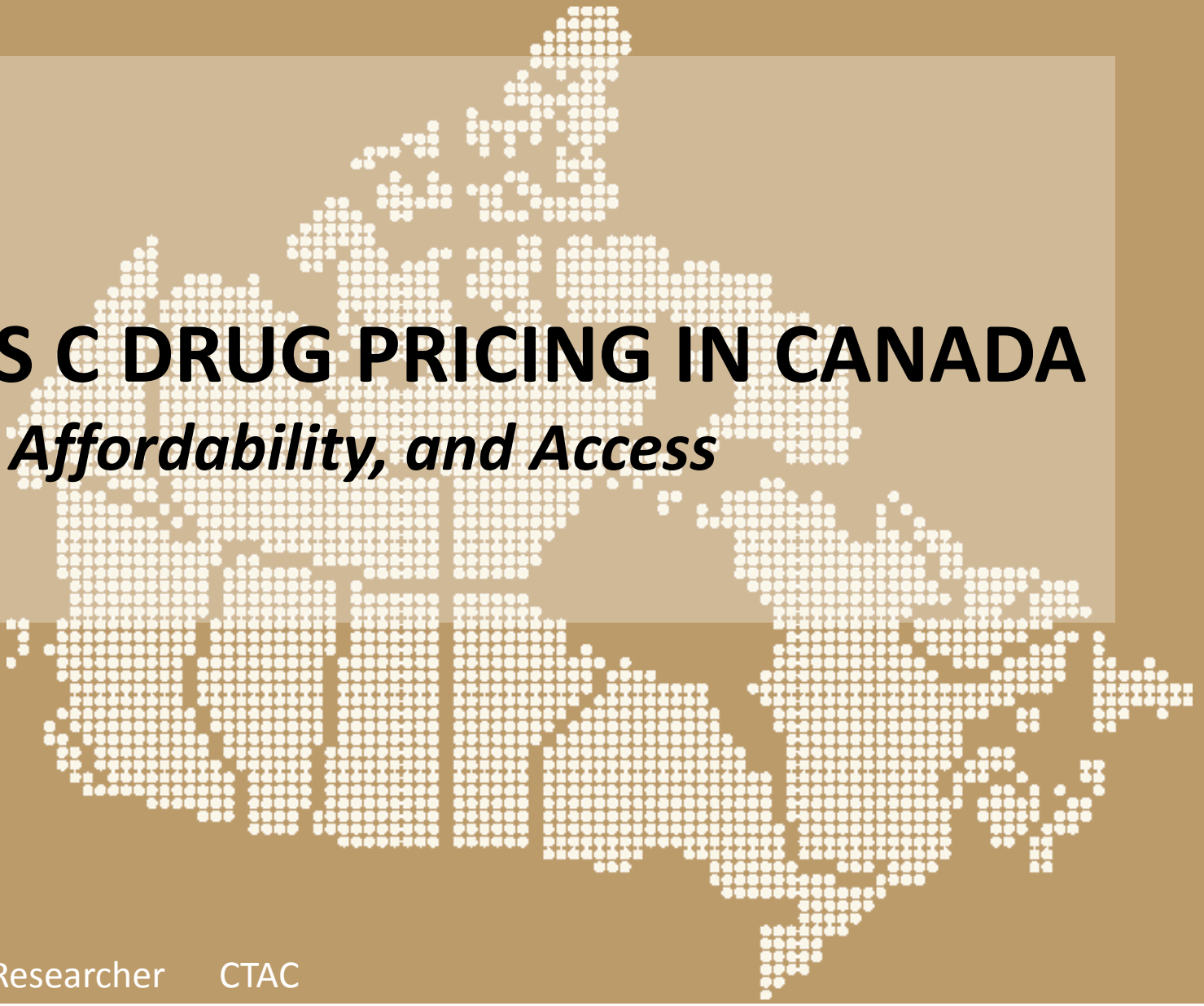


HEPATITIS C DRUG PRICING IN CANADA

Price, Cost, Affordability, and Access

ADAM COOK, Policy Researcher CTAC

Adam Cook, Policy Researcher

Canadian Treatment Action Council

Policy Researcher

CTAC is Canada's National Civil Society Organization addressing access to treatment for people living with HIV and/or hepatitis C

CTAC has provided over 20 PGI reports to CADTH and other agencies

ACTION HEPATITIS CANADA
AHC
ACTION HÉPATITES CANADA

Communications Executive Committee

AHC is a pan-Canadian coalition of over 55 agencies responding to the hepatitis C epidemic in Canada

BestMedicinesCoalition

Board of Directors

The Best Medicines Coalition (BMC) is an alliance of organizations and individuals with a shared vision of equitable and consistent access for all Canadians to safe, effective and good quality drugs improving patient outcomes.

