Government of Canada Gouvernement du Canada

Filing submissions electronically

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Companies are required to file submissions electronically to Health Canada in either Electronic Common Technical Document (eCTD) format or non-eCTD format, depending on the regulatory activity type. The sections below include links to documents that provide detailed information on these formats and other information related to filing submissions electronically.

Due to their format, some documents are only available and labeled as "available upon request". If you have an email client set up on your computer, when you click the link to these documents, an email message should appear with some information pre-filled; Simply 'Send' this message. If an email message does not automatically appear, create an email to no-reply.ereview.non-reponse@hc-sc.gc.ca, and use the requested subject line as specified for each document below.

Guidance documents, notices and supporting documents

All electronic formats

- Regulatory Enrolment Process (REP)
    - REP is a common submission intake method across product lines (i.e. prescription drugs for human and veterinary use, biologics and radiopharmaceuticals for human use, medical devices for human use and disinfectants) and filling formats (i.e. eCTD and non-eCTD format).
- Dossier ID Request Form for Pharmaceutical/Biologic Dossiers
    - **Dossier ID Process** – the Dossier ID Request Form must be the **only** method used to request for a Dossier ID from Health Canada for REP and eCTD dossiers (Master Files, veterinary drugs and Clinical Trial eCTD Pilot excluded). A request for a dossier ID should be sent a maximum of eight weeks prior to filing a regulatory transaction.
- **Organisation and Document Placement for Canadian Module 1** (available upon request: Click here to submit an email request to no-reply.ereview.non-reponse@hc-sc.gc.ca). Please ensure the text 'Request for Placement of documents in the Regional Structure' is in the subject line of the email. [2022-06-28]
    - This table details the organization and placement of documents within the Canadian Regional Module 1 section of the Common Technical Document (CTD) structure. It lists the Module 1 sections/subfolders, along with a list of the possible documents that must be placed in these sections/subfolders when provided as part of a regulatory transaction to Health Canada.
- **Regulatory Transaction Descriptions** (available upon request: Click here to submit an email request to no-reply.ereview.non-reponse@hc-sc.gc.ca). Please ensure the text 'Request for Regulatory Transaction Descriptions' is in the subject line of the email. [2021-04-07]
    - A list of descriptions, by regulatory activity type, that details the reason for filing a transaction. Note: This document is updated

frequently.

eCTD format only

Depending on the regulatory activity type of the drug, this may be either the mandatory or recommended format.

- Clinical Trial Applications in eCTD format (available upon request via email no-reply.ereview.non-reponse@hc-sc.gc.ca). Please ensure the text 'Request for Clinical Trial Applications in eCTD Format' is in the subject line of the email. [2022-03-04]
  - Dossier ID Request Form for Biologic Clinical Trial Dossiers
  - Dossier ID Request Form for Pharmaceutical Clinical Trial Dossiers
- Validation Rules for regulatory transactions filed in eCTD format [2022-05-13]
- Guidance Document - Preparation of Regulatory Activities in eCTD Format and Common Electronic Submissions Gateway (CESG) Health Canada Reference Guide (available upon request via email: Click here to submit an email request to no-reply.ereview.non-reponse@hc-sc.gc.ca). Please ensure the text 'Request for eCTD Guidance Document' is in the subject line of the email. [2020-03-31]
- Creation of the Canadian Module 1 Backbone - Guidance Document [2012-09-07]
- Canadian Module 1 Schema Version 2.2 [2012-07-06]
- Notice: Phase II of the XML PM Project (Product Monograph in the Extensible Markup Language Format)

Non-eCTD format only

The alternative electronic format for regulatory activities not mandatory or accepted in eCTD format.

- Guidance Document - Preparation of Regulatory Activities in Non-eCTD Format [2022-02-28]
- Validation Rules for regulatory transactions filed in non-eCTD format [2022-05-13]

- Folder structure
  - The table below contains the zip files of the folder structure for each product line as outlined in section 2.2 of the Guidance Document – Preparation of the Regulatory Activities in the non-eCTD format.

Product line	**zip file***
Human Drugs, Disinfectants and Clinical Trials (Division 1 and 5)	zip file – Folder Structure
Veterinary drugs (Division 1 and 8)	zip file – Vet Drugs
Master File (Type I, II, III, IV)	zip file – MF Type I zip file – MF Type II zip file – MF Type III zip file – MF Type IV

*** zip files** - zip files compress data and therefore save time and space, and make downloading software faster.

How do I open a zip file? After you have installed zip software, you can open a zip file by double clicking it in your browser and choosing "Unzip or install from an existing zip file" in the WinZip Wizard. If you do not

have zip software on your computer, you can download many free versions.

Consultations and upcoming activities

- **Closed:** Release of Draft Guidance Document: Canadian Module 1 Technical Implementation Guide for the Electronic Common Technical Document (eCTD) v4.0 Format [2019-06-26]

Supporting documents and pages from the International Council for Harmonisation (ICH)

- ICH Working Group on Electronic Standards for the Transfer of Regulatory Information (ESTRI)
- ICH eCTD Specification and Related Files
- ICH M4: The Common Technical Document (CTD)

Additional information

- Common Electronic Submissions Gateway (CESG)

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2022-06-28