How new medicines are reviewed, approved and funded in Canada

Drug Development Process in Canada

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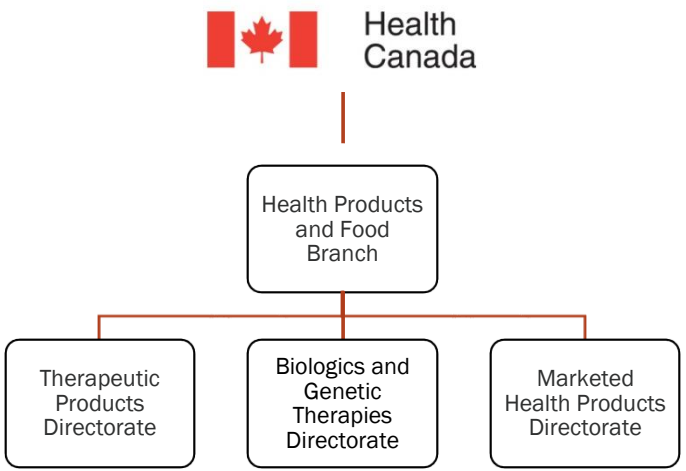
Role of Health Canada

Health Canada's Health Products and Food Branch (HPFB) is the national authority that regulates, evaluates and monitors the safety, efficacy and quality of therapeutic and diagnostic products available to Canadians.

Health products – drugs, biologics, genetic therapies, medical devices, natural health products – are reviewed and authorized by the HPFB through either the Therapeutic Products Directorate (TPD) or the Biologic and Genetic Therapies Directorate (BGTD).

Applications to conduct clinical trials are also managed by HPFB.

The Marketed Health Products Directorate is responsible for surveillance, benefit-risk assessments and information sharing for approved health products.



- Review scientific information
- Assess benefits and risk
- Review clinical trials
- Monitor evolving safety of products in development

- Adverse reaction & incident data monitoring
- Benefit-risk assessments
- Product-risk communication
- Advertising regulatory requirements
- Marketed product regulation

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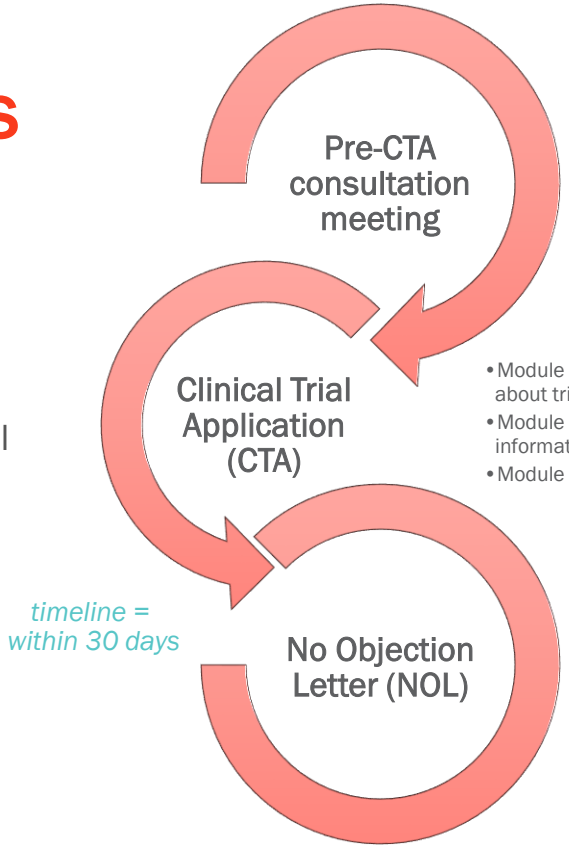
Clinical Trials Application Process

When a manufacturer opts to conduct a clinical trial in Canada, it must submit a Clinical Trial Application (CTA) for review and approval by the Health Products and Food Branch (HPFB).

CTAs are required for phase I to III clinical trials, regardless of whether a trial has been authorized in another country.



- Optional consultation meeting with Health Canada
- Opportunity to present data, discuss concerns and resolve issues
- HC can provide guidance on acceptability of proposed trials

- Module 1: administrative and clinical information about trial
- Module 2: Quality (Chemistry and Manufacturing) information about drug products
- Module 3: additional supporting Quality information

timeline = within 30 days

- Review decision issued
- Trial registration in Clinical Trials Database

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Initiating the Drug Approval Process

When a drug manufacturer or “sponsor” opts to seek to market a drug in Canada, it must file a New Drug Submission (NDS) with the Health Products and Food Branch (HPFB).

A sponsor can submit an NDS whether clinical trials were done in Canada or other countries.

An NDS includes:

- Information and data about the drug’s safety, effectiveness and quality
- Results of pre-clinical and clinical trials
- Details on drug production
- Packaging and labelling details
- Information regarding therapeutic claims and side effects