Published Author, Patient Advocate, Community Mobilizer

Objective

Demonstrate how hepatitis C drug pricing highlights inequities, exposes vulnerabilities, and *trips every wire* in our public drug regulatory processes

The hepatitis C virus (HCV) also exposes challenges in maintaining a coherent, collaborative, and communicative *health care system*

Approached from the Public Health and Patient Advocacy Perspective

Objective

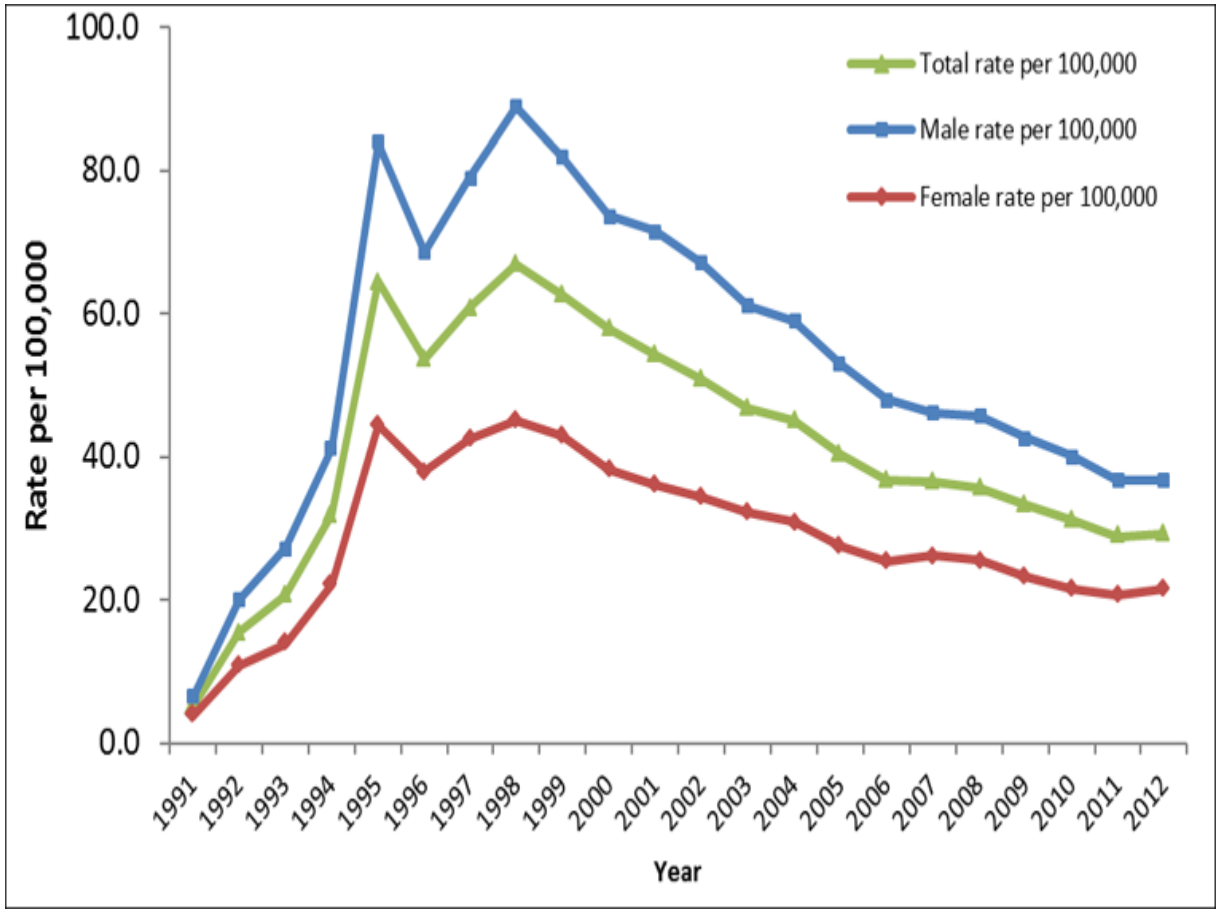
Follow a general trajectory of HCV treatments through the Regulatory Access *Pathway*

