Drug Approval Process in Canada: An Overview

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Agenda

- Welcome and introduction
- Objectives
- Approval Process overview
- Special Access Program (SAP)
- Health Canada Drug Approval
- Pricing (PMPRB)
- Health Technology Assessment - HTA (CADTH/INESSS)
- Pan-Canadian Pharmaceutical Alliance – pCPA
- Provincial coverage through Product Listing Agreements – PLA
- Q & A

Objectives

- Provide an overview of the drug approval process in Canada
- Review some of the major entities that are involved in the process.
- Timelines for the various reviews
- Where and how patient input is accepted
- Address any questions from the audience.

How drugs are approved in Canada:

Drug Company Develops a new drug

Health Canada
Should the drug be sold in Canada?

Review scientific evidence to determine weather a drug is safe, of suitable quality and works as intended. Does not weigh in on price or effectiveness compared to existing drugs already on the market.

Canadian Agency for Drugs and Technologies in Health (CADTH)/ Institut national d'excellence en sante et en services sociaux (INESSS)
Does the drug offer value for money?

Conduct health technology assessment to evaluate the clinical benefits and cost of drugs. Issue recommendations for or against public funding

Pan Canadian Pharmaceutical Alliance (pCPA)
Can we negotiate a lower price?

Jointly negotiates drug prices and coverage criteria with manufacturers on behalf of the public drug plans.

Public Drug Plans (Provinces / Territories / Institutes)
Will we cover this drug for our beneficiaries?

Consider factors such as needs of those served by their drug plan and the drug's potential budget impact to determine whether to add it to the plan's formulary.

Out of Pocket Payer
Can I afford to pay for this out of pocket?

Pay for drug out of pocket if they are not covered by a drug plan, if their drug costs are lower than their plan's deductible or if they have exceeded their plan maximum.

Private Drug Plans
What is the annual or lifetime cap per beneficiary?

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.

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Special Access Programme (SAP)

- Health Canada has a mechanism to provide access to treatments that are not approved in Canada or are unavailable in Canada.
- A physician must request access on behalf of the patient.
- Must include reason for the request and supporting evidence from any and all jurisdictions.
- The requests are processed quickly and if approved, works with the manufacturer to get the medication directly to the patients.
- Some therapies for rare disease and cancer end up being used through this process.

Drug Approval Process for Public Coverage

rare **strength**

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Health Canada

- Drugs are submitted to Health Canada for approval
- New Drug Submission, New Indications, and new formulations need to be submitted.
- Health Canada reviews the product for safety, efficacy, and quality – Should the drug be sold in Canada?
- The review leads to a NOTICE OF COMPLIANCE (NOC), NOTICE OF COMPLIANCE with CONDITIONS (NOCc), or NOTICE OF DEFICIENCY (NOD).
- A Priority Review – May be granted for the treatment, prevention, or diagnosis of serious, life-threatening or severely debilitating illness or condition where a) there is no existing drug b) where the new product represents a significant improvement/benefit over existing products.
  - 180 day review period
- Standard Review – all other submissions – Requires a 300-day review period
- This process is mostly closed to the public.

Pricing (PMPRB)

- In Canada, we have regulated pricing for patented or brand name drugs through the Patented Medicine Price Review Board (PMPRB).
- Mandate is to ensure that prices of patented medicines in Canada are not excessive
- Uses the median of seven comparator countries – USA, Switzerland, Germany, UK, France, Spain, Italy
- Also reports on price trends and research and development investment.
- Annual Report from 2018 found Canadian prices were the 4th highest among the 7 comparator countries.
- Recently proposed changes to guidelines would change the comparator countries from 7 to 11, plus it would also introduce pharmacoeconomic information and net pricing information into it's review and assessment. Introduction of these guidelines has been delayed twice and is now scheduled to be introduced in January 2022.

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Health Technology Assessment (HTA)

- There are two major bodies – Canadian Agency for Drug and Technologies in Health (CADTH - CDR and pCODR) and INESSS (Quebec)
- Review oncology and non-oncology products and recommendations are issued based on:
  - Clinical studies for efficacy and safety
  - Therapeutic advantage versus current therapies
  - Cost effectiveness versus current standard of care
- These recommendations are then used by the provinces and pCPA towards listing decisions.
- This review process is more open and does request for patient input.
  - Patient groups and individual patients can provide input through an online portal/templates.
  - Input is sought early and included prior to the initiation of the review
  - Best to reach out to your association (AAMAC) if you are interested in providing input. AAMAC might reach out to you!
  - Patient groups can also provide feedback on draft recommendations.
  - Physicians and physician groups are also able to provide input towards a review at the HTA.

