and material submitted is deemed acceptable for review.

### 2.6.2 Incomplete Original Information

#### *2.6.2.1 Screening Deficiency Notices*

If deficiencies are identified during the screening of a Class III or IV Licence Application or Class III or IV Licence Amendment (for significant changes), a Screening Deficiency Notice will be issued by the Bureau of Device Licensing Services by email. Class III and Class IV device licence applications will be identified as deficient if the review components are not provided in sufficient detail as described in the guidance documents, Guidance on Supporting Evidence to be Provided for New and Amended Licence Applications for Class III and IV Medical Devices, not including In Vitro Diagnostic Devices (IVDDs) or the Health Canada IMDRF Table of Contents for Medical Device Applications Guidance.

The manufacturer will then have fifteen (15) calendar days from the date of the Screening Deficiency Notice to submit all of the requested information in a question and answer format. The Directorate will acknowledge receipt of the Screening Deficiency response from the applicant by email. The response will then be subject to a new fifteen (15) calendar day screening period upon receipt in the Directorate. Provided that the application is acceptable for review, a Screening Acceptance Letter will be issued to the manufacturer by the Bureau of Device Licensing Services.

If the original application is grossly deficient, a Rejection Letter will be issued.

#### *2.6.2.2 Rejection Letters*

Failure to submit the information requested in a Screening Deficiency Notice within fifteen (15) calendar days from the date of the letter or the submission of information which is incomplete or deficient will result in the application not being accepted for examination and the issuance of a Rejection Letter by the Bureau of Device Licensing Services.

If an original application is grossly deficient, it will not be accepted for examination. A Rejection Letter will be issued by the Bureau of Device Licensing Services for failure to provide a complete application. A Class III, IV application is considered grossly deficient when there is an omission of review components (as applicable) in the application as listed and described in the guidance documents, Guidance on Supporting Evidence to be Provided for New and Amended Licence Applications for Class III and IV Medical Devices, not including In Vitro Diagnostic Devices (IVDDs) or the Health Canada IMDRF Table of Contents for Medical Device Applications Guidance.

All decisions to reject an application are without prejudice to re-filing. If the manufacturer wishes to resubmit an application at a future time, it will be processed as a new application.

Fee status: A fee (10% of applicable fees) will be levied upon issuance of a Rejection Letter.

A manufacturer may appeal the Directorate's decision to reject their application by following the Opportunity to be heard process outlined in Section 2.14 of this document.

## 2.7 Administrative Processing

All applications will be subject to a three (3) day administrative processing period where the Directorate will process and generate the appropriate regulatory decision letters and/or licenses to be issued to the manufacturer.

## 2.8 Review

Upon issuance of a Screening Acceptance Letter, applications will enter the review queue of each Device Evaluation Division. The Manager of each Division is responsible for managing the Division's workload and assigning new work items to their staff, taking into account performance targets.

The review target for Class III Licence Applications and Class III Licence Amendments (for Significant Changes) is sixty (60) calendar days from the date of the Screening Acceptance Letter (this includes a three (3) day administrative processing period).

The review target for Class IV Licence Applications and Class IV Licence Amendments (for Significant Changes) is seventy-five (75) calendar days from the date of the Screening Acceptance Letter (this includes a three (3) day administrative processing period).

Fee status: In the case of Class III and IV Licence and Amendment Applications, 100% of the applicable fee will be levied upon issuance of a Screening Acceptance Letter.

### 2.8.1 Clarification Requests

At any point during the review process, manufacturers may be requested by email to clarify or add precision to information or data within a Licence Application, or Licence Amendment (for Significant Changes). This information must be of a minor nature in order to be considered a clarification request.

Clarification requests do not contain requests for new data and manufacturers will have ten (10) calendar days to submit the requested information in question and answer format. The review clock does not stop during this time provided the responses are considered acceptable.

There is no limitation on the number of such requests that may be issued for one application; however, the same request will not be repeated.