1. Health Canada's Therapeutic Products Directorate (TPD)
2. Patented Medicines Pricing Review Board (PMPRB)
3. Canadian Agency for Drugs and Technologies in Health (CADTH)
4. pan-Canadian Pharmaceutical Alliance (pCPA)
5. Federal/Provincial/Territorial Public Drug Plans

International symbol of slowly reforming cynics

The Curious Case of HCV

The Most Burdensome Infectious Disease in Canada



-Attacks the liver

-Becomes chronic and largely asymptomatic; causes liver damage quietly over decades

-leading cause of Liver Cancer
-fibrosis, cirrhosis, ESLD, transplant, Death

-Extrahepatic manifestations: cognitive impairments, anxiety, neuropathy, etc

Bad Data: At Least 250,000 Canadians, approx 110,000 Ontarians

Data from *PHAC*

The ~~Curious~~ Exceptional Case of HCV

HCV disproportionately impacts socially marginalized populations

-*Social Determinants of Health* play a large role

-Low political priority due to increased stigma

-Can be asymptomatic and therefore deprioritized

-HCV not cleared from our National blood supply until 1992

-Majority of those infected are *Baby Boomers* (1945-75)

-WE HAVE NO NATIONAL STRATEGY IN CANADA
Who does? Egypt, Georgia, Mongolia

THERE IS A CURE!

You have to be sick enough to qualify for the CURE

The ~~Curious~~ Frustrating ~~Exceptional~~ Case of HCV

-Cure is expensive: $45,000 - $70,000 per 8-12 week course of treatment

-Almost all international and domestic agencies recommend early treatment

-Canadian jurisdictions control access through *Exceptional Access Programs;* Most require significant liver damage to be eligible

-*Cost-Containment Strategies* vs *Eligibility Criteria*

-We treat 1.4% of our burden, would need to increase that to 6% in order to keep abreast of new infections. Consider the impact to public health budgets

-COST of the treatment is impacting ACCESS

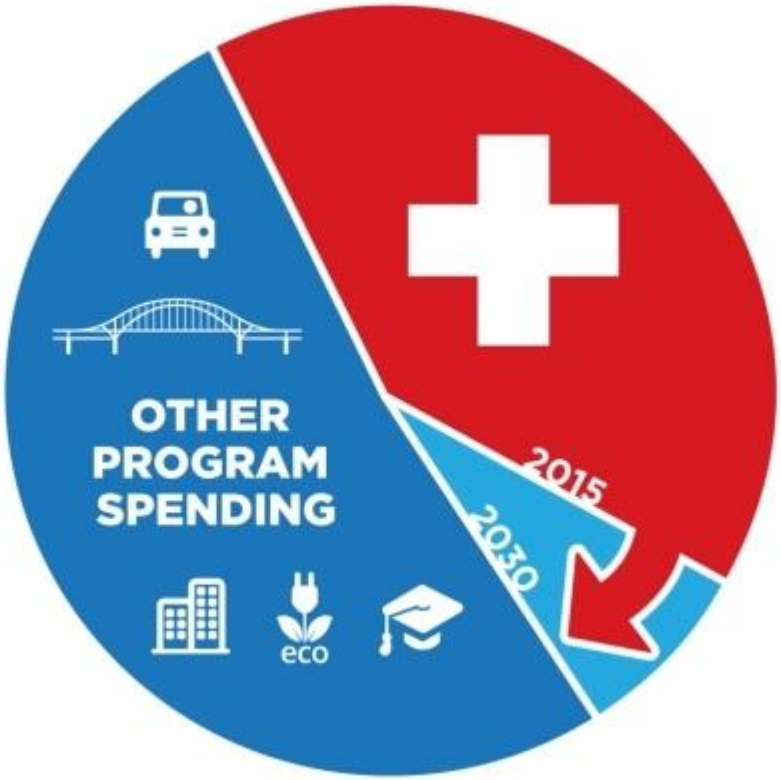


Image from Fraser Inst.

