Regulatory roadmap for radiopharmaceutical (Schedule C) drugs in Canada

From Health Canada

This regulatory roadmap gives comprehensive, general information about the regulation of radiopharmaceutical drugs for human use in Canada.

All drugs marketed in Canada are subject to the Food and Drugs Act and the Food and Drug Regulations. Radiopharmaceutical drugs are listed in the Schedule C of the Food and Drugs Act. Schedule C to the Food and Drugs Act identifies two entities:

- Drugs, other than radionuclides, which are sold or represented for use in the preparation of radiopharmaceuticals; and
- Radiopharmaceuticals

Health Canada's Biologics and Genetic Therapies Directorate (BGTD) is the Canadian regulatory authority that regulates the market authorization of radiopharmaceutical drugs for human use based on satisfactory evaluation of safety, efficacy, and quality of radiopharmaceutical drug submissions. Market authorization by Health Canada is required before a radiopharmaceutical drug can be sold in Canada.

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Who this document is for

This roadmap was written for:

- sponsors
    - wanting to market a radiopharmaceutical drug in Canada
    - wanting to conduct clinical trials in Canada with a radiopharmaceutical drug
    - seeking information about post-market requirements and post-approval changes
- other interested stakeholders, such as academics and patients

About radiopharmaceuticals

Radiopharmaceutical drugs are a group of pharmaceuticals which contain a radioactive compound. These compounds travel to specific targets where they can assist with the diagnosis and treatment of

disease. Radiopharmaceuticals can be used to diagnose some of the following:

- bone disease
- kidney and liver disease
- brain diseases
- cardiovascular and lung disease
- some types of cancer, including thyroid, brain, and lymphoma

Radiopharmaceuticals can also be used clinically in the treatment of certain conditions; most often cancerous tumors.

A sponsor must collect enough scientific evidence about a radiopharmaceutical drug before Health Canada's BGTD can consider authorizing it for market. The evidence must show the radiopharmaceutical is:

- safe
- effective
- of suitable quality

The regulatory requirements for radiopharmaceutical drugs are similar to other drugs in Canada. They are subject to the same general submission requirements, and the same process for obtaining market authorization Radiopharmaceutical drugs differ from other drugs because of their unique radioactive properties for which there are specific submission data requirements.

The specific regulations for radiopharmaceutical (Schedule C) drugs are in Division 3 in Part C of the Food and Drug Regulations. These regulations take into account the unique and distinct manner and mode of action of these drugs.

Roadmap for radiopharmaceutical (Schedule C) drugs

Health Canada provides guidance, information and support on how to meet the regulatory requirements for radiopharmaceutical (Schedule C) drugs.

A guidance document is an official document that provides information that helps stakeholders:

- understand how to best follow and implement Canadian Regulations
- harmonize with international guidance documents and standards

Guidance documents also assist the BGTD's regulatory staff in implementing Health Canada's mandate and objectives in a way that is:

- fair
- effective
- consistent

Health Canada is an official member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The department has adopted a number of ICH guidance documents covering topics related to:

- quality
- safety
- efficacy
- multidisciplinary topics

Sponsors should inform themselves of the requirements and the processes before making an application or a submission to Health Canada for a radiopharmaceutical drug. The Guidance for Industry: Management of Drug Submissions outlines the way Health Canada manages information and material submitted by the sponsor, as well as performance standards.

This guidance applies to all drug submission types relating to radiopharmaceutical drugs, including:

- Clinical Trial Applications (CTA) and Amendments (CTA-A)
- New Drug Submissions (NDS)
- Supplements to New Drug Submissions (SNDS)
- Supplements to New Drug Submissions - Confirmatory (SNDS-C)
- Abbreviated New Drug Submissions (ANDS)
- Supplements to Abbreviated New Drug Submissions (SANDS)
- Notifiable Changes (NC)
- Guidance - Use of Positron-emitting Radiopharmaceuticals in Basic Clinical Research
- Submissions Relying on Third Party Data (SRTD)
- Use of Foreign Reviews
- Development Safety Update Report (DSUR)
- Yearly Biologic Product Report (YBPR)
- Post-Authorization Division 1 Change-Biologics (PDC-B)

Clinical Trial Applications

In order to conduct a clinical trial in Canada, a Clinical Trial Application (CTA) is required. Sponsors are encouraged to seek advice from Health Canada about their CTA during a pre-CTA meeting with Health Canada. Health Canada gives advice at no cost to clinical trial sponsors. Refer to the Guidance for Clinical Trial Sponsors: Clinical Trial Applications to learn how to request a pre-CTA consultation meeting.

