Patented Medicine Prices Review Board Canada

Conseil d'examen du prix des médicaments brevetés Canada

Patented Medicine Prices Review Board

Transition Binder 2023
to the Chairperson

Canada

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1. The Patented Medicine Prices Review Board (PMPRB) of Canada

a. PMPRB: An Overview

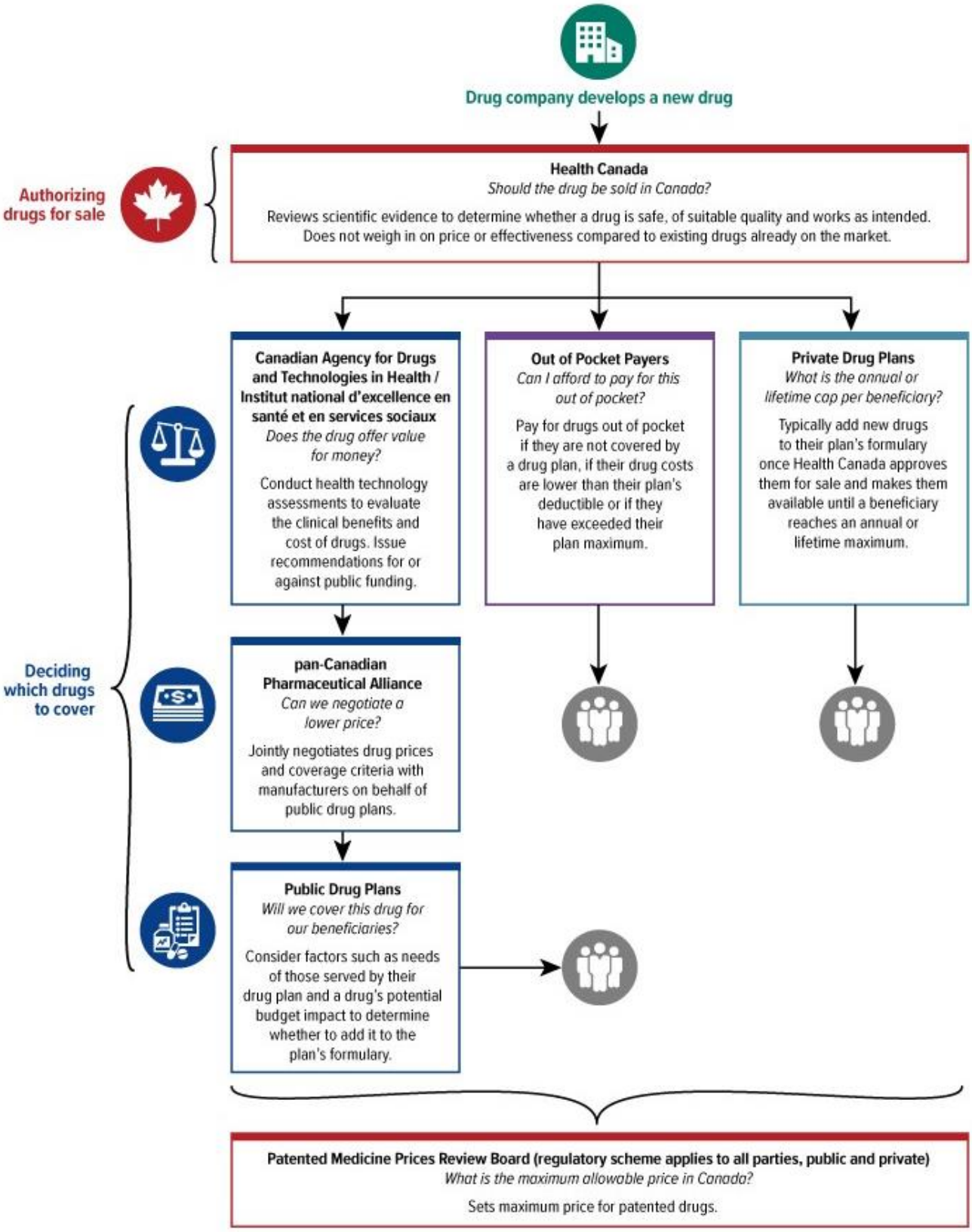
Created by Parliament in 1987 under the *Patent Act*, the PMPRB is an independent quasi-judicial body that protects the interests of Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive. The Minister of Health is responsible for the pharmaceutical provisions of the *Patent Act* as set out in sections 79 to 103.

The PMPRB has a dual mandate: in its regulatory role, it protects consumers by ensuring that the prices of patented medicines are not excessive. It does this by reviewing the prices that patentees charge for each individual patented drug product in Canadian markets. If a price is found to be excessive, the Board can hold public hearings and order price reductions and/or the offset of excess revenues. The PMPRB regulates the "factory gate" prices and does not have jurisdiction over prices charged by wholesalers or pharmacies, or over pharmacists' professional fees.; The PMPRB is also responsible for reporting on trends in pharmaceutical sales and pricing for all medicines and for reporting research and development spending by patentees.

In its reporting role, the PMPRB provides information on pricing trends in the pharmaceutical industry via its Annual Reports.

Further to a directive from the Minister of Health under section 90 of the Act, the PMPRB also supports informed and evidence-based health policy by reporting on medicine price, utilization and cost trends under the National Prescription Drug Utilization Information System (NPDUIS) initiative.

b. Canada's Regulatory and Reimbursement Ecosystem



c. Recent Federal priorities and pan-Canadian Initiatives

Health Canada:

In the Supply and Confidence Agreement (March 2022), the government expressed its commitment to pass a Canada Pharmacare Act by the end of 2023 and tasked the Canadian Drug Agency (2021) with developing a national formulary of essential medicines and a bulk purchasing plan. The Canadian Drug Agency Transition Office (CDATO) is responsible for developing options for a vision, mandate and plan to create the Canadian Drug Agency (CDA).

- Amendments to the Patented Medicines Regulations (June 2022);
- Improving Affordable Access to Prescription Drugs (2022): federal funding for PEI to cover new drugs;
- National strategy for drugs for rare diseases (2021);
- The biomanufacturing and life sciences strategy (2021); and
- Improving the regulatory review of drugs and devices (2020): collaborating with international partners on issues related to drug and medical device clinical trials, authorizations, risk assessments, and potential shortages.

Pan-Canadian Pharmaceutical Alliance (pCPA):

The pan-Canadian Pharmaceutical Alliance conducts joint negotiations for brand name and generic drugs in Canada in order to achieve greater value for publicly funded drug programs and patients through its combined negotiating power.

- pCPA Strategic Revitalization;
- pCPA's transition to a stand-alone organization (2023);
- The agreement on generic initiatives set to expire on April 1, 2023; and
- pCPA supported Ontario Health with pan-Canadian Biosimilars Initiative Evaluation Framework and Toolkit (2021) under pan-Canadian Oncology Biosimilars Initiative.

Canada's Drug and Health Technology Agency:

Canada's Drug and Health technology Agency conducts health technology assessments to evaluate the clinical benefits and cost of drugs. Issue recommendations for or against public funding.

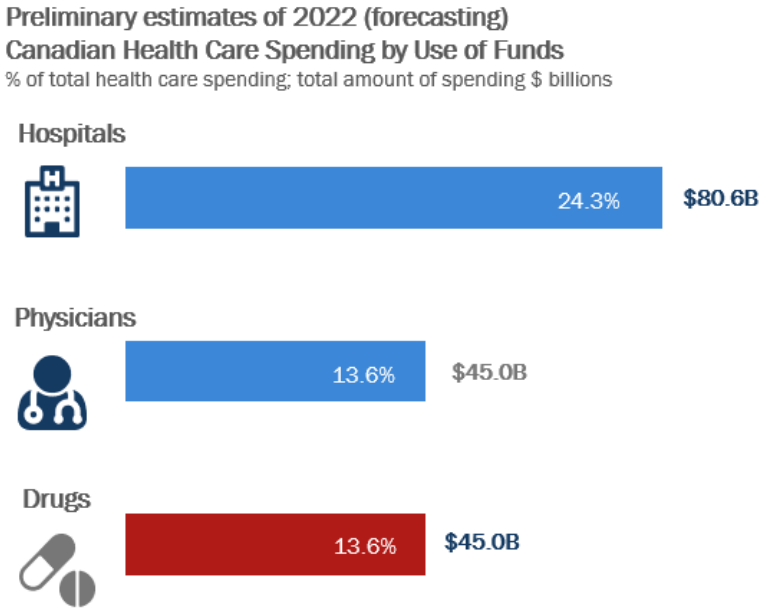
- 2022-2025 Strategic Plan: Ahead of the Curve: shaping future-ready heath systems;
- Advisory Panel, Pan-Canadian Formulary, launched in September 2022;
- Post-Market Drug Evaluation (PMDE) Program, launched in September 2022; and
- CADTH launched a collaborative for the development of a strategic framework for Canada's use of Real-world evidence (RWE) to support decision-making.

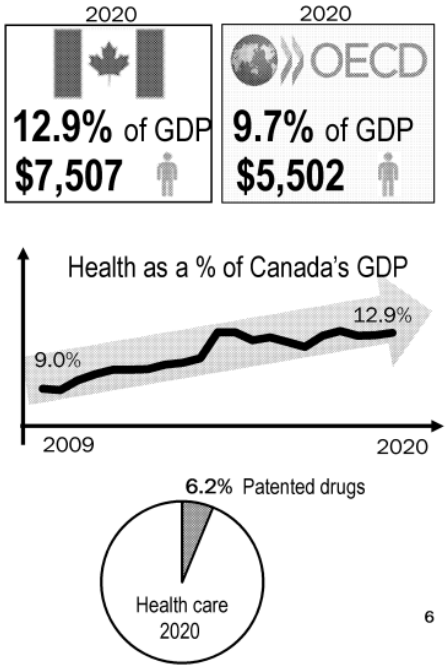
d. Drug Spending in Canada

Pharmaceuticals are important to the health of Canadians and form a vital part of our health care system. Drugs are helping to cure or manage previously debilitating or fatal diseases, allowing Canadians to live longer, healthier and more satisfying lives.

New classes of drugs, including biologics and genetic therapies, have begun offering innovative treatments for such diseases as hepatitis C, HIV and arthritis.

- In 2022, Canadians spent just around $45 billion on pharmaceuticals; and
- At 13.6% of total health care spending, spending on drugs is as same as that on physicians.
- Canada is among the highest spenders on health care in the Organization for Economic Co-operation and Development (OECD), calculated at $7,507 per person in 2020, or 12.9% of GDP (just below US), well above OECD norms;
- Total health expenditure captures an increasing share of Canada's GDP, from about 9% in 2009 to 12.9% in 2020;
    - CIHI reports that drugs spending in Canada grew at 1.6% in 2020 and is projected to increase 4.1% in 2021 and 5.4% in 2022 due to continued growth in claims associated with specialty drugs and to higher costs per claimant for chronic maintenance users.
- Canada had the 2nd highest spending per Capita on patented drugs* in the OECD in 2021, only after the US; and
- Patented drugs accounted for 6.2% of health care spending in 2020.