The ~~Curious~~ Case of HCV

~~Frustrating~~ ~~Exceptional~~

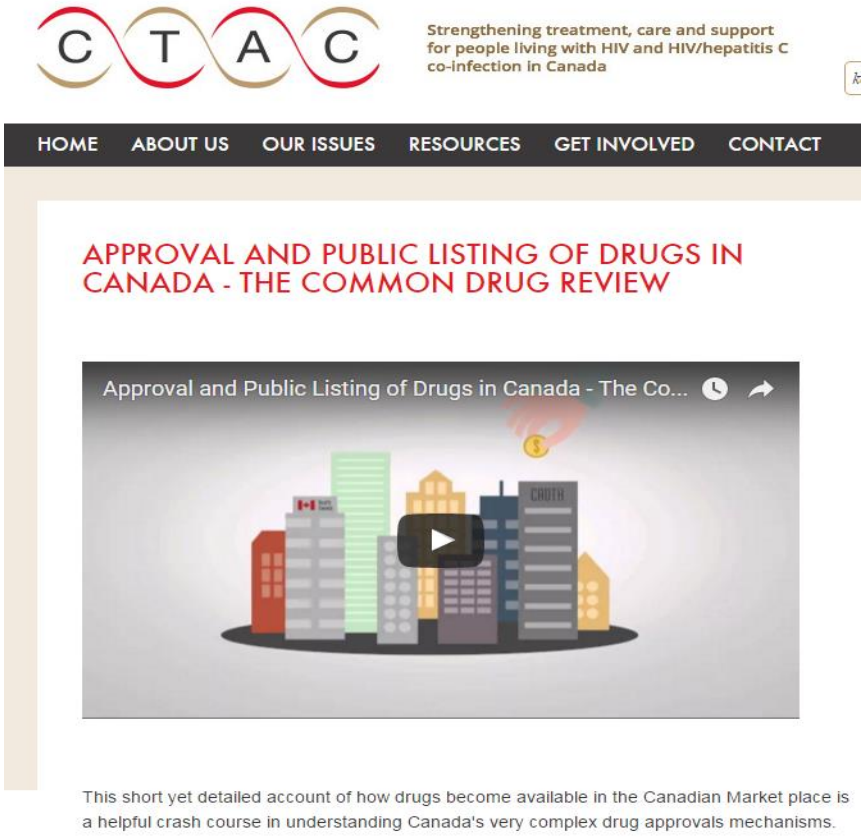
EXPENSIVE

"The total cost of treating all patients with hepatitis C would be equal to at least a tenth of the current annual cost for all medicines in all of the countries studied. In some countries where prices are high and the burden of disease is large, the total cost of treating all infected patients would be more than the cost of all other medicines put together." S. Iyengar et al

Iyengar S, Tay-Teo K, Vogler S, Beyer P, Wiktor S, de Joncheere K, et al. (2016) Prices, Costs, and Affordability of New Medicines for Hepatitis C in 30 Countries: An Economic Analysis. PLoS Med 13(5): e1002032. doi:10.1371/journal.pmed.1002032

The "Pathway" We're Walking

- "Pathway" to public drug plan cost-coverage is long and complex
  - "Pathway" = Process for the approval, marketing, and cost-coverage of prescription drugs
  - Step-by-step, many months, thousands of pages of submissions and evidence, many decision-makers along the way to public drug coverage
  - Process is initiated by manufacturer
  - Also involves federal, provincial and territorial authorities, drug experts, and "patient groups"



http://www.ctac.ca/resources/videos/approval-and-public-listing-of-drugs-in-canada---the-common-drug-review

Regulatory Pathway

MANUFACTURER

Health Canada review & approval (safety, efficacy & quality) = NOC, PM, clinical indication

Patient Input (MEDAVIE Blue Cross)

Private drug insurance coverage

MANUFACTURER

Patient Input

Health Technology Assessment (HTA) #1: CADTH/CDR (comparative clinical and cost-effectiveness) = recommendation on public listing

MANUFACTURER

MANUFACTURER

Price negotiations (pCPA, public drug plans, Gilead) = Price Listing Agreements

Executive Officer, Provincial Public Drug Programs

Provincial Program (eg. Ontario Drug Benefit (ODB)

Formulary GB, Formulary LU, Exceptional Access Program, EAP FA

- ODSP/OW
- Seniors
- Trillium Drug Plan

Regulatory Pathway

MANUFACTURER

Patented Medicine Prices Review Board / Conseil d'examen du prix des médicaments brevetés

Health Canada

Patient Input (MEDAVIE Blue Cross)

Private drug insurance coverage

MANUFACTURER

CADTH Evidence Driven.

Patient Input

MANUFACTURER

THE COUNCIL OF THE FEDERATION

MANUFACTURER

Ontario

Provincial Program (eg. Ontario Drug Benefit (ODB)

Formulary GB, Formulary LU, Exceptional Access Program, EAP FA

- ODSP/OW
- Seniors
- Trillium Drug Plan

CTAC

ENGAGE. CONSULT. FIND SOLUTIONS. ACT COLLECTIVELY.