Formatting for Clinical Trial Applications

Since June 2016, Health Canada has stopped accepting paper copies of clinical trial regulatory activities and their related transactions. The accepted format is "non eCTD electronic-only".

To help understand formatting requirements, consult these guidance documents:

- Preparation of Drug Regulatory Activities in the Common Technical Document (CTD) format
- Preparation of Regulatory Activities in the "Non-eCTD Electronic-Only" format

Requirement for Good Clinical Practices

All sponsors conducting a clinical trial must comply with Good Clinical Practices (GCP). GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

For more information, refer to the Good Clinical Practices guidance document.

How to prepare a Clinical Trial Application

The Clinical Trial Sponsors: Clinical Trial Applications guidance document provides guidance to all sponsors seeking authorization to sell or import a drug for the purpose of a clinical trial in Canada. It also contains instructions on how to:

- prepare a CTA
- request a pre-CTA consultation meeting

Additional information can be found at the following locations:

- Filing of Clinical Trials Frequently Asked Questions
- Clinical Investigation of Medicinal Products in the Pediatric Population
    - Addendum: Clinical Investigation of Medicinal Products in the Pedeatric Population
- Considerations for Inclusion of Women in Clinical Trials and Analysis of Sex Differences
- Studies in Support of Geriatric Populations: Geriatrics ICH Topic E7: Guidance for industry

Investigator's Brochures

An Investigator's Brochure must be included for each product in a CTA. The brochure must include all currently available pre-clinical and clinical safety and efficacy information. It should also include the global status of what the product is approved for and where.

Refer to the Good Clinical Practice: Integrated Addendum to E6(R1)ICH Topic E6(R2) guidance document for more information. Refer to the ICH Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance for suggested format of the Investigator's Brochure.

Investigator's Brochures that include all safety and efficacy information and global status for the drug(s) under investigation must be filed annually. Any new information and changes in the updated Investigator's Brochure should be highlighted to help our review and evaluation. If an Investigator's Brochure is updated more than once a year, submit it as required.

Clinical Trial Application Amendments

Before a sponsor can make changes to a clinical trial, a CTA-A must be authorized by Health Canada. If a sponsor proposes to make changes to an authorized CTA, they must file the following:

- for changes to clinical trial drug supplies, a Quality CTA-A
- for changes to a previously authorized protocol, a Clinical CTA-A

For more information, refer to Clinical Trial Application Amendments.

Related resources

Guidance - Use of Positron-emitting Radiopharmaceuticals in Basic Clinical Research

Clinical Trials

Clinical Trials Database

Health Canada's Clinical Trials Database lists specific information about Phase I, II and III clinical trials in patients. Health Canada encourages sponsors to register clinical trials within 21 days of the start of the trial.

Sponsors may also use a publicly available registry that conforms to international standards for registries. Examples include the ClinicalTrials.gov site under the sponsorship of the U.S. National Institutes of Health's and the ISRCTN registry.

Basic Research Application: PERs

A positron-emitting radiopharmaceutical (PER) is a radioactive drug that is comprised of a positron-emitting radionuclide which has been chemically attached to a biologically active molecule. The radiation emitted from the PER is detected using a positron-emitting tomography scanner (PET), producing an image that allows a physician to diagnose or determine the state of a disease.

Health Canada recognizes that basic clinical research using PERs is generally considered safe when PERs with known safety profiles are administered in relatively low doses.

Health Canada has developed appropriate regulatory oversight for the use of PERs in basic research that mitigates the risks to humans and optimizes the information and regulatory requirements to help ensure that the PERs used are of high quality and safe.

Related resources

Guide for the preparation of Applications for Authorization of PERs Used in Basic Clinical Research Studies

New Drug Submissions

A sponsor must prepare a New Drug Submission (NDS) for the BGTD. This occurs when that sponsor wants to seek market authorization for a new drug in Canada. The NDS contains:

- information and data about the drug's
  - safety
  - quality
  - efficacy
- results of the pre-clinical and clinical studies, whether done in Canada or elsewhere
- details regarding the production of the drug
- packaging and labelling details
- information regarding therapeutic claims and side effects

Before submitting its NDS for a radiopharmaceutical drug, the sponsor can make a brief presentation to the BGTD. This meeting gives the sponsor a chance to discuss details of the submission with the regulator. It also provides a chance to get feedback about any areas of concern. The sponsor should request a pre-submission meeting at least 3 months before the proposed submission date.

