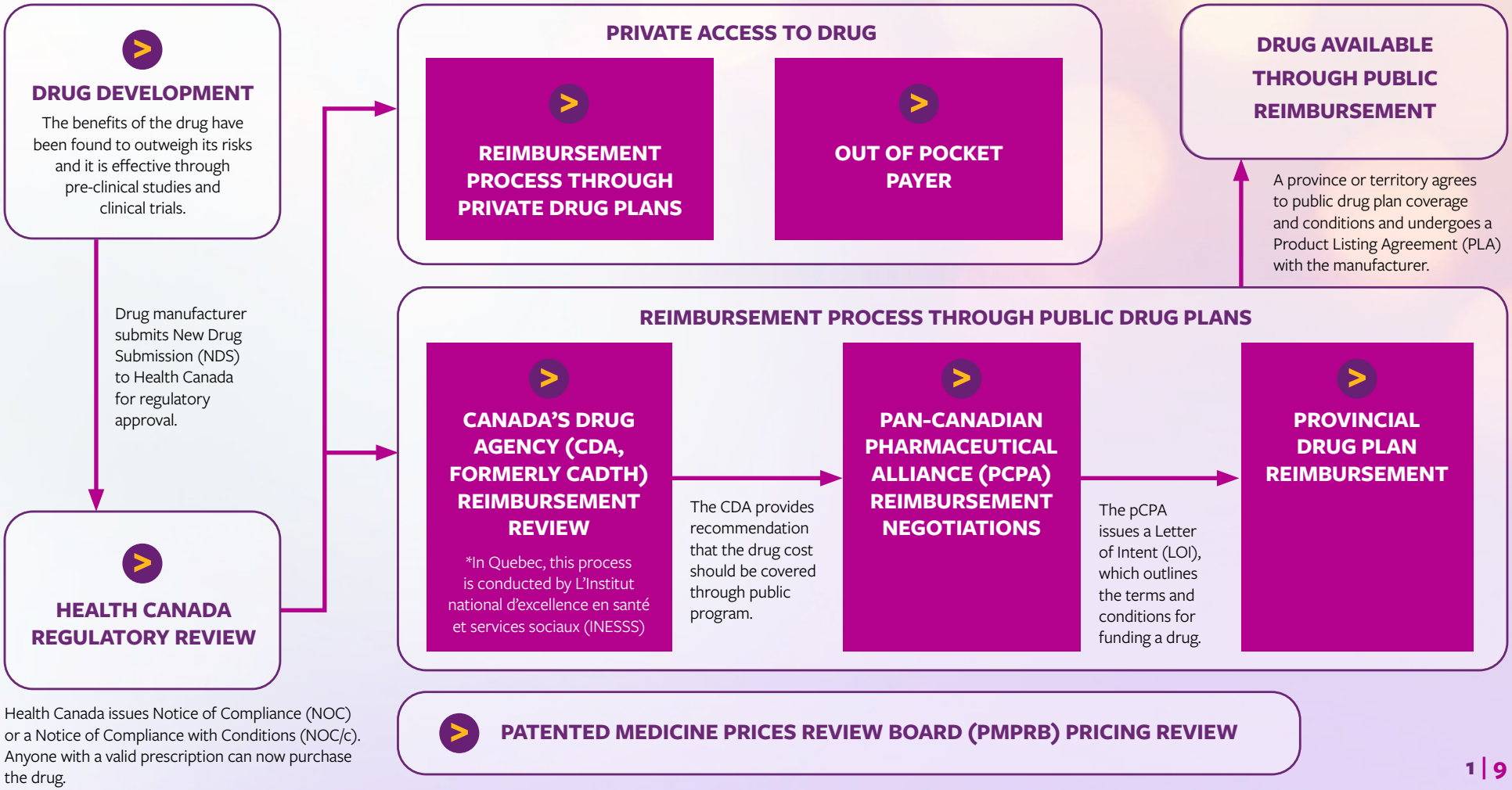
ALS CANADA'S

Canadian Drug Access Pathway

The Canadian Drug Access Pathway is the process for new drugs to be approved for access by Canadians. It is a complex, lengthy process that is impacted by federal, and provincial policies. It takes 8 to 15 years from drug discovery to a drug being available on the market, with the drug approval process taking approximately one to four years of that time range.

CLICK ON > IN EACH SECTION to learn more about each component of the pathway. Scroll to the end of the document to see a summary chart of the processes.



DRUG DISCOVERY

Creating new drugs starts with testing thousands of different compounds to determine which may be suitable to treat an illness or condition.