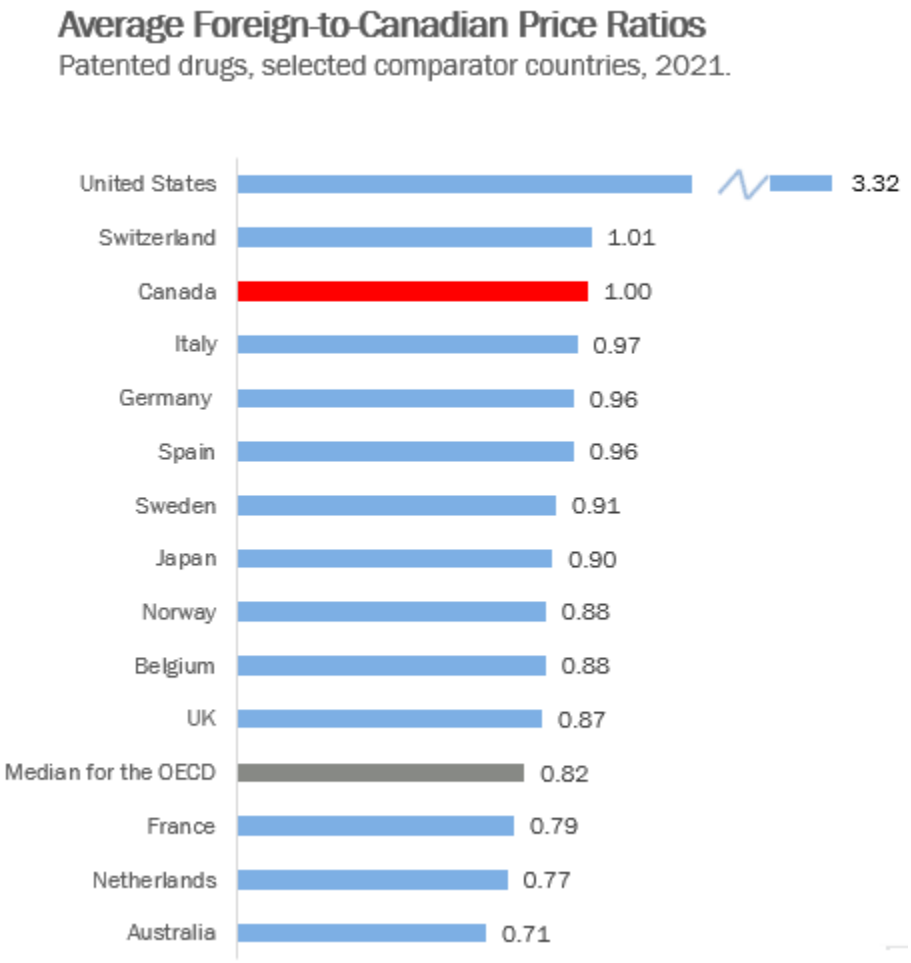




Source: CIHI, National health expenditure rends, CIHI 2022

Canadians are paying some of the highest prices for patented drugs.

- Patented drug prices in Canada are the third highest in the world behind only the US and Switzerland;
- Moreover, Canadians are paying 22% more, relative to the OECD average, for the same patented drugs;
- This disparity is costing Canadians and their public and private drug plans billions of dollars each year; and
- 1 in 5 Canadians report having no prescription drug coverage while many more are underinsured or face high deductibles or co-pays. Almost 1 in 10 Canadians have had to forego filling a prescription drug in the past year for reasons related to cost.

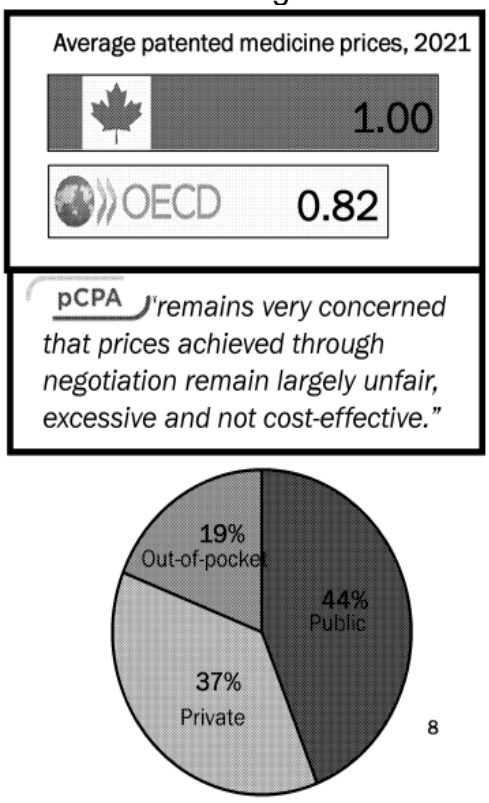


Source: PMPRB Annual Report 2021

Example: In Ontario, a top-selling arthritis drug (Humira) costs $17,000/year. That same drug costs $12,000/year in the United Kingdom. Paying the United Kingdom's list price would have saved Canadians $250 million last year on just that one drug.

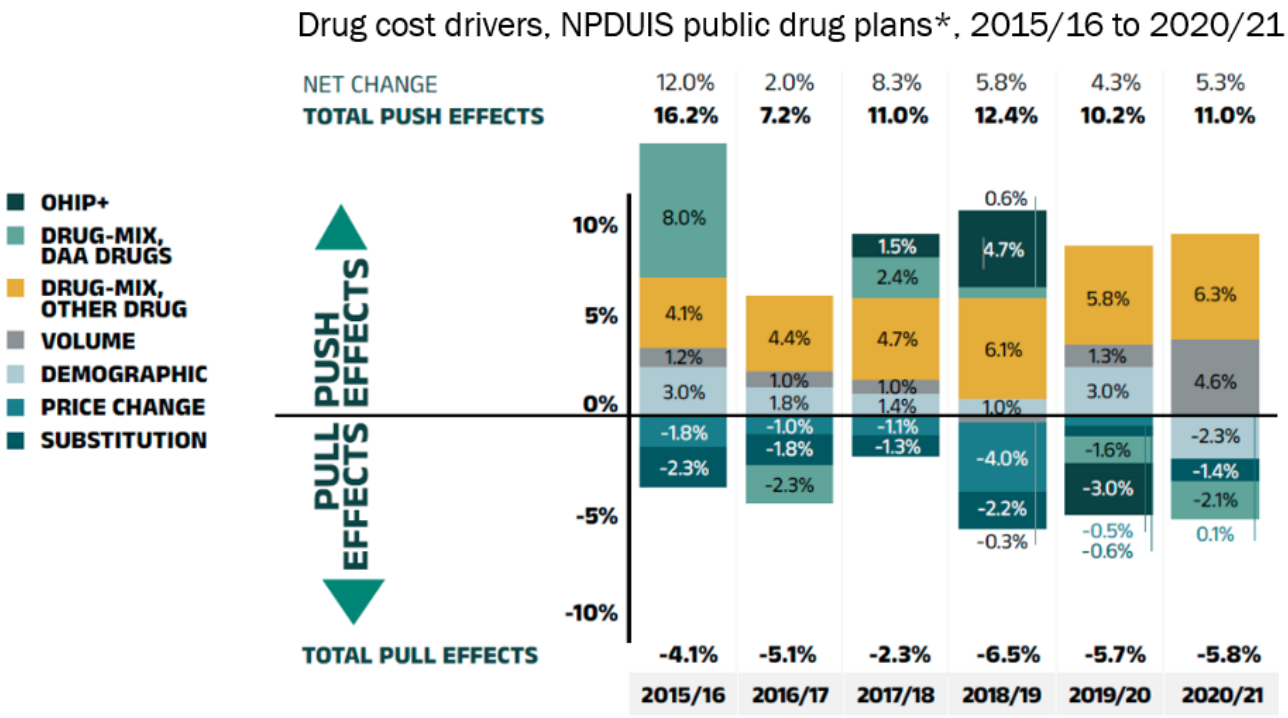
A significant share of the Canadian market pays list price.

- Confidential rebates are offered to Canadian public payers who jointly negotiate the reimbursed prices through the pan-Canadian Pharmaceutical Alliance. However, this has now been an international practice for many years and other countries are also paying lower negotiated prices;
- Given that list prices are now the starting point for price negotiations, Canada is at a disadvantage as its starting point is 22% higher than the OECD norm;
- Canada is the only developed country with a universal public healthcare system that does not include universal coverage of prescription drugs;
    - This means that pCPA negotiated prices which are available to public payers would cover only half (44%) of the Canadian spending on drugs; and
    - The majority of the spending is covered by private and out-of-pocket payers. These payers either do not negotiate prices to the same extent, or do not negotiate at all.
- Payers (2018) expressed concerns that "extremely high drug prices and growing costs threaten drug program affordability, sustainability and access for patients" and called for the "federal implementation of pricing controls through the PMPRB's proposed modernization changes".



Source: CIHI, Prescribed Drug Spending in Canada, 2021, House of Commons' Standing Committee on Health

Higher-cost medicines put greater pressure on spending.

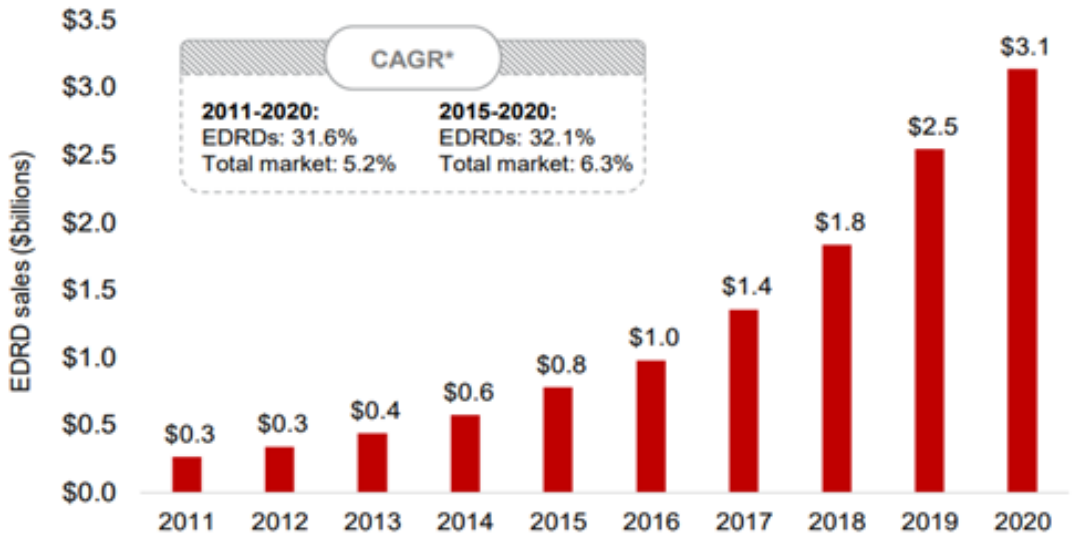


Source: Newly released CompassRx NPDUIS report

Expensive drugs for rare diseases account for a sizable and growing share of drug sales.