Small and medium-sized radiopharmaceutical companies are especially encouraged to request a pre-submission meeting. The sponsor may also seek eligibility for alternate review pathways, such as Priority Review or a Notice of Compliance with Conditions. For information about alternate pathways, refer to the section on Accelerated Pathways for Drug Approval.

More information is available on how to request a pre-submission meeting in the Guidance for Industry: Management of Drug Submissions.

Also refer to:

- Radiopharmaceuticals, Kits, and Generators: Submission Information for Schedule C Drugs
- Guidance Document: Preparation of Drug Regulatory Activities in the Common Technical Document Format

Format for the New Drug Submission

Health Canada accepts drug submissions in the eCTD format. The ICH developed the CTD format to harmonize drug submissions worldwide. In terms of CTA elements, the current CTD does not allow the unique information on radioactive drugs to be captured. Templates, such as QIS-R and QIS-PER, are designed to capture submissions for all radiopharmaceutical drugs that contain drug substances of purely synthetic chemical origin.

Consult eCTD Common Technical Document guidance documents for applications and submissions to learn how to file a submission in the eCTD format.

Technical requirements

Health Canada is an official member of the ICH and is committed to adopting and implementing ICH guidance and standards. Once adopted by Health Canada, ICH guidelines become official Health Canada guidance documents for:

- safety
- quality
- efficacy
- multidisciplinary topics

Clinical: safety and efficacy

Refer to relevant ICH guidelines on:

- safety

    - All ICH Safety Guidelines
- efficacy
    - All ICH Efficacy Guidelines

Product monograph guidance and templates are available to assist sponsors in developing product monographs with acceptable format and content.

When submitting non-clinical study data to support a submission or application, sponsors should refer to:

- Guidance Document on Non-Clinical Laboratory Study Data Supporting Drug Product Applications and Submissions: Adherence to Good Laboratory Practice

Quality: chemistry and manufacturing

Refer to relevant ICH guidelines on:

- quality
    - All ICH Quality Guidelines

Multidisciplinary guidelines and ICH Considerations documents that are not labelled as quality have implications for quality. Consult all ICH Multidisciplinary guidelines for more information.

Related Resources:

Draft Guidance for Industry, Preparation of the Quality Information for Radiopharmaceuticals (Schedule C Drugs) using the Quality Information Summary-Radiopharmaceuticals (QIS-R) and Certified Product Information Document

Quality Overall Summary - Chemical Entities (New Drug Submissions/Abbreviated New Drug Submissions)

Risk Management Plan

Health Canada has adopted and integrated the use of Risk Management Plans (RMPs) and the ICH E2E Guideline into the regulatory review of drugs in Canada in order to:

- Support a life cycle approach to drug vigilance
- Enhance the quality of Health Canada's regulatory assessments
- Support Canadians' timely access to safe, efficacious and high quality drugs
- Support ongoing evaluation of information that could have an impact on the benefit-risk profile of health products, and
- Align drug vigilance with international best practices

Sponsors should submit a Risk Management Plan as part of their drug submission for a radiopharmaceutical drug. The Guidance Document on Submission of Risk Management Plans and Follow-up Commitments has more information.

Labelling

The label and package are the first points of interaction between a health product and a healthcare professional or patient. It is essential that all labelling and packaging regulatory requirements be met. In order to ensure these requirements are met, the BGTD reviews all labels for radiopharmaceutical drugs according to the specific labelling regulations found in Division 3 of the *Food and Drug Regulations*. This includes:

- package inserts
- inner and outer labels
- the product monograph/prescribing information

Health Canada also reviews the proposed brand name(s) for the drug.

Consult these guidance documents for more information:

- Guidance Document for Industry - Review of Drug Brand Names

- Guidance Document Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs
- Product Monograph Guidance Document

Accelerated pathways for drug approval

Health Canada offers sponsors 2 alternate accelerated pathways for drug approval, which can shorten review times.