Areas of Input to HTA – Patients

- Info about you or your patient organization
- How the information was gathered
- Disease experience
- Experience with current therapies
- Improved outcomes
- Experience with drug under review (through trials or SAP)
- Diagnostic testing
- Other info
- Conflict of interest
  - Did you have outside assistance?

Areas of Input at HTA - Physicians

- About your clinician group
- How was the information gathered
- Current treatments
- Treatment goals
- Treatment gaps (unmet need)
- Place in therapy
- Additional information
- Conflict of Interest.
  - "each clinician that contributed to the input" must complete the conflict-of-interest declaration.

Review Feedback on Draft Recommendation Template

- **Six Y/N questions:**
  - **Stakeholder agreement on the Draft Recommendation**
  - **Expert Review Committee consideration of the stakeholder input**
  - **Accuracy of the Summary of Stakeholder Input**
  - **Clarity of the Draft Recommendation (2 questions)**
  - **Reimbursement conditions**

Quebec (INESSS) – Institute National d'Excellence en Sante et en Services Sociaux

- In Quebec, manufacturers submit branded drugs, generics, and biosimilars to INESSS for evaluation and listing on the public formulary.
- Reviews focus on therapeutic value, cost effectiveness, and impact on health budget (budget impact analysis)
- Reviews take six months, and a priority review option is available for urgent medications.
- Patient and physician input is sought in this process
  - A questionnaire is filled out and submitted to INESSS.

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Pan-Canadian Pharmaceutical Alliance (pCPA)

- Established in 2010 to provide joint provincial and territorial negotiation for brand name and generic drugs to achieve greater value for public reimbursement.
- Objectives:
  - Increase access to clinically effective and cost-effective treatment options
  - Achieve lower drug costs for participating provinces
  - Reduce duplication of effort and resources
  - Improve consistency of decision on drug listings across the country.
- All brand name drugs coming forward through CADTH are considered for pCPA negotiations and concluded with a Letter of Intent (LOI).
- pCPA members include all provinces (except Quebec) and territories, plus federal plans (NIHB, Corrections Canada, and Veterans.
- Once a LOI has been issued, the manufacturer may then proceed to provincial listings agreements. Not all provinces are bound to list a product.
- The average negotiation period is 10 months (some files have concluded in 2 months, while some have been in negotiations for over 2 years).

pCPA Activities Overview (October 18, 2021)

Status	Total Negotiations	Summary
Active Negotiations	30	Non-oncology: 20 Oncology: 10
Under Consideration for Negotiation	34	Non-oncology: 21 Oncology: 13
Completed Negotiations	454	With Letter of Intent: 393 Without agreement: 61
Negotiations That Were Not Pursued	85	