- Over the last decade, there has been a significant shift in pharmaceutical development toward more specialized medicines;
    - An increasing number of higher-cost medicines are being launched and gaining market share.
- A combination of new market entries and growth of existing medicines caused sales of EDRDs to increase at a compound annual growth rate of 31.6% between 2011 and 2020, greatly outpacing the overall pharmaceutical market; and
- In the latter half of the decade, compound annual growth was 32.1%, resulting in sales of $3.1 billion in 2020, more than one tenth of the total market.

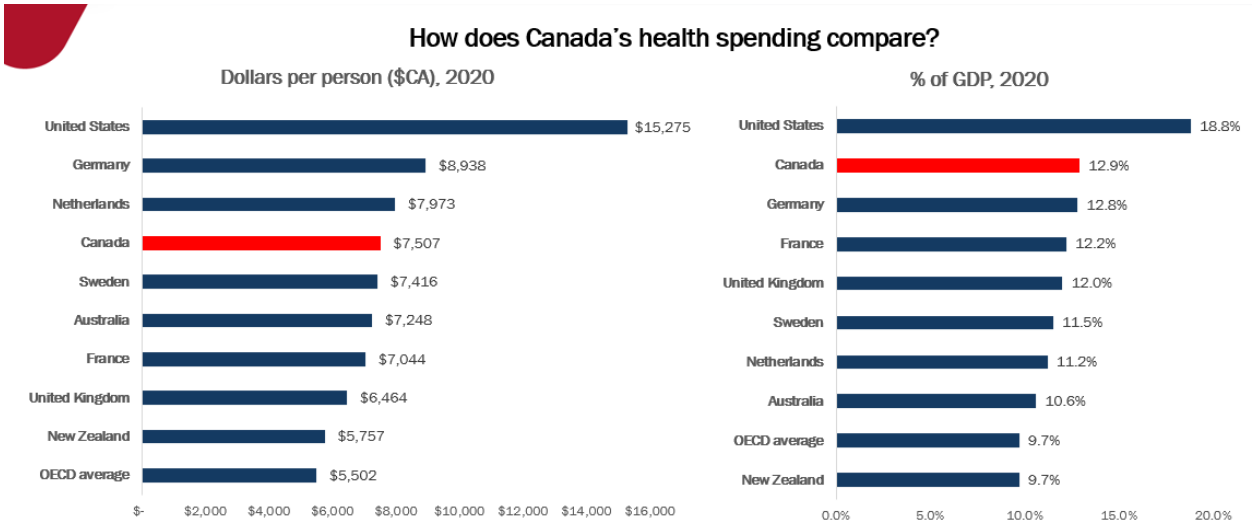
Sales of EDRDs in Canada, 2011 to 2020



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Annual growth rate	-	28.1%	29.5%	30.6%	36.1%	25.3%	38.5%	35.3%	38.8%	23.2%
Share of Canadian pharmaceutical market	1.4%	1.7%	2.2%	2.8%	3.5%	4.2%	5.4%	7.0%	9.1%	10.4%
Share of patented medicine sales	2.2%	2.8%	3.4%	4.0%	5.2%	6.3%	7.8%	11.7%	15.1%	17.4%

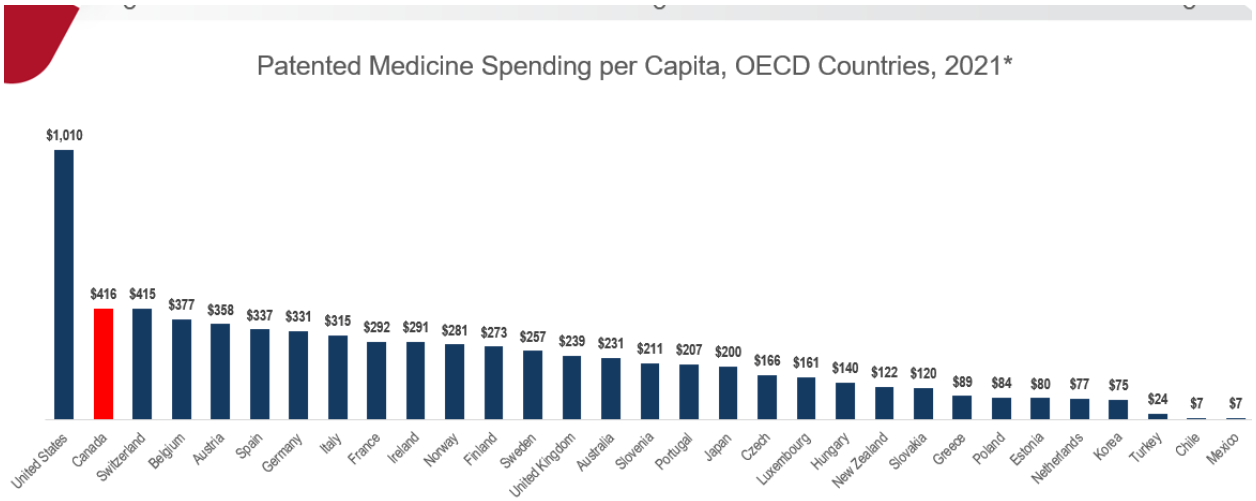
Notes:**For this analysis, EDRDs are medicines with >=1 orphan designation (FDA or EMA), and est. treatment cost > $100K/year (non-oncology) and $7,500 per 28 days (oncology).
Sources: PMPRB, IQVIA MIDAS Database, 2012 to 2020 (all rights reserved), IQVIA Private Pay Direct Drug Plan Database

Canada is among the highest spenders on health care in the OECD, calculated at $7,507 per person in 2020, or 12.9% of GDP (just below US), well above OECD norms.



Source: CIHI, National health expenditure trends, 2022-Snapshot

Canada had the 2nd highest spending per Capita on patented drugs* in the OECD in 2021, only after the US.



* Patented drugs were identified based only on the patents in Canada in 2021;
Data Source: IQVIA Midas for the country's patented meds spending and OECD for the country's population.

Patented drugs accounted for 6.2% of health care spending in 2020.

1. According to National health expenditure trends, 2022-Snapshot (CIHI), Canada's health spending is 12.9% of total GDP in 2020

2. Patented medicines sales per GDP

Table 20. Sales of Patented Medicines, 1990 to 2020

Year	Patented medicine		5-year compound annual growth rate	Sales of patented medicines as a share of all medicine sales*	Patented medicine sales per capita	Change in patented medicine sales per capita	Patented medicine sales per GDP
	Sales ($billions)	Change					
2020	$17.5	1.6%	3.0%	54.7%	$460.37	0.4%	0.795%
2019	$17.2	3.5%	4.5%	57.5%	$458.60	2.7%	0.748%
2018	$16.7	-0.6%	4.5%	59.0%	$446.30	-1.7%	0.751%

Sources: PMPRB, Annual Report 2020 Table 20

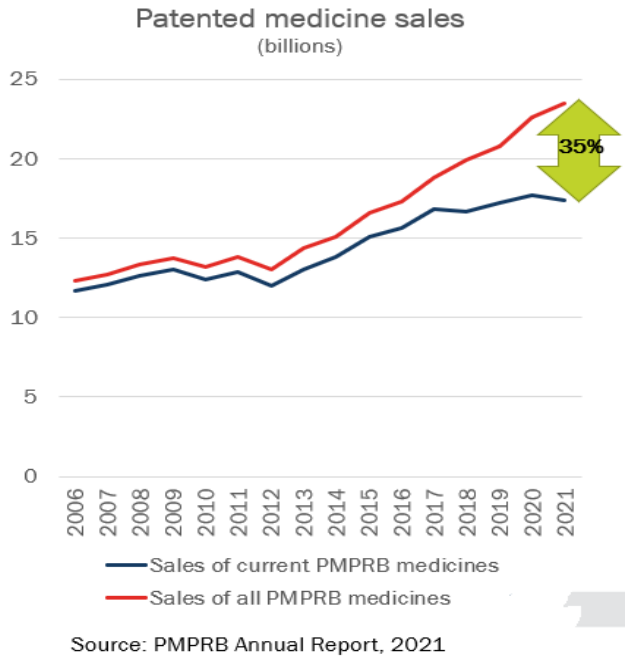
3. Share of patented medicines sales over health spending in Canada = patented medicines sales per GDP / health spending per GDP = 0.795% / 12.9% = 6.2%

e. New Drug Landscape

- Pipeline:
  - Oncology continued to dominate the therapeutic mix in 2021, with cancer treatments representing one third (35%) of medicines in all phases of clinical trials; and
  - One third (33%) of medicines in Phase III clinical trials or pre-registration had an early orphan designation approved through the US FDA or the EMA.
- New drug approvals:
  - Orphan and oncology medicines are making up a significant portion of new approvals;
  - Over 60% of new medicines with sales had high treatment costs;
  - Fewer new medicines were approved by Health Canada than by the FDA and EMA – consistent with the patterns reported since 2009; and
  - Canada performed better than the OECD median and most PMPRB11 countries in terms of the number of new medicines with sales.

f. Considerations

- Canada will remain a high-price and high-spending country for patented medicines for the foreseeable future;
  - Prices of existing medicines will remain at the higher-end of the PMPRB11 over the next decade.
- The changing pharmaceutical landscape towards biologics and specialty medicines means that competition from generic/biosimilar medicines will not result in the disinvestment that has allowed the market penetration of new medicines in the past; and
- Off-patent medicines are a growing market segment, highlighting the importance of ensuring non-excessive pricing during the life of the patent.
  - While the sales for off-patent medicines were 5% above the patented sales in 2006, by 2021, they were 35% above.



Source: PMPRB Annual Report, 2021

g. Innovation and an international context

- Domestically, the introduction of innovation drug products in Canada has remained 'stable and consistent'. The Pandemic-impact appears negligible. The year 2021 witnessed the highest number of New Active Substances (NAS) approvals in over a decade.
    - Over 75% of all Health Canada approved NOC for NAS' (between 2011 to 2021) have market presence in Canada.
- Internationally, Canada is a priority launch market, with stable monetary governance and a predictable market-access landscape.
- Canada firmly stands within the top-5 nations worldwide in terms of launch destinations – ahead of traditional 'superpowers' such as Japan and France.
    - Based on the PMPRB's Meds Entry Watch, Canada is lagging only behind the United States and Germany in terms of market launch - 55% of New Active Substances (NAS) were introduced in Canada over 2015-2020.
    - Canadian's access to new innovative health technologies is approximately seven folds higher than New Zealanders.
    - Canadians have good equitable access across newly emerging technologies in health. On average, 60% of NAS' are being launched in Canada across all ATC classifications.
    - Of concern is the rare disease market. On an international-scale, one-in-three NAS' inaccessible to Canadians are rare disease or indication related.
- From a geo-political perspective, Canada has remained a tier-one market over the past (almost) 40 years. In 1985, Canada represented 2% of global sales. With the dramatic rise of the BRICS nations (including China) and multi-lateral

agreements (African Union, MENA, Asia-Pan Pacific), Canada has demonstrated an extra-ordinary resilience in maintaining it's global positioning to this day. Largely due to its attraction as a high-price market.