PRE-CLINICAL STUDIES

If there are promising compounds, the drug undergoes pre-clinical studies in various cell, tissue, and animal models. The drug discovery and pre-clinical studies can take three to seven years. If the results of the studies show that the compound is safe at effective doses and has significant efficacy, it can proceed to clinical trial.

CLINICAL TRIAL

For a drug to be approved in Canada, it must undergo clinical trials where the drug is administered to humans to see if it is safe and effective for people. Clinical trials can take an additional six to seven years to complete. There are four phases of a clinical trial:

- **Phase I:** This phase of a trial is done on a small group of people (<100) to determine a safe and effective dosage range as well as if there are side effects of the drug.
- **Phase II:** This phase of a trial is done on a larger group of people (>100) to see how well the drug treats a disease, the best dose for treating a disease and how safe the drug is with a wider range of people.
- **Phase III:** This phase of a trial is done with a larger group of people than Phase II (>1,000) to see if it's still effective within a larger population, compare it to other treatments, and monitor side effects. If the drug is proven to be safe and effective in Phase III, it is likely to be submitted for Health Canada regulatory review.
- **Phase IV:** Some drugs go onto this phase, which occurs after the drug is approved for public consumption to collect information on long-term effects. Phase IV trials can have thousands of participants.

If the clinical trials prove that the drug can effectively treat a condition and the benefits are greater than the risks, the manufacturer can apply to Health Canada to receive approval to market the drug.

HEALTH CANADA REGULATORY REVIEW

ABOUT HEALTH CANADA

Health Canada is the federal institution responsible for helping Canadians maintain and improve their health by regulating products such as drugs, medical devices, consumer products, and food. The branch of Health Canada that reviews drugs for market approval is the Health Products and Food Branch (HPFB). The HPFB consists of scientists who review scientific evidence to determine if a drug is safe, of suitable quality, and works as intended.

QUESTION THEY WANT ANSWERED:
SHOULD THIS DRUG BE SOLD IN CANADA?

HOW IT WORKS:

1. The drug manufacturer files a New Drug Submission (NDS) with Health Canada, which must be submitted before regulatory review begins.
2. After conducting a thorough review, Health Canada will conclude their review and make one of the following decisions:
    a. Notice of Compliance (NOC): This means the drug is approved to be in market.
    b. Notice of Compliance with (NOC/c): This means the drug is approved to be in market under the condition that the manufacturer conducts additional studies to confirm the benefits of the drug.
    c. The drug is not approved to be sold in Canada.
3. All drugs that receive an NOC or NOC/c will receive a Drug Identification Number (DIN), which indicates that the drug is approved in Canada.
4. If the drug does not receive an NOC or NOC/c, the drug manufacturer can resubmit the application at a later date with additional supporting data or ask Health Canada to reconsider its decision.

HOW LONG IT TAKES:

There are three timelines under which Health Canada conducts drug reviews:

- 300 days: Standard Review
- 200 days: Notice of Compliance with Conditions
- 180 days: Priority Review
    - This may be granted for the treatment of serious, life threatening, severely debilitating illness where:.
        - there is either no existing treatment; or
        - the new product represents a significant improvement benefit over existing products.

This process is mostly closed to the public and Health Canada only considers the clinical evidence and safety profile of the drug in its review. There are opportunities to advocate to push a drug to be considered for priority review.

ABOUT CANADA'S DRUG AGENCY (CDA):

Canada's Drug Agency (formerly known as the Canadian Agency for Drugs and Technologies in Health, or CADTH) is a pan-Canadian health organization acting as a producer and broker of health technology assessments for federal, provincial, and territorial governments with the exception of Quebec, which has its own body, L'Institut national d'excellence en santé et services sociaux (INESSS). A health technology assessment determines the cost effectiveness of a treatment to taxpayers i.e., whether the cost of the drug will be covered by public drug benefit plans in Canada.

QUESTION THEY WANT ANSWERED:
DOES THE DRUG OFFER VALUE FOR MONEY?

HOW IT WORKS:

- The CDA and the INESSS for Quebec conduct a reimbursement review, which consists of evaluating:
  - Clinical studies for efficacy and safety
  - Therapeutic advantage of a new drug in comparison to current drugs on the market
  - Cost effectiveness in comparison to current standard of care
- Once the review is complete, the CDA or the INESSS issues reimbursement recommendations or review reports to federal, provincial, and territorial agencies overseeing public drug plans and allow them to make decisions about whether the drug costs will be covered through public programs.
- At the conclusion of the reimbursement review, one of the following recommendations is made:
  - The drug is reimbursed;
  - The drug is reimbursed with clinical criteria and/or conditions; or
  - The drug is not reimbursed.
- The agencies almost always align with the recommendations and criteria that the CDA or INESSS put out.