Health Canada

-Therapeutic Products Directorate and the Notice of Compliance

-Priority Review: Initiated by manufacturer; review target of 180 days instead of 300

-Harvoni applied for priority review; took 35 days to receive approval of priority

Review: clinical efficacy, safety, quality basis for decision

Non-Clinical Basis for Decision: ***does not include price analysis***

Health Canada

Are we missing an opportunity to comment on price, cost, and affordability earlier in our process?

Are we prepared to consider breakthrough treatments demonstrating significant improvements at Phase II?

As HCV treatments enter a *backbone* era, what lessons can be learned from HIV and earlier/provisional approval?

HCV is testing our ability to recognize life-savers earlier and make informative statements about cost and access priorities

Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

PMPRB

-Ensure prices are *not excessive* and protect the Canadian consumer

-Develops thresholds based on 7 OECD comparator countries

-Shown great foresight and anticipation of an evolving health care landscape, and PMPRB's role within it: *Modernization Process*

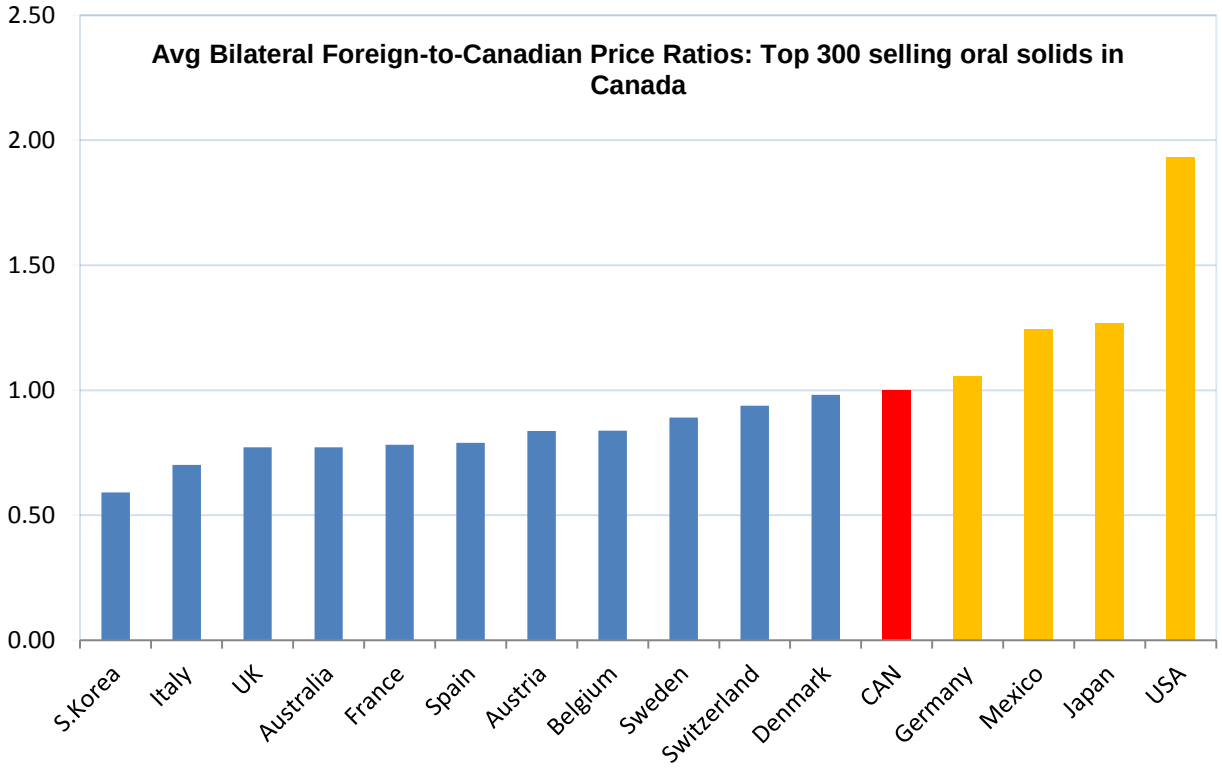
-Greater communication between PMPRB goals and F/P/T plan budgets and values

Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

PMPRB

-Comparator countries are non-representative:

France, Germany, Italy, Sweden, Switzerland, UK, and US



-Mandate not to get *best* price, but *least excessive*

-Evaluations could better reflect Canadian *Realities*

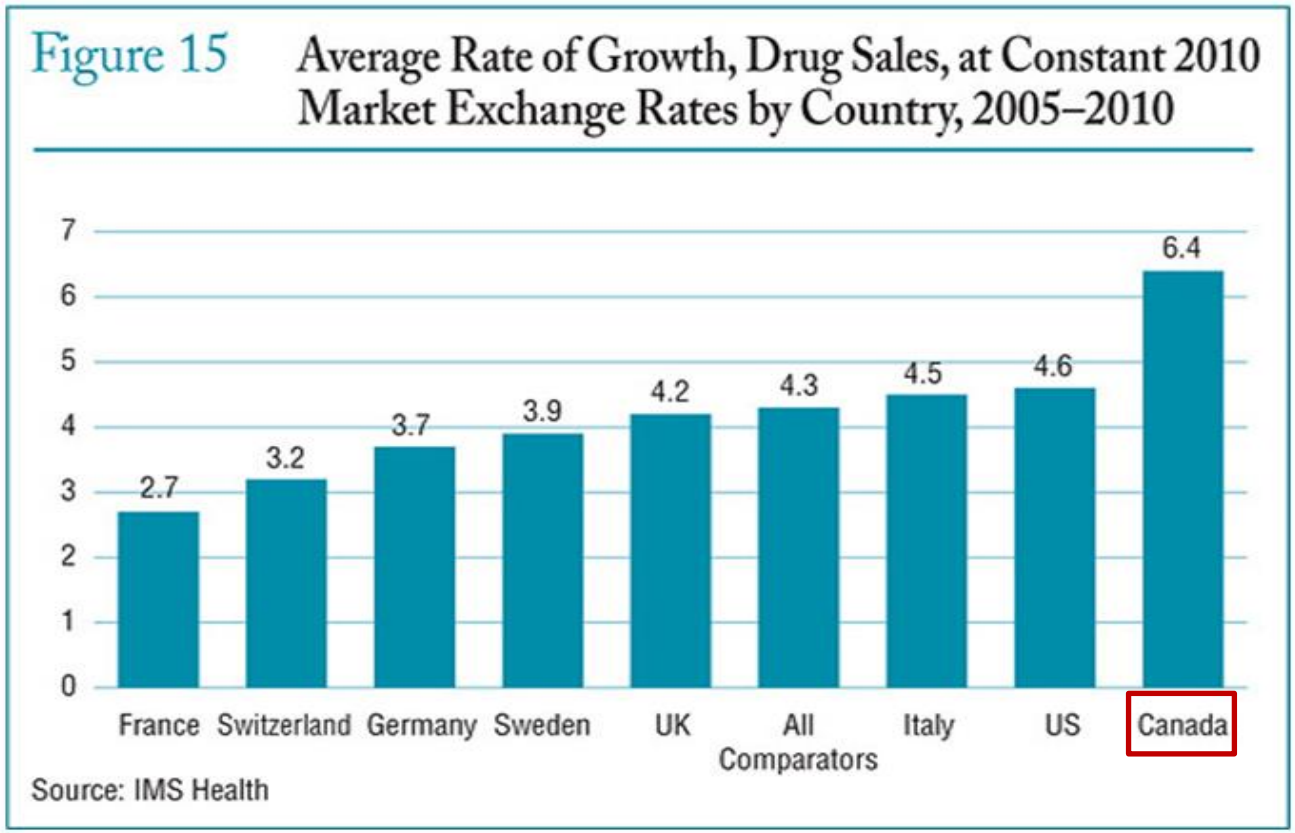
-Are there more *relevant* comparators: demographics; health system structure; R&D, etc.

IMS Health Data, 2010

Data from *PMPRB/IMS Health*

Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

PMPRB



-Canadians spent $28.8 BN on prescription drugs in 2014 (CIHI)

"We are among the highest spenders in the OECD … and that hasn't led to any longer life expectancy or any other improved health outcomes."*