2. PMPRB Key Deliverables for 2023-24

Patented Medicine Price Review Program

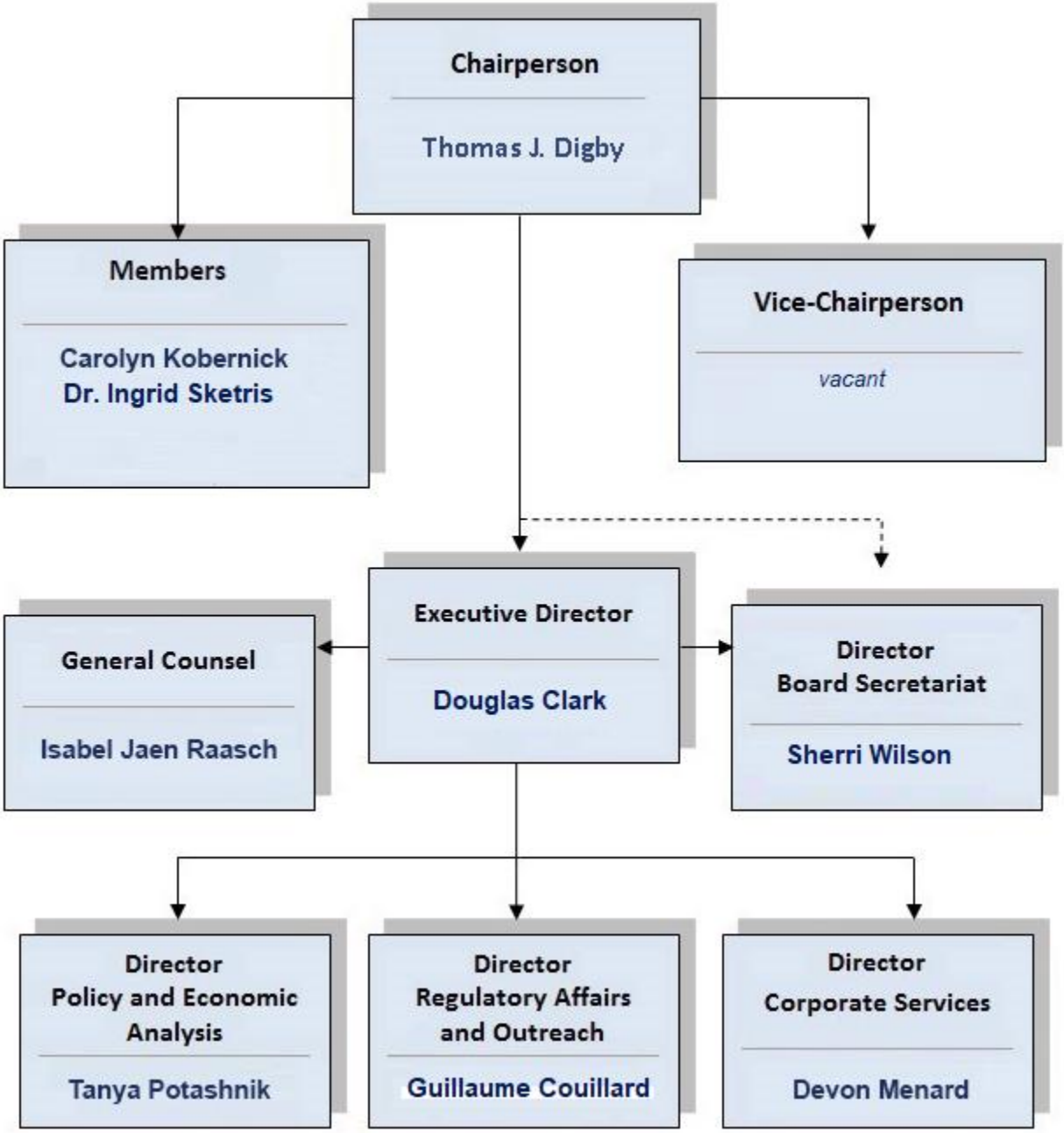
- Price reviews
- Investigations
- Board Hearings
- Judicial Reviews
- Outreach

Pharmaceutical Trends Program

- Annual Report (AR)
- NPDUIS and ad- hoc reporting
- Stakeholder engagement and public education

3. Organizational Structure: Patented Medicine Prices Review Board

a. Senior Leader Structure



b. Board Structure – Branches: Roles and Responsibilities

GENERAL COUNSEL

Advises the PMPRB on legal matters, leads the legal team representing Staff in proceedings before the Board, and liaises with counsel for the Attorney General in PMPRB-related proceedings before federal and provincial courts.

EXECUTIVE DIRECTOR

Responsible for advising the Board and for the leadership and management of Staff.

Board Secretariat, Communications and Strategic Planning

Manages the Board's meeting and hearing processes, including the official record of proceeding.

Policy and Economic Analysis

- Develops policy and strategic advice;
- Leads stakeholder consultations;
- Makes recommendations on possible amendments to the PMPRB's Guidelines;
- Conducts research and analysis on medicine prices, pharmaceutical market and R&D trends; and
- Publishes studies aimed at providing F/P/Ts and other stakeholders with centralized, objective, and credible information in support of evidence-based policy.

Regulatory Affairs and Outreach

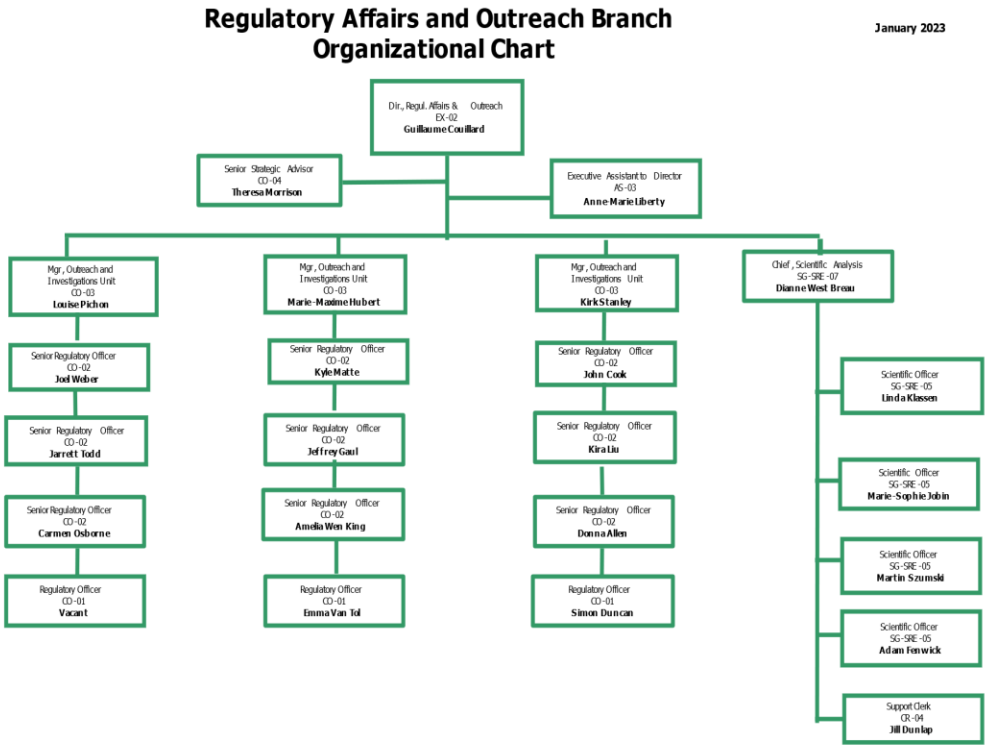
- Reviews the prices of patented medicines sold in Canada;
- Ensures that patentees are fulfilling their filing obligations;
- Encourages patentees to comply voluntarily with the PMPRB's Guidelines;
- Implements related compliance policies; and
- Investigates complaints into the prices of patented medicines.

Corporate Services

- Provides advice and services in relation to human resources management, facilities, procurement, health, safety and security, information technology, and information management;
- It coordinates activities pursuant to the Access to Information Act and the Privacy Act, and is responsible for strategic planning and reporting;and
- Responsible for financial planning and reporting, accounting operations, audit and evaluation, and liaising with federal central agencies on these topics.

4. Organizational Branch Overview

a. Regulatory Affairs and Outreach Branch Organizational Chart 2023



RA&O Branch – Overview

- Reviews rights holders' filings to ensure that they meet the requirements under the Regulations;

- Reviews pricing information submitted by rights holders to identify cases of potential excessive pricing;
- Encourages rights holders to comply voluntarily with Board's Guidelines;
- Implements related compliance policies; and
- Investigates complaints into the practices of patented medicines.

Review Process for Patented Medicines (as per the 2010 Guidelines)

Filing Requirements Pertaining to Price Reviews

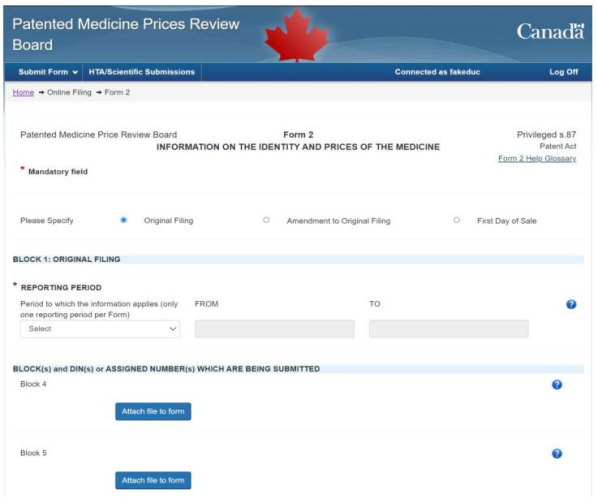
The Online Filing Tool (OFT) is an online portal which facilitates rights holders' filing obligations based on the PMPRB's guiding legislation.