HOW LONG IT TAKES:

Health Canada, the CDA, and INESSS have an aligned review process where the reimbursement review will accept submissions six months before they expect to receive a Notice of Compliance from Health Canada. The review has a target timeline of **approximately six months** but there are multiple variables that can affect the process and extend the review timeline to one year or more.

OPPORTUNITIES FOR PUBLIC INPUT:

- There have been formal mechanisms for patient and clinician input since 2020.
- Patient groups are invited to share their experiences, perspectives, and expectations for the drug under review and areas of input can include disease experience, experience with current therapies, improved outcomes, experience with the drug under review through clinical trials or the Special Access Programme, and diagnostic testing
- Clinicians have the opportunity to comment on the benefits of the therapy from a clinical perspective and areas of input can include current treatments, treatment goals, treatment gaps, and place in therapy.

PAN-CANADIAN PRICING ALLIANCE (PCPA) REIMBURSEMENT NEGOTIATIONS

ABOUT THE PAN-CANADIAN PHARMACEUTICAL ALLIANCE (PCPA):

The pan-Canadian Pharmaceutical Alliance (pCPA) was established in 2010 to provide joint provincial and territorial negotiation for brand name and generic drugs to achieve greater value for public reimbursement. This coalition is made up of and funded by all provinces and territories and representative from federal public drug plans such as the Non-Insured Health Benefits program, Corrections Canada, and Veterans Affairs. The pCPA is a stand-alone organization with its own internal governance. The pCPA is a more efficient platform for provincial, territorial, and federal agencies to make decisions around public reimbursement for a drug.

QUESTION THEY WANT ANSWERED:
CAN WE NEGOTIATE A LOWER PRICE FOR A GIVEN DRUG?

HOW IT WORKS:

- The pCPA jointly negotiates drug prices and coverage criteria with manufacturers on behalf of the public drug plans across Canada.
- All brand name drugs coming forward through the CDA are considered for pCPA negotiations and concluded with a Letter of Intent (LOI), which has the terms and conditions for funding a drug.
- Once an LOI is received, the drug manufacturer can use this to negotiate and execute a product listing agreement (PLA) with each province and territory.
- While the LOI forms the basis of the listing agreement, the provinces and territories are not bound to what's outlined in the LOI as it is not a legally binding document.

HOW LONG IT TAKES:

It can easily **take up to a year** to complete, but there are no clear timelines provided. Some files have concluded in two months, while some have been in negotiation for more than two years. In 2023, the average review time was 293 days.

OPPORTUNITIES FOR PUBLIC INPUT:

There is no opportunity for patient input during this process, but there are opportunities for advocacy including advocating to provincial and territorial governments to speed up their negotiations.

PUBLIC DRUG PLAN REIMBURSEMENT NEGOTIATIONS

ABOUT THE PUBLIC DRUG PLAN REIMBURSEMENT:

Each provincial and territorial government offers a drug benefit plan for eligible groups. Some are income-based universal programs. Most have specific programs for population groups that may require more enhanced coverage for high drug costs (i.e., seniors, people living with diseases that are associated with high drug costs).

QUESTION THEY WANT ANSWERED:
WILL WE COVER THIS DRUG FOR OUR BENEFICIARIES?

HOW IT WORKS:

- Each jurisdiction does its own independent review of a drug and negotiation with the drug manufacturer to determine if and how the drug will be covered by its particular public drug plan.
- Once the review is complete, the jurisdiction's health authority (e.g., Ministry of Health) will make the final decision about public drug plan coverage.
- Federal, provincial, and territorial drug plans choosing to cover the therapy in whole or in part will have a Product Listing Agreement with the manufacturer.

HOW LONG IT TAKES:

The Product Listing Agreements with individual federal, provincial, and territorial drug plans can easily **take up to two or more years** to complete, depending on the jurisdiction. In 2019, the average time to access a drug was 690 days or 1.9 years from the time that the NOC is issued.

OPPORTUNITIES FOR PUBLIC INPUT:

This process is not open to the public but there are opportunities for advocacy including advocating to provincial, territorial, and federal agencies that oversee public drug plans to push for urgency in negotiating with drug manufacturers after the LOI has been signed.