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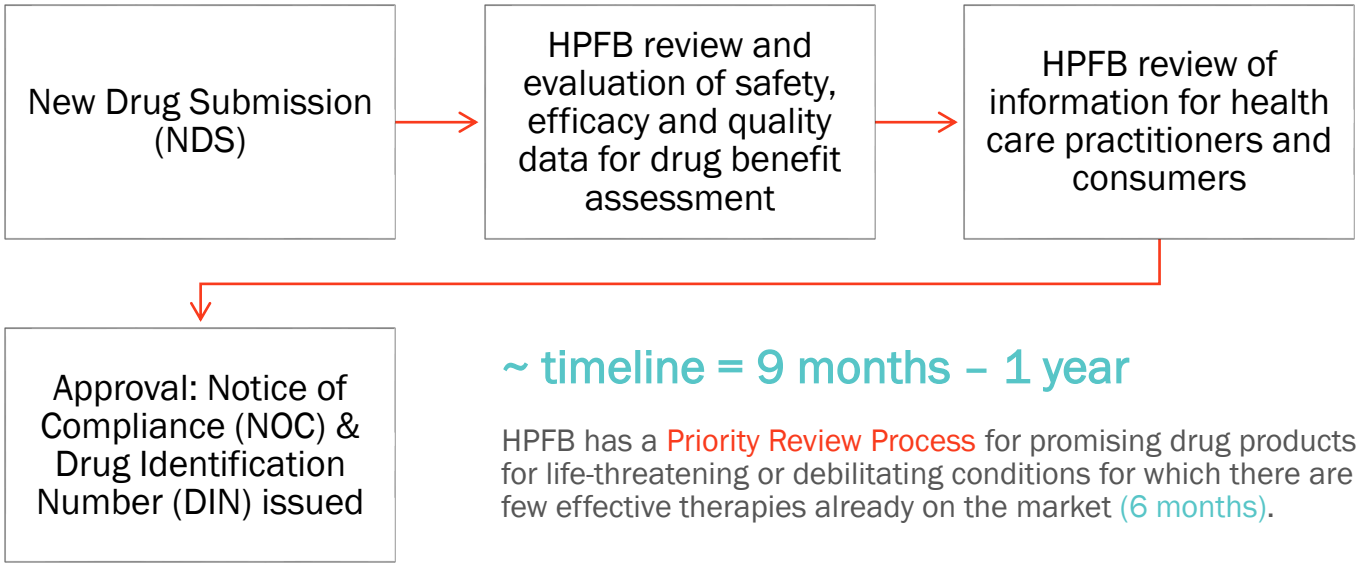
Drug Approval Process



~ timeline = 9 months – 1 year

HPFB has a Priority Review Process for promising drug products for life-threatening or debilitating conditions for which there are few effective therapies already on the market (6 months).

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Patented Medicines Pricing Review Board

The Patented Medicines Review Board (PMPRB) is a quasi-judicial body which oversees and limits the prices of patented medicines sold in Canada.

It assesses drugs for therapeutic benefit relative to existing therapies and assigns a ceiling price based on:

- Median international price;
- Highest price in the domestic therapeutic classes, or;
- Some combination of the two.

** The PMPRB is currently subject to reforms that will change its review and regulation process.*

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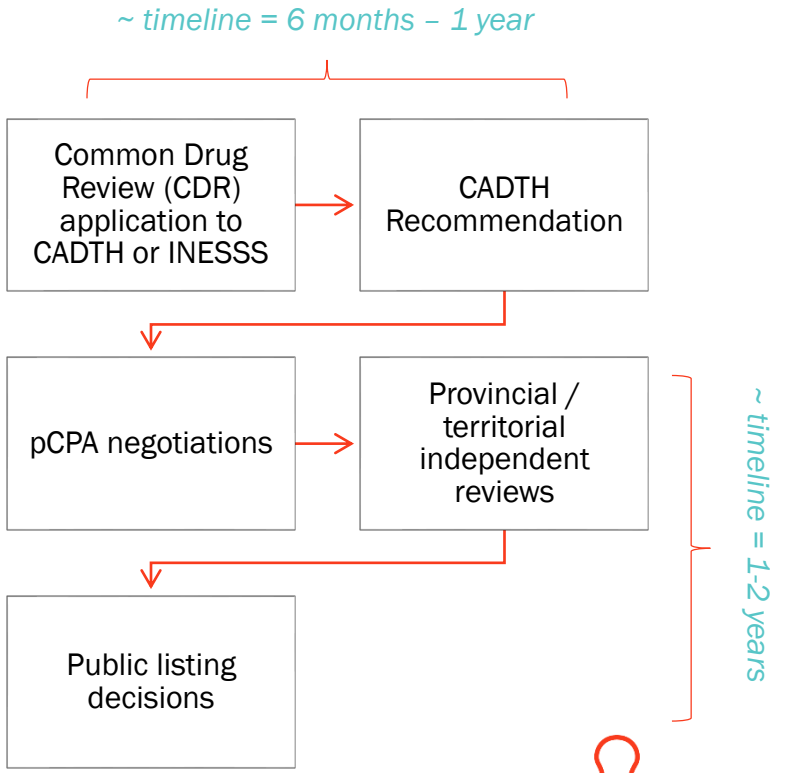
Drug Funding + Formulary Listings

The Canadian Agency for Drugs and Technologies in Health (CADTH) or Institut national d'excellence en santé et en services sociaux (INESSS) in Quebec, provides advice and recommendations on whether drug costs should be covered by publicly-funded formularies (federal, provincial, territorial).

Following a recommendation for reimbursement, provinces and territories can choose to work together through the pan-Canadian Pharmaceutical Alliance (pCPA) to determine what public reimbursement could look like within each jurisdiction based on negotiation with the manufacturer.



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Work-in-Progress: Proposed Reforms

The federal government has introduced PMPRB reforms that will come into effect July 1, 2020 and changes the list of countries used for price comparison, requires that prices reports factor in discounts and adds analysis on whether price of a drug reflects its value for patients.

The federal government has also committed to developing a model of pharmacare that includes:

- Creation of a Canadian Drug Agency to negotiate prescription drug prices on behalf of Canadians.
- A National Formulary, a list of prescribed drugs to provide the basis for a consistent approach to formulary listing across the country.
- A National Strategy for high-cost drugs for rare diseases to gather and evaluate evidence on high-cost drugs for rare diseases, improve the consistency of decision-making and access across the country, negotiate prices with drug manufacturers, and ensure that effective treatments reach the patients who need them.

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