### 2.8.2 Requests for Additional Information

At any point in the review process, significant deficiencies or information omissions that preclude the ongoing review of a Licence Application, or Licence Amendment (for Significant Changes) may be transmitted to the manufacturer in an Additional Information (AI) Letter. Such letters will be issued by the relevant Device Evaluation Division and the manufacturer will be given sixty (60) calendar days from the date of the letter in which to submit the requested information in question and answer format. The Directorate will target to issue one AI letter. In certain situations a second AI letter may be issued.

The review clock is stopped from the date of the Additional Information Letter. Upon receipt of the response to the AI Letter, an email acknowledging the receipt of the Additional Information will be issued to the manufacturer by the Bureau of Device Licensing Services, and a new forty-five (45) calendar day review period begins (this includes a three (3) day administrative processing period). The Medical Devices Directorate reserves the right to request clarification of the information submitted.

### 2.8.3 Refusal Letters

A **Refusal Letter** will be issued by the Directorate in the following circumstances:

- failure to submit the requested information in response to an Additional Information Letter within the sixty (60) calendar days specified, or submission of an incomplete or deficient response

- failure to meet the requirements of the Medical Devices Regulations or any provisions of the Act, after a comprehensive review by the relevant Device Evaluation Division or
- the applicant has made a false or misleading statement in the application

The Refusal Letter will contain the specific reasons or deficiencies that resulted in the decision to refuse issuance of a Medical Device Licence.

All decisions to refuse an application are without prejudice to re-filing (see Section 2.9 below). If a manufacturer wishes to resubmit an application at a future time, the application will be processed as a new application. Information and data submitted to support the original application may be cross-referenced if re-filing occurs within six (6) months (see Section 2.11.1 below).

Fee status: Full application fees will be levied upon issuance of an application Refusal Letter.

A manufacturer may appeal the Directorate's decision to refuse their application in accordance with the Opportunity to be heard process outlined in Section 2.14 of this document.

### 2.8.4 Withdrawal Letters

At any time during the review of their application, manufacturers may withdraw their application by informing the Directorate of their intent in a Withdrawal Letter. All Withdrawal Letters will be acknowledged in writing by the Directorate. The status of the application will be recorded as "withdrawn by manufacturer".

Withdrawal of an application is without prejudice to re-filing. If a manufacturer wishes to resubmit an application at a future time, a new Application number will be assigned and the application will be processed as a new application. Information and data to support the original application remain the property of Health Canada. Such data may be crossed-referenced if re-filing occurs within six (6) months of withdrawal (see Section 2.11.1 below).

## 2.9 Reviewer's Reports

Following receipt of a Refusal Letter, an applicant (manufacturer) may request reviewers' reports by writing to the Directorate Director and referencing the Application number.

The Directorate will target to provide a copy of the requested reports to the applicant within fifteen (15) calendar days of receipt of the request.

## 2.10 Unsolicited Information

Manufacturers are encouraged to submit at any time during the review, updated information on the regulatory status of the device in other countries and safety information enhancing the safe use of the medical device, including updated safety-related labelling and problem reports submitted to other Regulatory Agencies. Such safety information does not include significant changes to the device under review, which should be filed as a new application.

Manufacturers are requested to clearly identify the relevant application in a cover letter so that the new information can be forwarded efficiently to the appropriate review team.

## 2.11 Re-Filed Applications

Manufacturers may re-file previously withdrawn applications, rejected applications or applications for which a Refusal Letter was issued.

In all cases, a re-filed application is considered to be a new application and will be managed according to this guidance document. In addition, a re-filed application is subject to any new policies, procedures or guidance documents that may be in effect at the time of re-filing.

Fee status: Full application fees will be levied for the re-filed applications.

### 2.11.1 Re-Filing Within Six (6) Months

If an application is re-filed within six (6) months of a Refusal Letter or Withdrawal Letter, the manufacturer may submit only the material requested in the outstanding Additional Information Letter or listed in the **Refusal Letter** provided there is appropriate cross-referencing to the original material submitted.