1. Priority Review

This policy applies to a NDS or SNDS for a serious, life-threatening or severely debilitating disease or condition for which there is substantial evidence of clinic effectiveness that the drug provides:

- Effective treatment, prevention or diagnosis of a disease or condition for which no drug is presently marketed in Canada; or
- A significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.

To learn more, read the Guidance for Industry: Priority Review of Drug Submissions.

2. Notice of Compliance with Conditions

Authorization under this policy may be granted for a drug product with promising evidence of clinical effectiveness providing it possesses an acceptable safety profile based on a benefit/risk assessment, and is found to be of high quality. NOC/c applies to:

- NDS and SNDSs for a serious, life-threatening or severely debilitating disease or condition for which there is promising evidence of clinical effectiveness based on the available data that the drug has the potential to provide.

- ANDS and SANDS in instances where the Canadian Reference Product still holds the NOC/c status.

To learn more, read the Guidance Document: Notice of Compliance with Conditions policy.

How to ask Health Canada to reconsider certain negative decisions about a human drug submission

A drug sponsor may formally request Health Canada to reconsider its decision about a human drug submission. This applies only to certain negative decisions that are issued. The Guidance Document: Reconsideration of Decisions Issued for Human Drug Submissions provides guidance about the formal reconsideration process, including:

- how and when sponsors may request reconsideration
- how and when the BGTD will respond
- the process provided to reach a resolution

Third-party data

Certain drug submissions, including radiopharmaceuticals, may meet the conditions and requirements for a Submission Relying on Third-Party Data. Third-Party Data can be used when sponsors are seeking market authorization for a drug product based largely on literature and market experience.

These criteria are set out in the Guidance Document: Drug Submissions Relying on Third-Party Data (Literature and Market Experience).

Sponsors should understand the implications of using third party data as laid out in the Guidance Document: Patented Medicines (Notice of Compliance) Regulations.

Use of foreign reviews

Health Canada strives to take into consideration the efforts, experience, and expertise of its peer regulatory agencies. Health Canada is working to develop and implement the necessary framework to make optimal and more consistent use of foreign reviews in regulatory review of health products in Canada. A foreign review may be submitted to Health Canada to aid in the regulatory decision making process.

When filing with Health Canada, refer to its information on the Use of Foreign Reviews when including a foreign review in one of the following:

- a submission
- an application
- other data packages

Master Files

A Master File Holder submits a Master File for the active ingredient and/or the dosage form, to Health Canada. This is only in cases where the company does not wish to disclose Confidential Business Information to the applicant of the drug submission.

There is a fee for filing and re-filing.

For more information on Master Files refer to Guidance Document: Master Files (MFs) - Procedures and Administrative Requirements.

Notice of Compliance and Drug Identification Numbers

A Notice of Compliance (NOC) and a Drug Identification Number (DIN) are issued by Health Canada when the:

- evidence supports the safety, efficacy and quality claims for an NDS or an SNDS
- benefits outweigh the risks

The NOC and the DIN indicate that Health Canada has authorized the drug for sale in Canada. This shows that the drug meets the required standards for safety, efficacy, and quality. For a medication to be sold in Canada, a DIN must appear on the product's label.

DINs for Schedule C drugs came into effect as of June 2018. They enable Health Canada to track effectively medications throughout the health care system and take appropriate actions should a new risk or disruption in supply occur.

All Canadian DIN owners require a Drug Establishment Licence (DEL). For more information, refer to the section on Good Manufacturing Practices/Establishment Licensing.

Cancellation of a Drug Identification Number

Health Canada requires that manufacturers of all DIN products notify Health Canada after discontinuance of a product or 12 months of no sales of a product to ensure that accurate information is maintained for all products with a DIN in the Drug Product Database.

Sponsors who discontinue the sale of a drug in Canada must follow certain requirements. The Cancellation of a Drug Identification Number (DIN) and Notification of the Discontinuation of Sales guidance document contains this information.

Related resources

Guidance Document: Drug Identification Numbers for Schedule C Drugs

Good Manufacturing Practices and Establishment Licensing

The Health Product Compliance Directorate within the Regulatory Operations and Enforcement Branch is responsible for assessing compliance with Good Manufacturing Practices regulatory requirements and issuing Drug Establishment Licences.