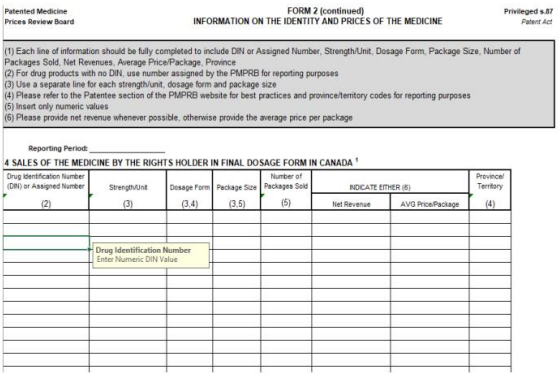
Form 1: Rights Holder and Medicine Information

Information	Timing	Patent Act	Regulations	Form
Identity of medicine, patentee and patent(s)	Earliest of: **Seven (7) days** after the date the first Notice of Compliance issued **Seven (7) days** after the date the medicine is first offered for sale in Canada	80(1)(a) 80(2)(a)	3(1) 3(2) 3(3)	1
Updating information on identity of medicine/patentee	**Within thirty (30) days** after any modification of information		3(4)	1

Form 2: Price and Sales Data

Information	Timing	Patent Act	Regulations	Form
Price and sales data for the medicine sold to province/territory in Canada Publicly available ex-factory price sold in Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden and United Kingdom	When a drug is first offered for sale in Canada, **no later than thirty (30) days** after the first day of sales On or before **July 30** (January 1 to June 30 reporting period) On or before **January 30** (July 1 to December 31 reporting period)	80(1)(b) 80(2)(b)	4(1) 4(2)	2





Form 3: Revenue and R&D Expenditures

Information	Timing	Patent Act	Regulations	Form
Revenues from sales and expenditures on R&D	**On or before March 1** of each year	88(1) 88(2)	5, 6	3

Filing Requirements Pertaining to Price Reviews - Points of Intervention by Chairperson

The Chairperson may be involved when there is evidence that a rights holder:

- Failed to file required information within the specified period or filed erroneous or false information.

The Chairperson may decide to:

- Refer the matter to a panel for a hearing related to an order requiring the rights holder or former rights holder to file the information within such time as is specified in the Order.
- Refer the matter to Public Prosecution Service of Canada to determine if summary conviction proceedings under the Patent Act should be commenced.

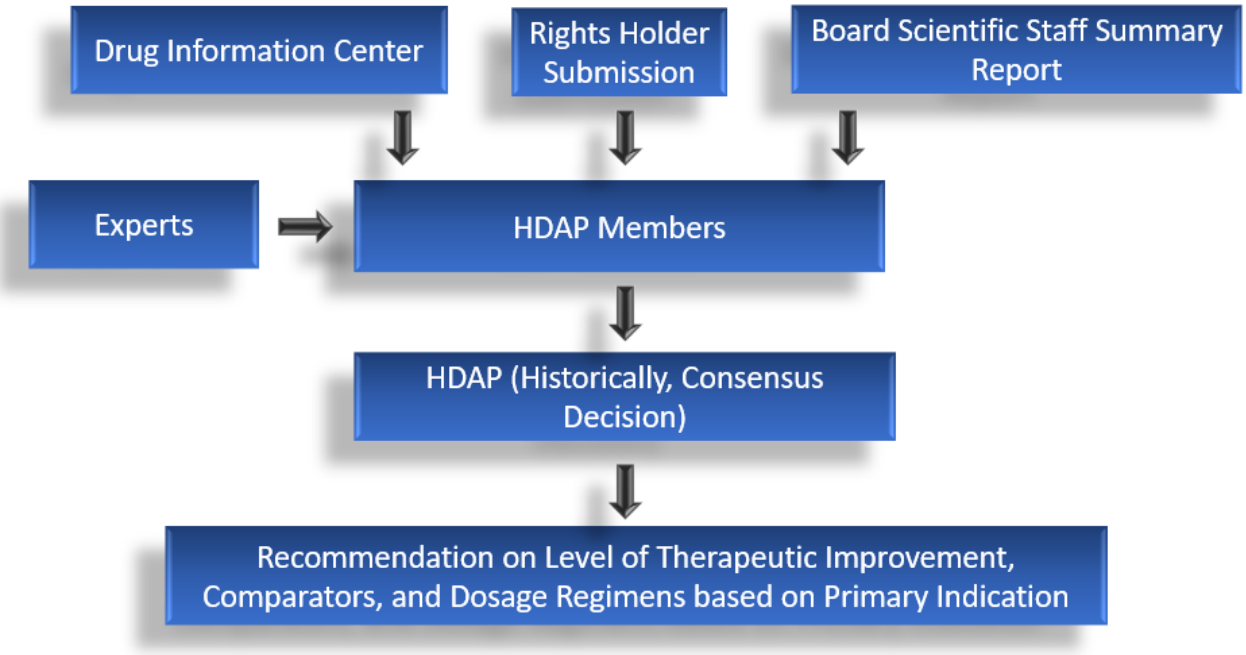
Compliance Information Management System: CIMS

- CIMS is an internal PMRPB database that houses rights holders' submissions including information on the identity of the medicine, price and sales data and Research and Development expenditures.
- It allows RAO staff to conduct the price tests and reports necessary to perform price reviews. It is integral to the operations of RAO.
- In recent years, efforts have been made to modernize CIMS to implement new regulations and guidelines.

Scientific Review Human Drug Advisory Panel (HDAP) (as per the 2010 Guidelines)

- The Chief of Scientific Analysis (manager) will make an assessment whether the new drug product will be referred to the Human Drug Advisory Panel (outside contractors) or be assessed internally by the Scientific Officers.
- All scientific assessments will:
    - Determine the primary indication/use of the drug product where required;
    - Recommend the Level of Therapeutic Improvement of the drug product
        - Breakthrough, Substantial, Moderate, Slight or No
    - Identify comparators
    - Identify comparable dosage regimens

Scientific Review: The Human Drug Advisory Panel (HDAP)



Scientific Review – Points of Intervention by Chairperson

The scientific review is a strict application of procedures set out in the Guidelines, and as such, does not require RAO staff to seek direction from Chairperson. The scientific review is not an adjudication and merely results in a recommendation to Staff.

Price Review – Introduction (as per the 2010 Guidelines)

The Level of Therapeutic Improvement recommended during the scientific review determines the price test used by Staff in the introductory price review.

Level of Therapeutic Improvement	Price Test Used
Breakthrough	Median International Price Comparison (MIPC) Test
Substantial Improvement	Higher of the top of the Therapeutic Class Comparison (TCC) test and the MIPC test
Moderate Improvement	Higher of the Midpoint between top of the TCC test and the MIPC test, and the top of the TCC test
Slight or No Improvement	Top of TCC test or Reasonable Relationship (RR) test where the new patented drug product is a line extension
All Levels of Therapeutic Improvement	Highest International Price Comparison (HIPC) Test

New patented medicines introduced 2017-2021 by level of Therapeutic Improvement

Slight/No Improvement	Moderate Improvement	Substantial Improvement	Breakthrough
89%	8.5%	0.8%	1.7%

Source: PMPRB Annual Report 2021

Price Review – Annual

Patented Medicines for Human Use Sold in 2021 – Status of Price Review as of March 31, 2022

	New Medicines Introduced in 2021	Existing Medicines	Total
Total	59	1,118	1,177
Within Guidelines Thresholds	12	771	783
Under Review	36	7	43
Does Not Trigger Investigation	3	162	165
Under Investigation	7	162	169

Subject to Voluntary Compliance Undertaking	1	11	12*
Price Hearing	0	4	4
Subject to Price Reduction Order (Stayed)	0	1	1

* The terms and conditions of previous years VCUs that have carried over into 2021 are not captured in this count. Source: PMPRB Annual Report 2021

Price Review – Points of Intervention by Chairperson

The introductory and annual price review procedures are strict application of the tests and processes set out in the Guidelines, and as such, do not require RAO staff to seek direction from Chairperson.

Commencing Investigations

Under the 2010 Guidelines, the criteria for commencing an investigation were:

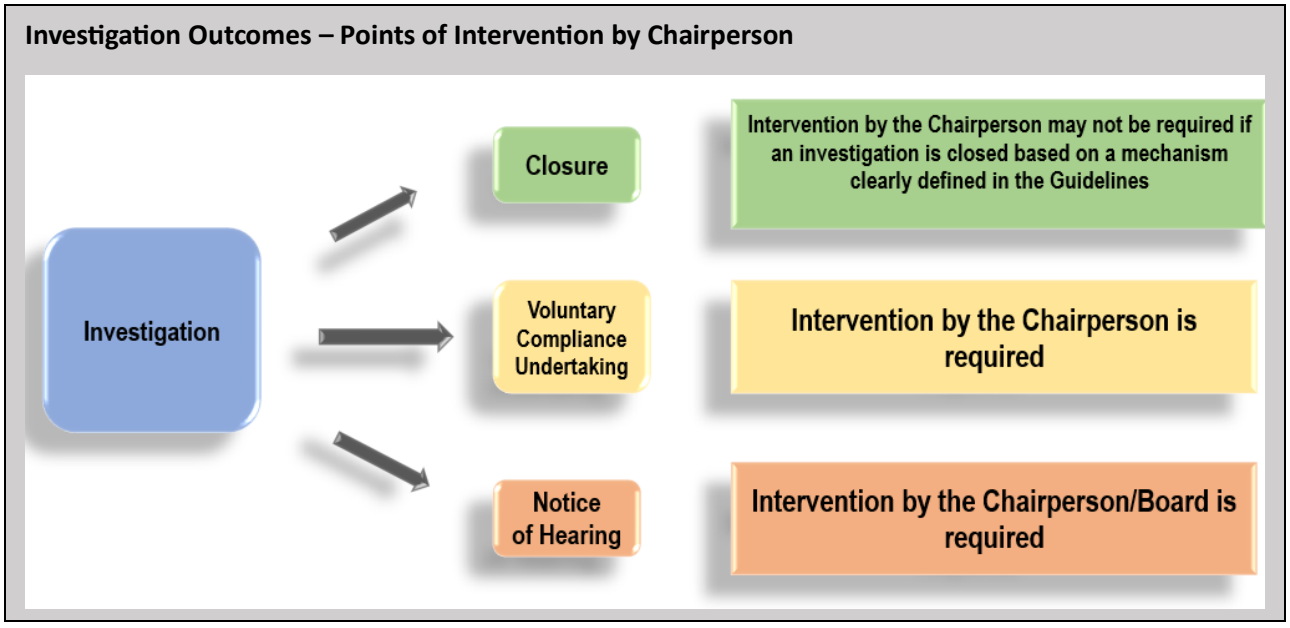
- The National Average Transaction Price and/or Market Specific-Average Transaction Prices exceed the Maximum Average Potential Price by more than 5% at introduction.
- Excess revenues for a new or existing product are $50,000 or more.
- The PMPRB receives a complaint.

Conducting Investigations

- Investigations are led by the CO-02 assigned to the rights holder and supported by a CO-01, in collaboration with scientific and legal colleagues, and guidance from the CO-03, CO-04 and Director, RAO as necessary.
- During an investigation, the CO-02 directs an in-depth review of the pricing history of the medicine from introduction. All information filed by the rights holder is analyzed and clarification may be sought.

- The team will also perform their own research and develop a case theory. They attempt to verify independently the information provided by the rights holder in support of closing an investigation.