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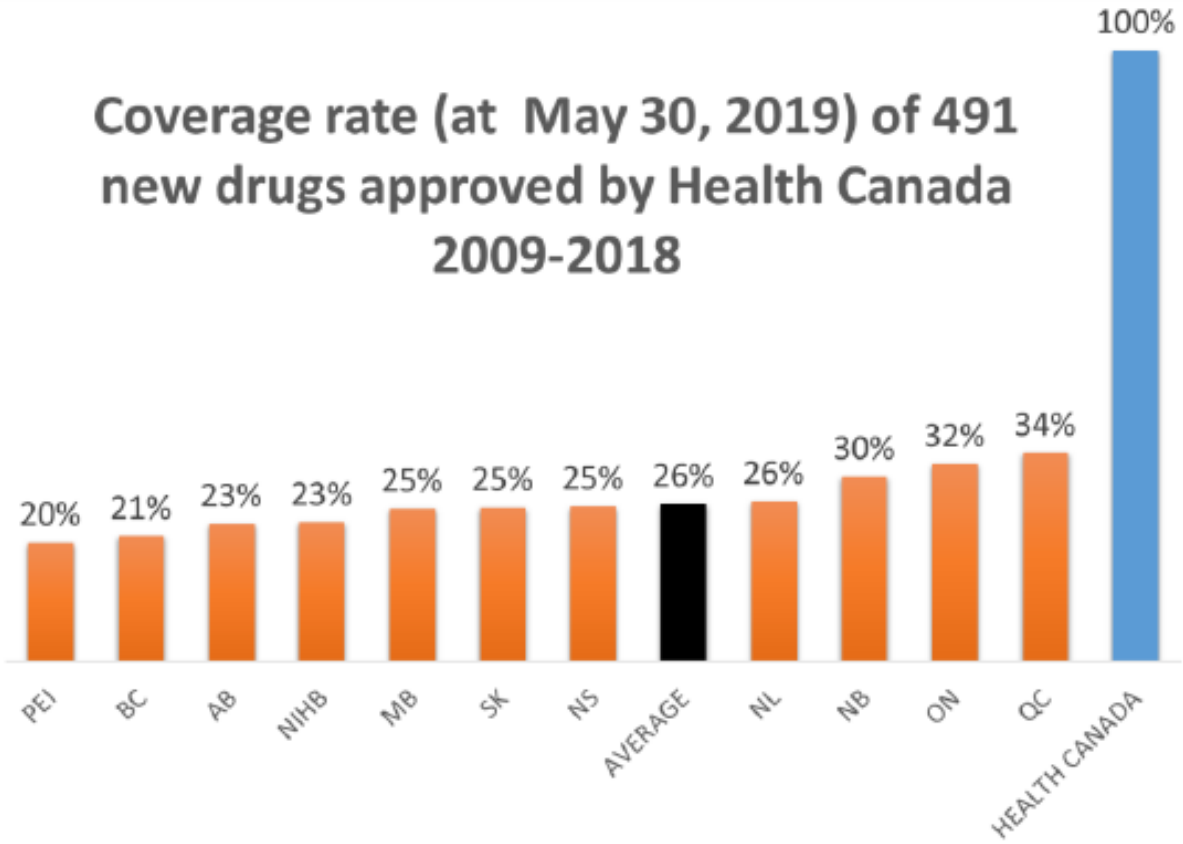
Provincial Drug Listing

- A letter of Intent must be obtained through the pCPA to proceed to Provincial listings.
- Provinces and territories have the final decision on whether a medicine is publicly funded or not through their Product Listing Agreement (PLA).
- The LOI from the pCPA forms the basis of the Listing Agreement with the Province. Usually includes negotiated price and criteria.
- Any Province can opt in or out of the listing at their will and during any time, including prior to or end of the pCPA negotiations.
- Federal Government has the final say with their 6 formularies (Non-Insured Health Benefit (NIHB) for First Nations and Inuit, veterans, Canadian Forces members, designated migrants, RCMP, and Corrections Canada)
- 19 different public formularies each with their own review and decision-making process.
- Patients and patient groups can have an impact at the provincial level with effective advocacy.
  - Encouraging your province to be part of the pCPA for a particular medication
  - Working with physicians to ensure education, knowledge, and awareness in the community.
  - Media campaign, political awareness, letter writing, etc.

Public Coverage Rate of New Drugs

- **Only 26% of new drugs approved by Health Canada (2009-2018) were covered by public drug plans**
- **Average time to list was 690 days from NOC (1.9 years)**
- **Most drugs listed as Special Authorization versus Full Benefit**



Coverage of new medicines in Federal-Provincial public drug plans in Canada 2009-2018 CHPI Sept 2019

Approval timelines (approx.):

Drug Company Develops a new drug

Health Canada
Should the drug be sold in Canada?

300 Days for standard review and 180 Days for Priority Review

Canadian Agency for Drugs and Technologies in Health (CADTH)/ Institut national d'excellence en sante et en services sociaux (INESSS)
Does the drug offer value for money?

6-9 Months

Pan Canadian Pharmaceutical Alliance (pCPA)
Can we negotiate a lower price?

3 – 12 Months

Public Drug Plans (Provinces / Territories / Institutes)
Will we cover this drug for our beneficiaries?

1 – 6 months

Out of Pockey Payer
Can I afford to pay for this out of pocket?

Immediate

Private Drug Plans
What is the annual or lifetime cap per beneficiary?

Immediate or 6 months for review.

10 months to 2 years

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Q & A

THANK YOU!