If the manufacturer chooses to cross-reference original material previously filed, certification that the original material pertaining to the device remains unchanged must be included with the re-filed application. Manufacturers must also clearly identify new and previously submitted information in the Table of Contents of the re-filed application.

Fee status: Full application fees will be levied for the re-filed applications.

### 2.11.2 Re-Filing After Six (6) Months

If an application is re-filed after six (6) months of a **Refusal Letter** or **Withdrawal Letter**, the manufacturer must submit a completely new application, i.e. no cross-referencing to previously submitted material is allowed. This procedure reflects the dynamic nature in the development of a medical device. The manufacturer should indicate, however, the components that were previously filed and certify the information that has remained unchanged. Any revisions should be high-lighted to facilitate the review.

Fee status: Full application fees will be levied upon the re-filed application after six (6) months.

### 2.11.3 Re-Filing of a Rejected Application

If an application has been rejected, the manufacturer must submit a completely new application, i.e., no cross-referencing to previously submitted material is allowed.

Fee status: Full application fees will be levied upon the re-filing of a rejected application.

## 2.12 Fees

For information on issues related to medical device licence application fees, refer to the guidance document Fees for the Review of Medical Device Licence Applications.

## 2.13 Pause the Clock

Pause the clock is a mechanism that allows for the review clock to be formally paused under specified circumstances. When there is a pause, the performance target date is shifted to account for the amount of time the clock has been paused.

The review clock can pause only during the review period (e.g. Review 1 and Review 2) for all cost-recovered submissions. Pauses can occur with these submissions in the following instances:

- For a combination product[3] where medical device performance standards apply, the review clock would pause when the review of the device portion of the product results in a positive recommendation but the drug review is ongoing. The manufacturer will be provided with a letter confirming the pause. The device review clock would resume upon completion of the drug review.
- For linked medical device applications where different timelines apply (e.g. a Class III implantable device and its associated Class II delivery system, where a system licence type may otherwise not be possible), the review clock would pause when the review of the device with the shorter timeline is complete but the review of the linked device application remains outstanding. The manufacturer will be provided with a letter confirming the pause. The device review clock would resume upon completion of the linked device application.

## 2.14 Opportunity to be Heard Process

The purpose of the opportunity to be heard process is to allow the Medical Devices Directorate (MDD) and a manufacturer to discuss issues related to a decision on an application. The Parties may clarify and justify their positions using information available to the MDD when the decision was made. The opportunity to be heard must be based on the same information and material as the original decision. Information and material not submitted at the time of the initial decision will not be accepted.

The opportunity to be heard procedures do not apply to the challenge of existing policies, guidance documents or standards. The Directorate maintains other mechanisms to review and revise these documents which involve input from and consultation with a broad range of stakeholders. The opportunity to be heard procedures also do not apply to issues related to changes in regulatory requirements that have resulted in other products reaching the market under less stringent or more favourable conditions. Where an opportunity to be heard involves these types of issues, the opportunity to be heard will be denied.

The opportunity to be heard process involves two levels: (a) the first level involves a reconsideration request with the Bureau Director responsible for the original decision; (b) the second level is an appeal to the Director General (DG) of the Directorate.

**Level 1 - Opportunity to be Heard: Reconsideration**

Reconsideration involves review of the Directorate's decision within a process that is managed by the review Bureau. This process provides for a fair re-assessment of the original decision. Although the original reviewer may be consulted to clarify the basis of the original decision, the review of the appeal is carried out by staff who did not undertake the original review. Exceptions may occur where the expertise related to the matter is highly specialized. This review may also involve external expertise related to the matter by a qualified expert. The results of the first level review are presented to the Director for re-consideration of the original decision. It is recognized that there will be considerable overlap between an administrative review and a "reconsideration" at this level.