Good Manufacturing Practices

Drugs that are for sale in Canada or used in clinical trials must be fabricated, packaged/labelled, tested and stored in compliance with the Good Manufacturing Practices in the *Food and Drug Regulations*. These requirements apply to:

- fabricators
- packagers/labellers
- testers
- distributors
- importers
- wholesalers

Consult these links for more information on applicable GMP requirements:

- Good Manufacturing Practices
- Good manufacturing practices guide for drug products (GUI-0001)
- Guidance Document - Annex 13 to the Current Edition of the Good Manufacturing Practices Guidelines Drugs Used in Clinical Trials (GUI-0036)
- Guidance Document Alternate Sample Retention Site Guidelines (GUI-0014)
- How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)
- Annex to the Good Manufacturing Practices Guidelines Good Manufacturing Practices (GMP) for Positron Emitting Radiopharmaceuticals (PERs) (GUI-0071)

- Guidance Document Annex 3 to the Current Edition of the Good Manufacturing Practices Guidelines - Schedule C Drugs (GUI-0026)

Establishment Licensing

An establishment licence is required in order to carry out any licensable activities on drugs as described in the *Food and Drug Regulations*. This includes:

- fabricating
- packaging/labelling
- testing
- importing
- distributing
- wholesaling

A licence must also list any foreign building involved in the fabricating, packaging/labelling or testing of an imported drug. These licensable activities include those related to bulk process intermediates used in making dosage forms of Schedule C drugs.

Consult these links for more information on establishment licences:

- Drug Establishment Licenses
- Guidance on Drug Establishment Licences and Drug Establishment Licensing Fees (GUI-0002)

Post-market requirements and post-approval changes

Once a drug is approved for sale in Canada, the next phase of the drug's life cycle begins. There are post-market requirements the sponsor needs to follow.

Post-market monitoring

Health products improve the lives of Canadians. However, these products can cause serious adverse drug reactions and medical device incidents, and Canadians can be hospitalized as a result of these events. Health Canada's monitoring of health product safety plays a vital role in public health and patient safety.

Market Authorization Holders of radiopharmaceutical drugs have a responsibility to ensure that any drugs sold to Canadians remain safe and effective after they are approved for sale.

Consult the following links for information on post-market adverse reaction reporting:

- Reporting Adverse Reactions to Marketed Health Products - Guidance Document for Industry
- About good pharmacovigilance practices (GVP) inspections

Annual Drug Notification report

Every DIN holder must submit an Annual Drug Notification Form (ADNF) before October each year. This confirms that all information previously supplied for that drug is correct. Failure to comply may result in cancellation of existing DINs.

Changes have been made to the information that is included in the ADNF. Approved and dormant products are added to the ADNF. For all discontinued drug products, manufacturers are required to provide the:

- lot number
- discontinuation date
- expiry date of the last lot sold

Summary reports

These are pharmacovigilance documents intended to provide an evaluation of the risk-benefit balance of radiopharmaceutical drugs at defined time points during the post-authorization phase. Health Canada's approach to the safety monitoring of post-market risks and benefits of health products includes guidelines for the preparation and submission details for two types of reports:

- Annual summary report e.g., periodic benefit-risk evaluation reports (PBRERs)
- Issue-related summary reports

For more information, consult these helpful links:

- Guidance Document: Periodic Benefit-Risk Evaluation Report (PBRER) International Conference on Harmonisation (ICH) Topic E2C(R2)
- Guidance Document for Industry - Preparing and Submitting Summary Reports for Marketed Drugs and Natural Health Products

Marketed products risk communications

Communicating about risk is a key component of Health Canada's approach to the management of the benefits and risks of marketed health products. The Marketed Health Products Directorate has guidance documents on risk communications for marketed products:

- Guidance Document for Industry: Issuance of Health Professional Communications and Public Communications by Market Authorization Holders
- Description of Current Risk Communication Documents for Marketed Health Products for Human Use: Guidance Document

Post-NOC Changes

Sponsors may make changes to any drugs that have received a Notice of Compliance (NOC) pursuant to the *Food and Drug Regulations*. There are four risk-based levels of post approval changes that can be made to a drug:

1. A Level I change is a change to the label of a drug that has the potential to increase the exposure levels of the drug. This occurs either by expanding the population it is exposed to or by increasing individual exposure.
2. A Level II (90 day) change is a change to the label that has the potential to improve the management of risk to the population currently indicated for use of, or in any other way exposed to, the drug.
3. A Level II (120 day) change is any change to the label that does not affect the conditions of use (it does not involve risk management, nor does it have the potential to increase exposure level of the drug) but for which prior approval by Health Canada is required.
4. A Level III (annual notification) change is any change to the label that is not expected to impact the safety, efficacy and/or effective use of the drug. The changes included in this reporting category may be implemented by the sponsor without prior review by Health Canada of the data supporting such a change.