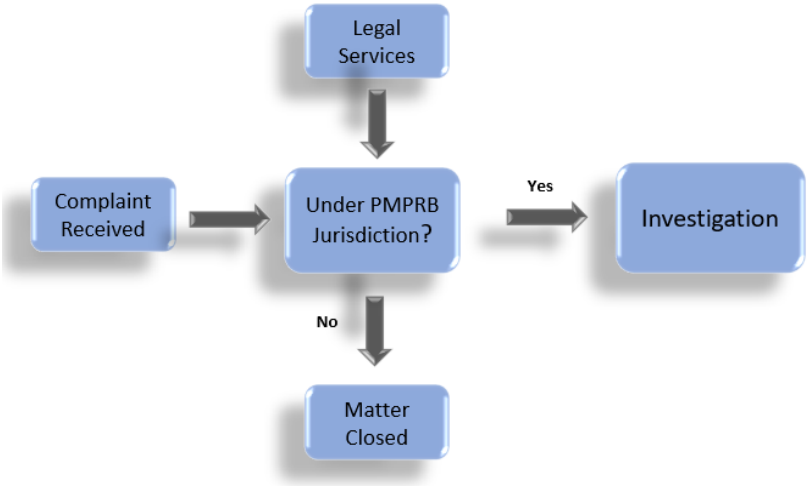
* Eight VCUs, covering 12 DINs, were accepted as of December 31, 2022, accounting



for $958,675.06 in potential excess revenues.

Complaints

The individual or group who submit a complaint will be informed of the outcome but will not be otherwise involved due to confidentiality issues.



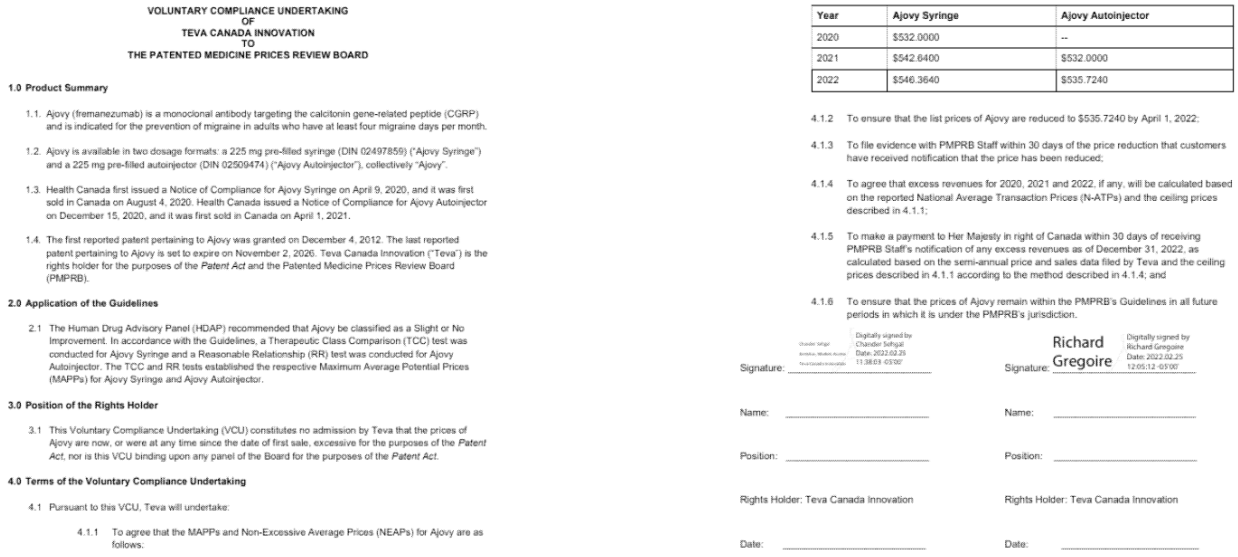
Interim Guidelines

- During the Interim Period, an investigation will not be triggered if the National Average Transaction Price of a medicine remains at or below the existing ceiling, and its list price does not increase.
- RAO is evaluating 2022 data to prepare status reports which detail the findings of the annual price review for each medicine and open new investigations.
- Target date for completion is March 17, 2023.
- All introductory price reviews of new medicines (103 DINs) have been on hold as of July 1, 2022.
- RAO continues to contribute to guideline modernisation efforts by participating in interbranch working groups.

Outreach

- RAO creates and hosts webinars to share targeted information with stakeholders.
- Recent topics include:
  - The launch of the online filing tool
  - 2021 guideline implementation.
- Upon request, RAO staff hold individual training sessions tailored to the specific interests of the rights holder.
- RAO staff also contribute content to the PMRPB website related to operations.

Voluntary Compliance Undertakings (VCU)



VOLUNTARY COMPLIANCE UNDERTAKING
OF
TEVA CANADA INNOVATION
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Ajovy (fremanezumab) is a monoclonal antibody targeting the calcitonin gene-related peptide (CGRP) and is indicated for the prevention of migraine in adults who have at least four migraine days per month.

1.2. Ajovy is available in two dosage formats: a 225 mg pre-filled syringe (DIN 02497859) ("Ajovy Syringe") and a 225 mg pre-filled autoinjector (DIN 02509474) ("Ajovy Autoinjector"), collectively "Ajovy".

1.3. Health Canada first issued a Notice of Compliance for Ajovy Syringe on April 9, 2020, and it was first sold in Canada on August 4, 2020. Health Canada issued a Notice of Compliance for Ajovy Autoinjector on December 15, 2020, and it was first sold in Canada on April 1, 2021.

1.4. The first reported patent pertaining to Ajovy was granted on December 4, 2012. The last reported patent pertaining to Ajovy is set to expire on November 2, 2026. Teva Canada Innovation ("Teva") is the rights holder for the purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Guidelines

2.1 The Human Drug Advisory Panel (HDAP) recommended that Ajovy be classified as a Slight or No Improvement. In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test was conducted for Ajovy Syringe and a Reasonable Relationship (RR) test was conducted for Ajovy Autoinjector. The TCC and RR tests established the respective Maximum Average Potential Prices (MAPPs) for Ajovy Syringe and Ajovy Autoinjector.

3.0 Position of the Rights Holder

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Teva that the prices of Ajovy are now, or were at any time since the date of first sale, excessive for the purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 Pursuant to this VCU, Teva will undertake:

4.1.1 To agree that the MAPPs and Non-Excessive Average Prices (NEAPs) for Ajovy are as follows:

Year	Ajovy Syringe	Ajovy Autoinjector
2020	$532.0000	--
2021	$542.6400	$532.0000
2022	$546.3640	$535.7240

4.1.2 To ensure that the list prices of Ajovy are reduced to $535.7240 by April 1, 2022;

4.1.3 To file evidence with PMPRB Staff within 30 days of the price reduction that customers have received notification that the price has been reduced;

4.1.4 To agree that excess revenues for 2020, 2021 and 2022, if any, will be calculated based on the reported National Average Transaction Prices (N-ATPs) and the ceiling prices described in 4.1.1;

4.1.5 To make a payment to Her Majesty in right of Canada within 30 days of receiving PMPRB Staff's notification of any excess revenues as of December 31, 2022, as calculated based on the semi-annual price and sales data filed by Teva and the ceiling prices described in 4.1.1 according to the method described in 4.1.4; and

4.1.6 To ensure that the prices of Ajovy remain within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Signature: Digitally signed by Chander Sehgal Date: 2022.02.25 11:38:03 -05'00'

Name:

Position:

Rights Holder: Teva Canada Innovation

Date:

Signature: Richard Gregoire Digitally signed by Richard Gregoire Date: 2022.02.25 12:05:12 -05'00'

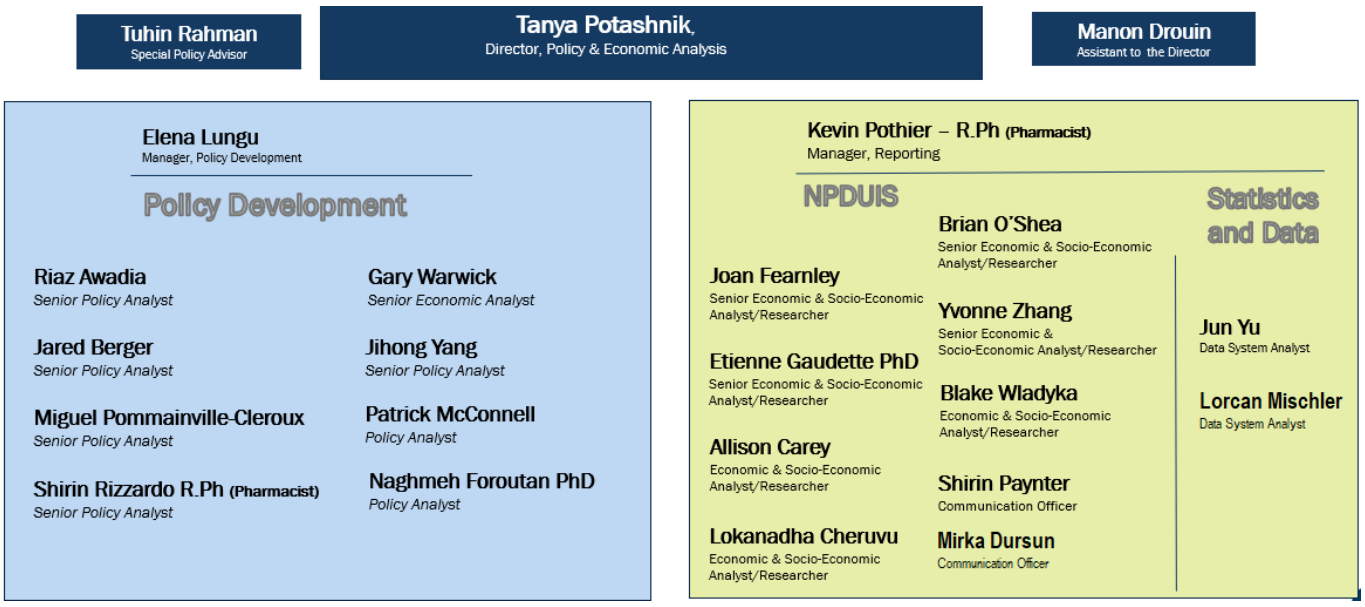
Name:

Position:

Rights Holder: Teva Canada Innovation

Date:

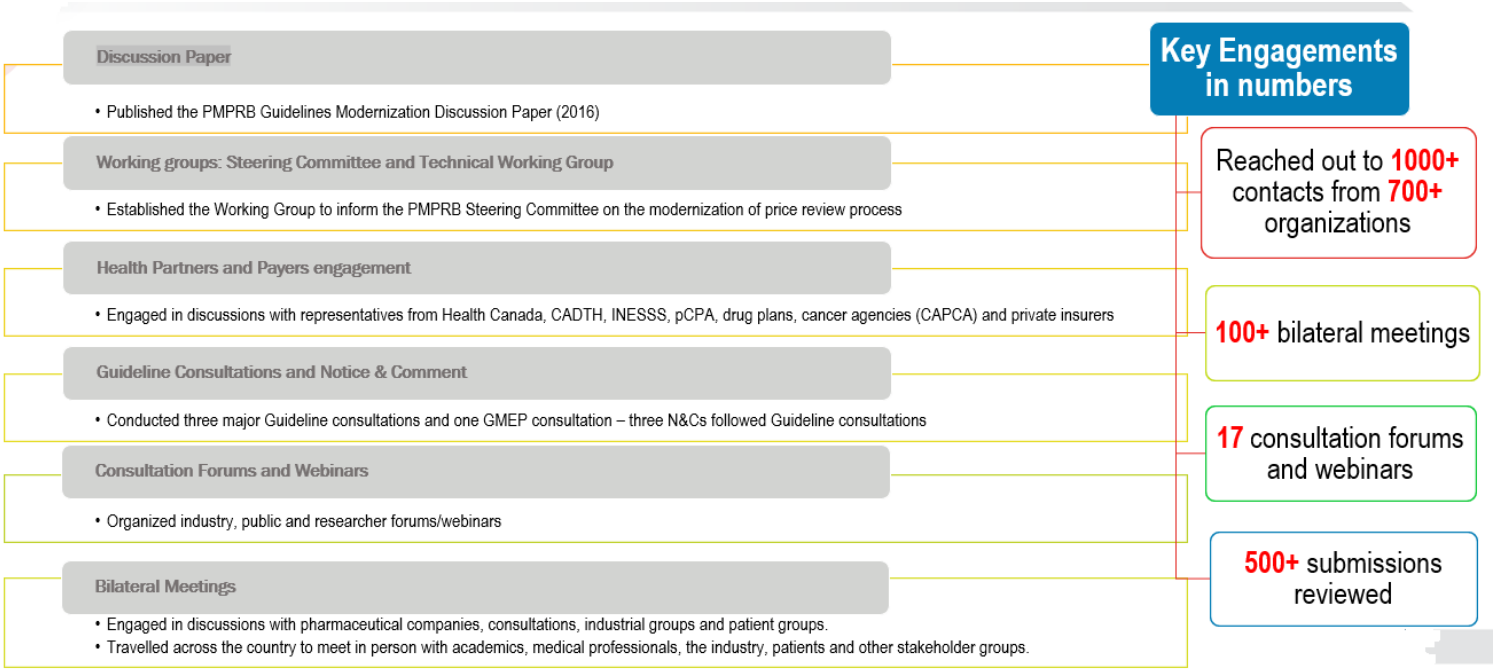
b. Policy and Economic Analysis Branch



Policy Development – The path to PMPRB Reform

The release of the Draft Guidelines is the culmination of a 7-year process, dating back to the release of the PMPRB's Strategic Plan in December 2015, when framework modernization was identified as a key priority.

Consultations held on Guidelines Reform



Amendments to the Patented Medicine Regulations – Key changes in effect since July 1, 2022

1. **An updated schedule of comparator countries (the new "PMPRB11"); and**

PMPRB7 (*retained in new basket)		Foreign-to-Canadian Price Ratio**
United States	✗	3.32
Switzerland	✗	1.01
Italy*	✓	0.97
Germany*	✓	0.96
Sweden*	✓	0.91
United Kingdom*	✓	0.87
France*	✓	0.79

Added countries	Foreign-to-Canadian Price Ratio**
Spain	0.96
Japan	0.90
Belgium	0.88
Norway	0.88
Netherlands	0.77
Australia	0.71

2. **Reduced reporting obligations for patented veterinary, over the-counter and generic medicines.**

Source: MIDAS Database, 2021, IQVIA (all rights reserved)

PMPRB Reform 2022 – A year in Review

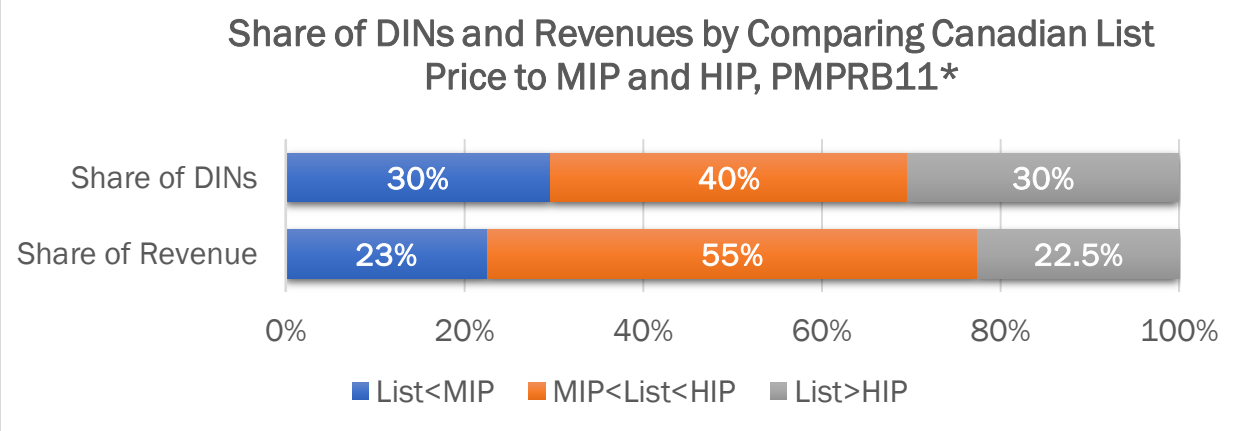
- Regulations Amending the *Patented Medicines Regulations* came into force on July 1
- The PMPRB launched and interim guidelines consultation on June 30:
  - A Notice and Comment was issued proposing the approach for reviewing the prices of patented medicines during the Interim Period between the

coming into force of the amended *Patented Medicines Regulations* and the publication of its new Guidelines, which was slated for end of 2022;
    - A total of 37 submissions were received in response to the Notice and Comment; and
    - Decision was released in August 2022.
- The PMPRB launched the Draft Guideline consultation on October 6:
    - The new draft Guidelines was released along with an accompanying Backgrounder document;
    - A series of webinars for industry and the public were hosted during the 60-day consultation period;
    - A total of 88 submissions were received; and
    - The Interim Guidance issued by the Board on August 2022 remains in place until further notice.

PMPRB11

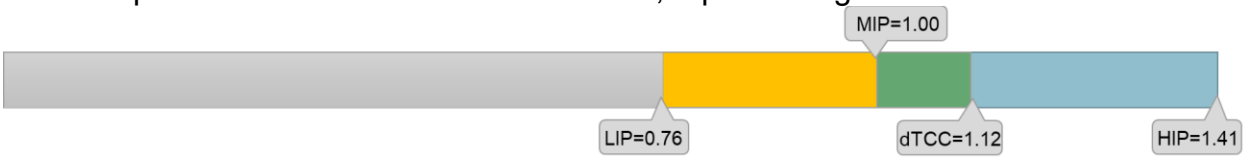
Most drugs are priced above the median of PMPRB11. Fewer drugs are priced above the highest of PMPRB11

- 70% of patented medicines have the Canadian list price higher than the MIP of PMPRB11, representing 77% of sales; and
- 30% of patented medicines have the Canadian list price higher than the HIP of PMPRB11, representing 23% of sales.



Top of dTCC generally higher than the LIP, MIP and HIP of PMPRB11 because of the systemic high pricing of existing medicines:

- Top of the dTCC > LIP for 93% of DINs, representing 93% of sales;
- Top of the dTCC > MIP for 83% of DINs, representing 88% of sales; and
- Top of the dTCC > HIP for 60% of DINs, representing 49% of sales.

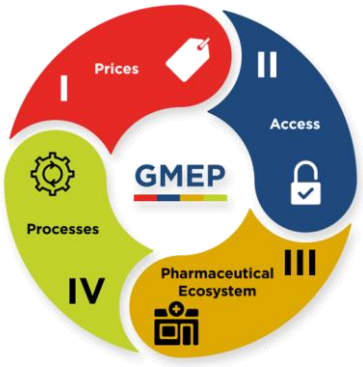


DIN – Drug Identification Number; **dTCC** – Domestic Therapeutic Class Comparison; **HIP** – Highest International Price; **LIP** – Lowest International Price; **MIP** – Median International Price

Source: PMPRB CIMS 2022 SA1; Sample of patented DINs (N=735)

Policy Development - Next Steps

- Advance framework modernization: to be determined based on Board direction; and
    - Implement Guidelines that bring effect to the new schedule of countries.
    - Consult and Implement a Guidelines Monitoring and Evaluation Plan (GMEP) that analyzes trends in the pharmaceutical market before and after the implementation of the new framework to assess whether it is working as intended, and to inform the need for any future adjustments.



Reporting - Annual Report

As required by the *Patent Act*, the PMPRB reports annually to Parliament through the Minister of Health on its price review activities, the prices of patented medicines and price trends of all prescription medicines, and on the R&D expenditures reported by pharmaceutical patentees.

Highlights from the 2021 Annual Report

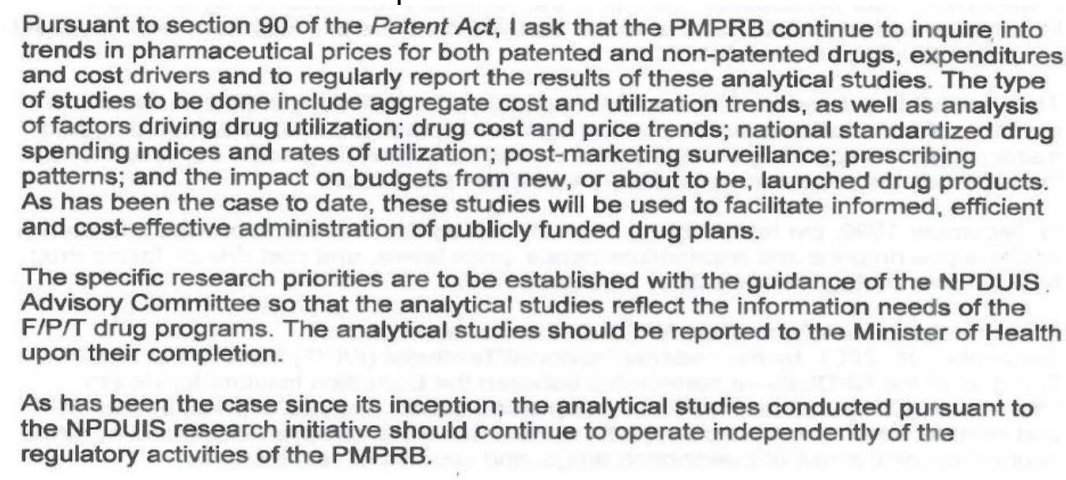
- 1,117 patented medicines for human use were reported to the PMPRB in 2021, including 59 new medicines;
- Sales of patented medicines in Canada were $17.4 billion in 2021, a 1.7% decrease from 2020;
- Canadian list prices were third highest among the 31 Organization for Economic Co-operation and Development countries, below only Switzerland and the US;
- Canada remains an important market for pharmaceuticals, representing 2.1% of worldwide sales;
- Canada spends nearly the same amount as the UK on pharmaceuticals despite having only half its population; and
- The average ratio of R&D expenditures to sales revenues for patentees was 3.4% in 2021, a 71% decrease from a peak of 11.7% in 1995.