**Level 2 - Opportunity to be Heard: Appeal**

The appeal involves review of the Directorate's decision in a process managed through the Director General's Office. This process provides for an independent review of the subject of the reconsideration under the direction of the DG or his/her delegate. Those involved at this level are operationally and administratively removed from the review Bureau. The appeal process provides for the consultation, where appropriate, of an Appeal Committee, a small group of scientific or medical experts with expertise relevant to the contentious issues of the appeal. This Committee makes recommendations to the Directorate. The Directorate does not devolve its regulatory decision-making authority to the Committee and continues to make final application decisions.

### 2.14.1 Reconsideration: Bureau Director

A manufacturer may request a reconsideration to the Bureau Director at the following stages during the application review process:

1. Rejection Letter
2. Refusal Letter
3. Additional Information Letter

Within ten (10) calendar days of the date of the letter with the Medical Devices Directorate decision, the manufacturer must submit, to the Bureau Director, a letter of intent to request a reconsideration, to the attention of the Manager, Device Licensing Services Division.

Within twenty (20) calendar days of the date of the letter of intent to request a reconsideration, or such time that the Bureau Director and the manufacturer may agree upon, the manufacturer must file an electronic comprehensive document containing the manufacturer's position and full supporting information, cross-referenced to previously submitted data, as applicable. Should the manufacturer wish to meet with Bureau officials, this should be indicated when filing the comprehensive document. The purpose of this meeting is to provide the manufacturer with an opportunity to reiterate the major aspects of their appeal as stated in their filed document. There will not be a debate of the issues or a reconsideration decision made at this meeting.

The reconsideration will be based only on the information and material upon which the original decision was made. Any new information referenced or contained in the comprehensive document will result in its return to the manufacturer for appropriate severances. This may result in denial of the reconsideration. The Bureau Director will inform the manufacturer of the outcome of the reconsideration and outline the basis for the decision within twenty (20) calendar days from the receipt of the manufacturer's supporting information or from the date of the meeting if one is requested.

### 2.14.2 Appeal: Director General or Delegate and Appeal Committee

A manufacturer may appeal the Bureau Director's reconsideration decision to the Director General at only the following stages during the application review process:

- Rejection Letter
- Refusal Letter

Within thirty (30) calendar days of the date of the Bureau Director's reconsideration decision, the manufacturer must submit to the DG, a letter of intent to appeal to the attention of the Manager, Device Licensing Services Division.

The manufacturer's letter should include only the following information:

- an electronic copy of the comprehensive document submitted at the time of the reconsideration request), and
- a copy of the Bureau Director's letter of reconsideration decision and attachments if any.

Within fifteen (15) days of the receipt of the manufacturer's intent to appeal, the DG or his/her delegate will acknowledge the receipt of the appeal and extend an invitation to the manufacturer to define the specific outstanding issues with the application at an informal meeting with the Directorate. This meeting will be non-confrontational and no debate of the issues will take place. The meeting will provide to the manufacturer an opportunity to ensure the DG or his/her delegate and the Office of Science, are aware of the salient points of the application that support the manufacturer's position. Members of the review Bureau responsible for the application may attend this meeting.

The DG or his/her delegate will forward to the Office of Science the request for the appeal and all of the attached information and will request the Office to make recommendations regarding the acceptability of the appeal submission, possible resolutions of the appeal, and the need for an Appeal Committee. In order to ensure a fresh look at the matter and in the interests of fairness and independent review, no one in the Directorate involved in the evaluation of the application or in making the original decision will be responsible for the review of the appeal. However, both the manufacturer and the bureau officials involved in the original decision may be consulted to expedite the review.

Within ninety (90) calendar days from the receipt of the manufacturer's notice declining to meet with the Directorate or from the date of the meeting if one is requested, the DG or his/her delegate will inform the manufacturer, with reasons, in writing, of:

1. the Directorate's decision to grant the appeal; or
2. the Directorate's decision to create an Appeal Committee; or
3. the Directorate's decision to uphold the original decision without consulting an appeal committee; or
4. any other regulatory options that result from the review of the matter.