Related resources

Post-Notice of Compliance (NOC) Changes: Framework Document

Guidance Document: Post-Notice of Compliance (NOC) Changes: Quality Document (if a quality-related change is being made)

Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document (if a safety or efficacy change is being made)

Management of safety updates

When Health Canada requires label changes of a radiopharmaceutical drug, the sponsor will receive an Advisement Letter. For these label changes, sponsors should follow the guidance and information provided in the Advisement Letter.

For more information, please consult:

- Notice: How Health Canada is managing safety updates when a serious health risk is identified under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)

Drug shortages

The guide to reporting drug shortages and discontinuations is intended for those who hold a drug authorization issued by Health Canada. This guide contains information that will help with compliance to sections C.01.014.8 to C.01.014.12 of the *Food and Drug Regulations*. This guide will help with understanding the process of:

- Reporting drug shortages and discontinuations, and
- Notifying Health Canada when twelve months have elapsed since the drug was last sold.

Fees

Sponsors pay fees so that Health Canada can recover the cost of regulating drug products. For more information, refer to the guidance Fees for the Review of Human Drugs and Disinfectant Submissions and Applications.

There is no fee for submitting a CTA to Health Canada.

There are also Drug Establishment Licensing Fees. The fees associated with a DEL cover a portion of the cost of Health Canada's regulatory programs for drugs. It covers the cost of review of an application for

establishment licensing, conducting inspections for good manufacturing practices and security inspections, and conducting drug analysis. Health Canada has facility inspe.ction programs in place to evaluate the compliance of establishments with regulatory requirements to engage in production, importation, testing and distribution of drugs.

The manufacturer that holds the DIN assigned to a Schedule C drug is currently not charged an annual fee for the right to sell that drug. The Schedule C drug exemption is a temporary measure as Health Canada is working to consult on, and revise its fees, including an expansion of the scope of the fees related to possession of a DIN to encompass Schedule C drugs.

A sponsor who intends to export a radiopharmaceutical drug product may apply for a Certificate of a Pharmaceutical Product. The sponsor must also pay a fee. The fee form is contained within the Guidance Document on the Application for a Certificate of a Pharmaceutical Product GUI-0024.

Contact us

For more information or assistance, contact these addresses:

For any inquiries concerning the regulation and submission process for radiopharmaceuticals drugs:

HC.bgtd.ora.SC@canada.ca

For any additional inquiries concerning radiopharmaceuticals drugs or this document:

Hc.bgtd.opic-bpci.dpbtg.sc@canada.ca

Canadian Nuclear Safety Commission

Health Canada and the Canadian Nuclear Safety Commission (CNSC) have different responsibilities with respect to the regulatory oversight of radiopharmaceutical drugs in Canada

Health Canada regulates the market authorization of radiopharmaceutical drugs based on satisfactory evaluation of safety, efficacy, and quality of radiopharmaceutical drug submissions. CNSC regulates the radiation safety aspect of radiopharmaceutical drugs with respect to the handling, shipping, packaging, transportation, import, export, storage, and disposal of radioactive materials. CNSC also regulates equipment that produces radionuclides for use in the preparation of radiopharmaceutical drugs, such as nuclear reactors, medical linear accelerators, and cyclotrons.

Contact info

Canadian Nuclear Safety Commission

280 Slater Street, P.O. Box 1046, Station B

Ottawa, Ontario

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Email: cnsc.info.ccsn@canada.ca

Telephone: 613-995-5894 or 1-800-668-5284 (toll free in Canada and the U.S.)

Fax: 613-995-5086

For more information

- How Drugs are Reviewed in Canada
- Drug and health product submissions under review
- Regulatory Decision Summaries
- Regulatory Decision Summary Search

- Summary Basis of Decision Search
- Patented Medicines (Notice of Compliance) Regulations
- Improving the regulatory review of drugs and devices
- Forms - Applications and submissions

Date modified:
2021-02-19