The National Prescription Drug Utilization Information System (NPDUIS) Initiative

The National Prescription Drug Utilization Information System (NPDUIS) is a research initiative established by federal, provincial, and territorial Ministers of Health in September 2001. It is a partnership between the PMPRB and the Canadian Institute for Health Information (CIHI). NPDUIS operates independently of the regulatory activities of the Board of the PMPRB.

Consistent with its mandate to provide drug plan managers with relevant information and intelligence on price, utilization, and cost trends in Canada and internationally, NPDUIS publishes a multitude of publications and reports.

NPDUIS Section 90 Letter Updated Oct-2017



Pursuant to section 90 of the *Patent Act*, I ask that the PMPRB continue to inquire into trends in pharmaceutical prices for both patented and non-patented drugs, expenditures and cost drivers and to regularly report the results of these analytical studies. The type of studies to be done include aggregate cost and utilization trends, as well as analysis of factors driving drug utilization; drug cost and price trends; national standardized drug spending indices and rates of utilization; post-marketing surveillance; prescribing patterns; and the impact on budgets from new, or about to be, launched drug products. As has been the case to date, these studies will be used to facilitate informed, efficient and cost-effective administration of publicly funded drug plans.

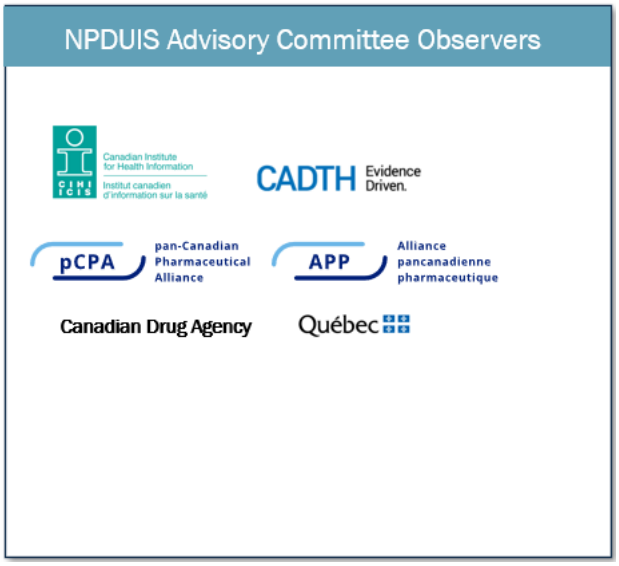
The specific research priorities are to be established with the guidance of the NPDUIS Advisory Committee so that the analytical studies reflect the information needs of the F/P/T drug programs. The analytical studies should be reported to the Minister of Health upon their completion.

As has been the case since its inception, the analytical studies conducted pursuant to the NPDUIS research initiative should continue to operate independently of the regulatory activities of the PMPRB.

The NPDUIS unit within the PMPRB includes a team of economic analysts, data scientists and publishing officers reporting to the Director of Policy and Economic Analysis.

NPDUIS Key Stakeholders

The specific research priorities and methodologies for NPDUIS are established with the guidance of the NPDUIS Advisory Committee. The PMPRB consults its Advisory Committee numerous times per year, including an annual in-person two-day meeting organised in partnership with CIHI, and two annual webinar meetings.



NPDUIS Public Reporting

NPDUIS informs decision makers and the public using a variety of media: annual publications, report series, focused reports, conference presentations, and webinars
Annual publications:

- CompassRx analyzes the cost pressures in Canadian public drug plans;
- Meds Entry Watch monitors the approval and sales of new medicines in Canada and internationally; and
- Meds Pipeline Monitor tracks significant medicines in the late stages of clinical evaluation.

Report Series:

- Market Intelligence Reports provide short, targeted analyses of therapeutic market segments of importance to Canadians. These reports are not published according to predetermined schedule; and
- Limited reports such as Formulary alignment and Private Drug Plans in Canada

Focused reports :

- Ex: The Drug Shortages in Canada and their Impact on Public Drug Plans, 2017/18 to 2019/20 provides insight into the impact of drug shortages in Canada.

Chartbooks :

- Offer a variety of short, graphic-based analyses on a specific topic.

Presentations and Webinars :

- NPDUIS staff routinely present results from their analysis to diverse audiences at Canadian and international conferences, as well as publicly available webinars.

NPDUIS - Ad hoc support

- The NPDUIS team supports stakeholders through ad hoc analysis on pricing and utilization of medicines both in Canada and internationally;
- International Collaboration through participation in the PPRI network;
- Policy Development Backgrounders and Market Intelligence Briefs are a type of economic and clinical analysis that are routinely produced to support price analysis, particularly when medicines are being considered for listing or negotiation; and
- Ad hoc analysis of Canadian sales and utilization are generated to support Health Canada and other stakeholders, e.g. during COVID-19, analysis of historical use of priority medicines to validate internal utilization projections.

NPDUIS- Data Sources

Extensive Insights into the Canadian Pharmaceuticals

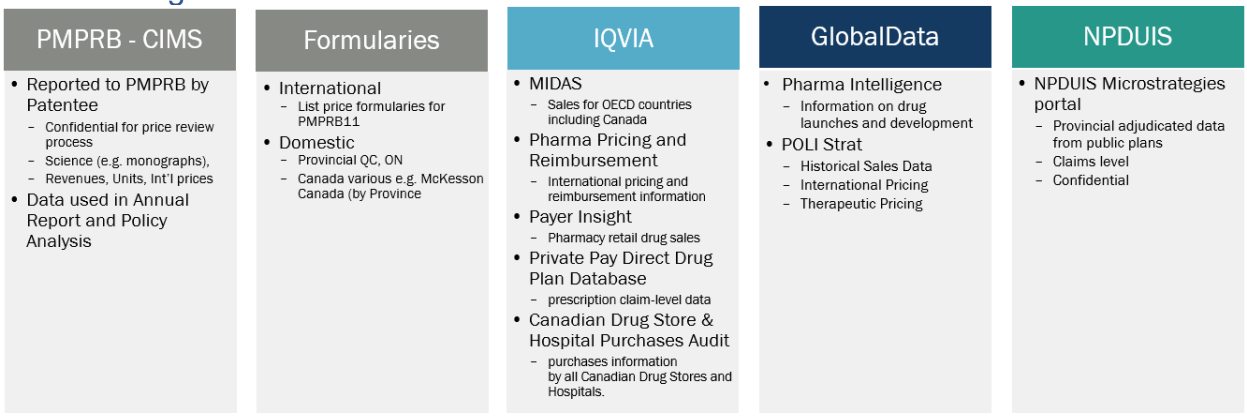
Because the Canadian pharmaceutical industry is complex, the NPDUIS draws from multiple data sources in its work. These sources allow tracking and reporting on access to medicines, pharmaceutical spending by both public and private entities, and comparisons with other countries sharing similar institutions.

Some Essential Resources:

- The NPDUIS Database houses pan-Canadian information on public drug programs. It contains prescription claims-level data collected from publicly financed drug benefit programs as well as formulary data;

- IQVIA Databases: MIDAS®, Private Plan Database, Payer Insights, Canadian Hospital and Drug Store Purchases Audit;
- GlobalData; and
- Health Canada: Notice of Compliance Database, Drug Product Database.

Data Holdings

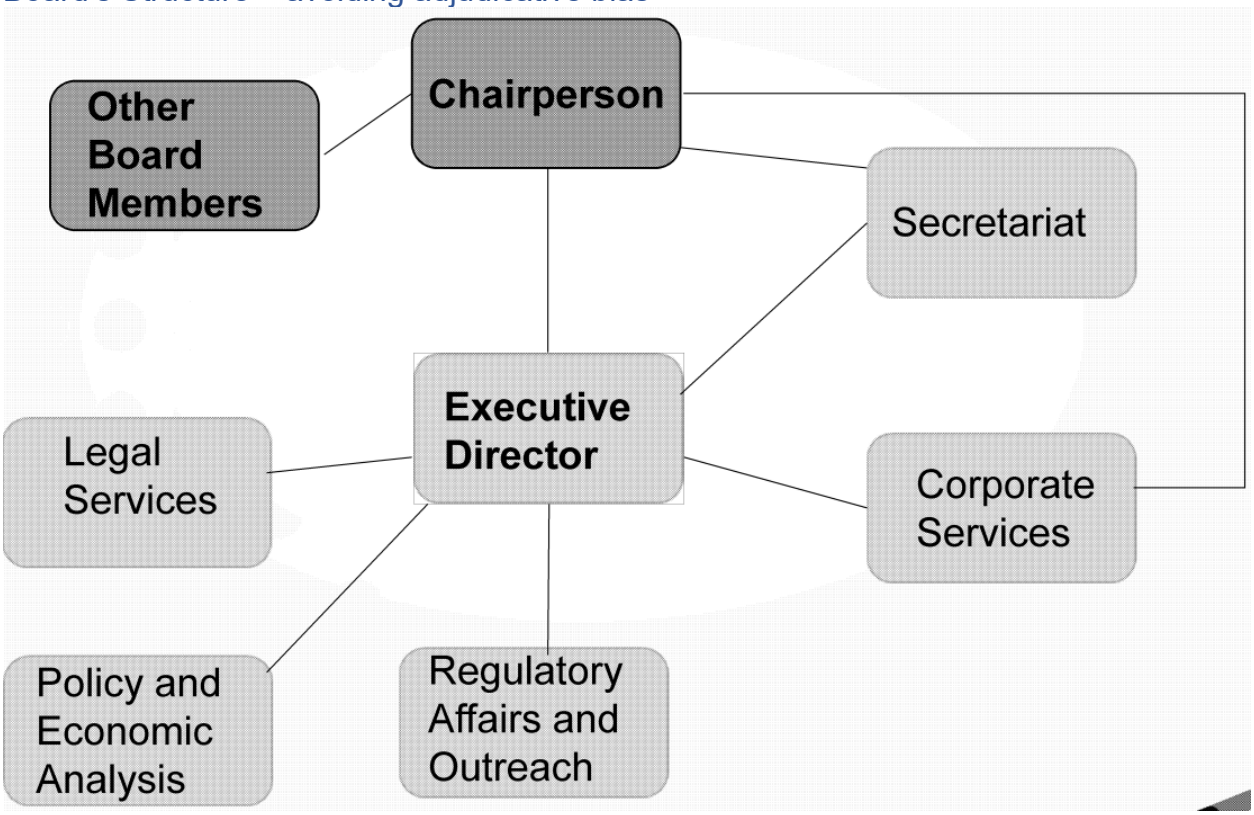


c. Legal Services Branch

Legal Services assists Board Members with legal questions related to their duties except for questions about hearings pending before Board Members.

- The Secretariat serves as the conduit for questions to Legal Services or other Board Staff from Board Members

Board's Structure – avoiding adjudicative bias



Roles and Responsibilities:

- providing legal advice, counsel and support to the PMPRB on all relevant law (*Patent Act* as well as the other laws).
- promoting respect for rights and freedoms, the law and the Constitution.