The DG or his/her delegate may consider an appeal without referring to an Appeal Committee based on the review of the matter including the report of the Office of Science and the recommendations made therein.

Some of the issues that may be appropriate for Appeal Committee consultation include:

- interpretation of available data;
- disagreement in applied methodology;
- relative weights given to data impacting on the risk benefit assessment of the application information;
- where the Directorate is not unanimous in its opinion on the application;

Issues that generally are not appropriate for Appeal Committee consultation include those that involve:

- insufficient data;
- data quality;
- application of false information;
- allegations of intellectual or regulatory bias;
- matters in which regulatory policy or procedures are the dominant concern; and
- where the Directorate has available recent outside independent expert opinion on the issue.

Where the DG or his/her delegate decides to consult an Appeal committee, the Committee will be formed with membership determined by the manufacturer and by the Directorate as follows:

- one member selected by the DG or his/her delegate from nominations by the manufacturer,
- one member selected by the DG or his/her delegate from nominations by the relevant Bureau Director, and
- one member, appointed by the DG or his/her delegate, who, when possible, is a member of an Expert Advisory Committee and who will chair the Appeal Committee.

The DG or his/her delegate will also appoint a member of the Medical Devices Directorate as coordinator of the Committee who will be responsible for managing the operation of the Appeal Committee.

Members will be chosen based on their experience, expertise, or analytical skills relevant to the review of a particular disputed issue. All committee members have to meet conflict of interest and security clearance requirements. Any person who was previously involved with decisions related to the application or reviewed information related to the application on behalf of the Directorate or manufacturer will not be eligible as a member of the Appeal Committee. For more information, please refer to Health Canada Policy on External Advisory Bodies, 2011.

The manufacturer will be requested to provide nominations for one member of the Appeal Committee with expertise in areas identified by the Directorate as relevant to the resolution of the matter. The manufacturer is required to include the Curriculum Vitae of their candidates and MDD must confirm that the candidates comply with the COI policy. To ensure that nominees can comply with COI requirements, the manufacturer should not provide them with any material for review prior to their official appointment by the DG or his/her delegate. The committee members should not have been involved with the manufacturer in the past and should not have expressed their views regarding the product in question. The coordinator of the Appeal Committee will be responsible for the material provided to the members for review. Costs incurred for all committee members will be paid by the Directorate.

The information considered by an Appeal Committee will be based on the same information contained in the application as that reviewed to arrive at the original decision. A Committee may receive oral representation from the manufacturer and/or the relevant review Bureau as considered to be necessary by a Committee member. The Committee will make recommendations to the DG. Each recommendation will be made on the concurrence of at least two of the three Committee members. Consistent with its advisory role, the Committee will not be asked to make a decision on the application. Rather, advice from the Committee will be solicited through one or more direct questions related to the specific outstanding issues that have been identified during the opportunity to be heard processes.

Within fourteen (14) calendar days of the receipt of a Committee's recommendation the DG or his/her delegate will consider the recommendations of the Appeal Committee and inform the manufacturer of the Directorate's decision.

### 2.14.3 Impact on Review Process

If the decision resulting from either the first or second level of the opportunity to be heard process is in favour of the manufacturer, the review process will resume according to this guidance document and the Target Performance Standards.

If the decision of the opportunity to be heard process is not in favour of the manufacturer, the Directorate decision will be considered upheld and effective on the date of the original decision for application management purposes.

[1] "Guidance for the Interpretation of Significant Change of a Medical Device".
[2] "Licence Amendment Fax-Back Form – Guidance for Non-Significant Additions/Deletions" and "Medical Devices Licence Amendment Fax-Back Form – Guidance for Changes to the Manufacturer's Name and/or Address of Existing Device Licences Only".
[3] For further information on combination products, refer to the "Policy-Drug/Medical Device Combination Products".