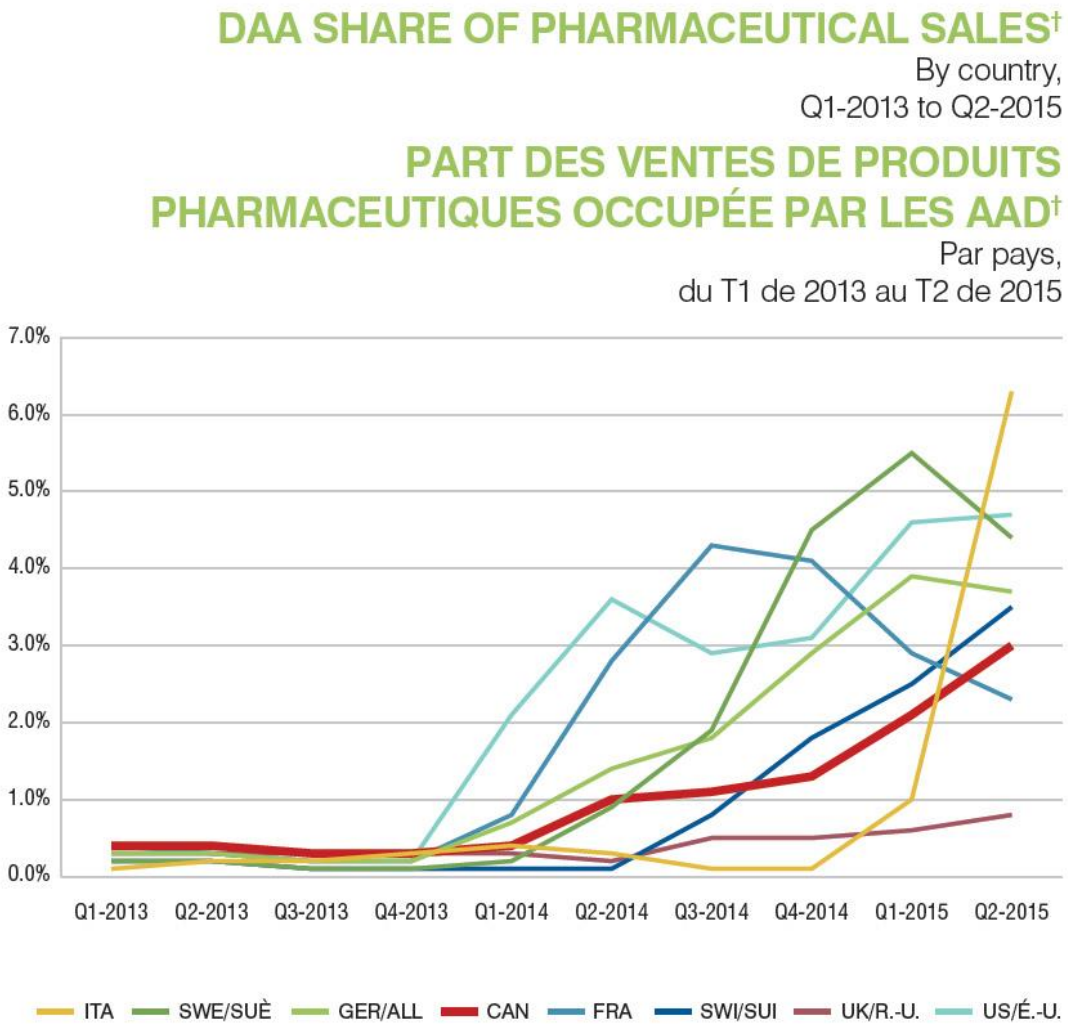
-SOME countries have negotiated the price of patented HCV drugs *down*

*Danielle Martin, vice-president of Medical Affairs and Health System Solutions at Women's College Hospital in Toronto.

Data from *PMPRB/IMS Health*

Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

PMPRB



Canada's spending on HCV cures is on the rise

Only ITALY has a higher rate of increased DAA sales over the past 2 years

3% of Canada's total Pharmaceutical sales are now in HCV drugs (and rising)

More than Six-Fold increase in sales since Q4 2013

All this in the absence of a national plan. So who is setting the access priorities?

Data from *PMPRB*

Patented Medicine Prices Review Board | Conseil d'examen du prix des médicaments brevetés