PATENTED MEDICINE PRICES REVIEW BOARD (PMPRB) PRICING REVIEW

ABOUT THE PATENTED MEDICINE PRICES REVIEW BOARD (PMPRB):

The Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial federal body that is part of the Health portfolio and operates at arm's length from the federal Minister of Health. Their purpose is to review the prices of patented medicines sold in Canada and report on pharmaceutical trends. The PMPRB's mandate is to ensure prices of patented medicines in Canada are not excessive by setting the maximum price at which companies sell their drug products in the Canadian marketplace.

QUESTION THEY WANT ANSWERED:
WHAT IS THE MAXIMUM ALLOWABLE PRICE IN CANADA?

HOW IT WORKS:

- While Health Canada approval and reimbursement reviews are in process, and throughout the duration of the drug's patent, the drug is subject to price controls, which fall under the PMPRB's authority. Drug manufacturers must submit specific pricing information to the PMPRB when the drug is first introduced and then on a semi-annual basis.
- The PMPRB regularly reviews pricing submitted by drug manufacturers to ensure that they comply with the PMPRB's guidelines. The PMPRB regulates the maximum price that a manufacturer can charge to a drug wholesaler, hospital, or pharmacy in Canada. They do not control the final price charged to patients or drug plans, which may be lower than this maximum price.
- To determine the compliance, the PMPRB uses several factors to assess the suggested price, including the price of other similar drugs already available in Canada, and the average price from a list of comparator countries.
- If pricing exceeds guidelines, the PMPRB can start an investigation which can result in one of the following:
  - The investigation is closed if the price is found to be within the guidelines
  - A Voluntary Compliance Undertaking by the drug manufacturer to reduce the price of the drug or another patented drug to offset excess revenues
  - A public hearing to determine if the price is excessive

HOW LONG IT TAKES:

There are no clear timelines for how long price negotiations can take.

OPPORTUNITIES FOR PUBLIC INPUT:

The price negotiations are closed to the public, but opportunities for engagement are available through submitting feedback on their guideline change proposals.

REIMBURSEMENT THROUGH PRIVATE DRUG PLANS

QUESTION THEY WANT ANSWERED:

WHAT IS THE ANNUAL OR LIFETIME CAP FOR A DRUG PER BENEFICIARY?

HOW IT WORKS:

Private drug plans evaluate the drug and negotiate terms with the manufacturer. They typically add new drugs to their plan's formulary once Health Canada approves them for sale and makes them available until a beneficiary reaches an annual or lifetime maximum. Those with private drug plans may access therapies months or years before someone who is waiting to access them through public drug plans.

OUT OF POCKET PAYER

QUESTION THEY WANT ANSWERED:

CAN I AFFORD TO PAY FOR THIS OUT OF POCKET?

HOW IT WORKS:

Individuals pay for their drug out of pocket if the individual is not covered by a drug plan, if the drug's cost is not covered by a drug plan, if their drug costs are higher than their plan's deductibles, or if they have exceeded their plan maximum.

SUMMARY CHART

	PURPOSE	QUESTION TO ANSWER	LENGTH OF TIME TO COMPLETE	OPPORTUNITY FOR PUBLIC INPUT
Health Canada Regulatory Review	Approval: To determine if a drug is safe, of suitable quality and works as intended	Should this drug be sold in Canada?	180 to 300 days	Closed to the public
Canada's Drug Agency Reimbursement Review	Reimbursement evaluation: To determine the cost effectiveness of a treatment in order to be covered by public drug benefit plans in Canada	Does the drug offer value for money?	Approximately six months	There are formal mechanisms for patient and clinician input
Pan-Canadian Pricing Alliance (pCPA) Reimbursement Negotiations	Pricing: To negotiate affordable prices for drugs and coverage criteria on behalf of the public drug plans across Canada	Can we negotiate a lower price for a given drug?	No clear timelines but the average in 2023 was approximately 9 to 10 months	This process is not open to the public
Public Drug Plan Reimbursement Negotiation	Independent reimbursement review: To conduct an independent review of a drug to determine if a drug will be covered by a particular public drug plan	Will we cover this drug for our beneficiaries?	Approximately two or more years	This process is not open to the public
Patented Medicine Prices Review Board (PMPRB) Pricing Review	Maximum reimbursement review: Reviews the prices of patented drugs sold in Canada and ensure they are not excessive	What is the maximum allowable price in Canada?	There are no clear timelines	This process is not open to the public