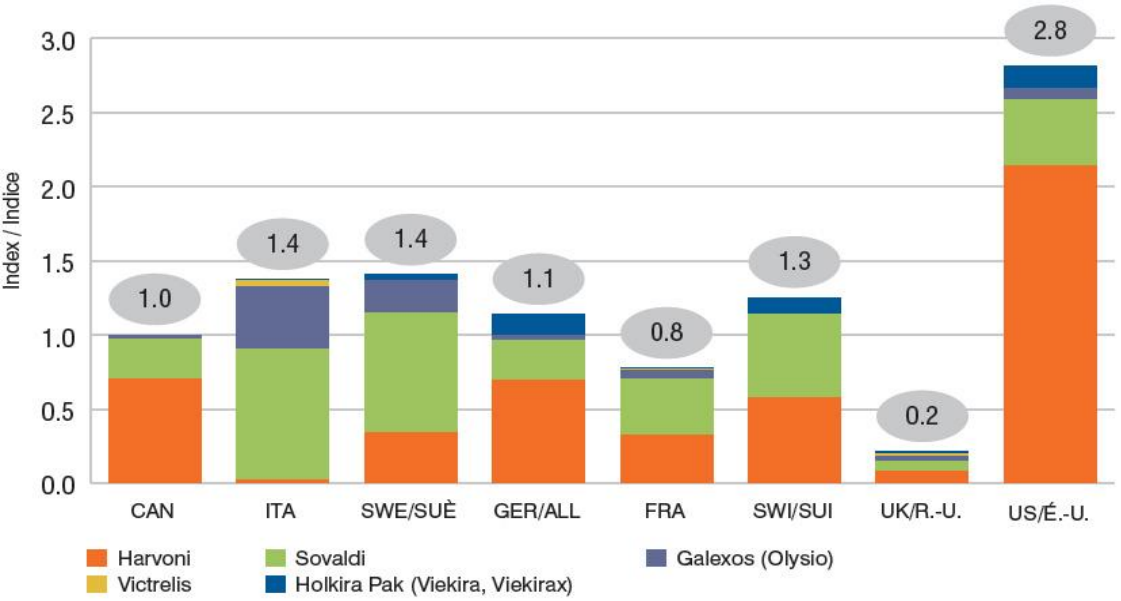
PMPRB

FOREIGN-TO-CANADIAN RATIO OF EXPOSURE† TO DAA DRUGS*

By country and by agent, January to June 2015

RATIO D'EXPOSITION† AUX AAD* DANS LES PAYS DE COMPARAISON PAR RAPPORT AU CANADA

Par pays et par agent, de janvier à juin 2015



*Includes drugs with significant sales. / *Comprend des médicaments à ventes élevées.

Canada uses the more expensive options more often than any other country (except US)

Canadian exposure to DAAs is less than Germany, Switzerland, Italy, and Sweden

How do we pay on the high end of OECD countries but receive less exposure than most of them?

Is price informing policy and restricting access?

HCV is testing our ability to get value for money within our regulatory system, and to make decisions based on extra-national data

Data from *PMPRB*

CADTH Evidence Driven.

CADTH Common Drug Review

- Common Drug Review (CDR) and Health Technology Assessment (HTA)
  - Canadian Drug Expert Committee (CDEC) reviews and recommends drugs for public drug plan cost-coverage
  - **CDEC reviews clinical**, **economic**, and **patient** and health care provider **evidence**
  - **Opportunity for *Patient Input***
  - **Not Binding! Recommendation only!**
  - **TALL ORDER! HCV cures! Rare Disorder Treatments! PrEP for HIV!**

CADTH Common Drug Review

CADTH recently *stopped* making price a condition of approval;
Observations and concerns on price are now reflected in notes and comments;
how do we know those cost concerns are being acknowledged/leveraged by pCPA?

CDR is now the ***Only*** part of the regulatory process that solicits patient input data; Patient-Informed, Real World Evidence, Qualitative Data unfound in product monographs.

-CDR Patient Input Template *asks no questions whatsoever regarding cost, price, or affordability* of the treatment in question or *the cost of living with experience of the condition or treatment*

CADTH Evidence Driven.

CADTH Common Drug Review

INESSS LE SAVOIR PREND FORME

-The Activism of INESSS: HTA for Quebec only. Introduced a *Scale-Back* model for HCV treatment access. *2 steps backward today for 3 steps forward in 3 years.*

Should we give CADTH *teeth*? Should all jurisdictions do as ON's CED has suggested? How to enforce?

HCV is testing our ability to enforce access recommendations, to achieve consistency across jurisdictions, and to make statements on price

THE COUNCIL OF THE FEDERATION

Pan-Canadian Pharmaceutical Alliance

-A negotiating practice between the Manufacturer and The Public Drug Programs (as represented by the pCPA)

-Has been *very effective* at containing costs and is a fundamental part of public drug coverage APPROXIMATELY $490 Million annual savings (2016)

-pCPA is a part of the public health landscape for good; do we need them to be accountable and transparent?

Mandate:

-Increase access to drug treatment options;
-Achieve lower drug costs and consistent pricing; and
-Improve consistency of coverage criteria across Canada

Pan-Canadian Pharmaceutical Alliance

Does a *Mandate Overlap* contribute to tension or increased cooperation?

How can we increase communication, collaboration between agencies in order to streamline the process and improve access?

PEI, Holkira Pak, and the Problem of Collective Negotiation

Mandate:

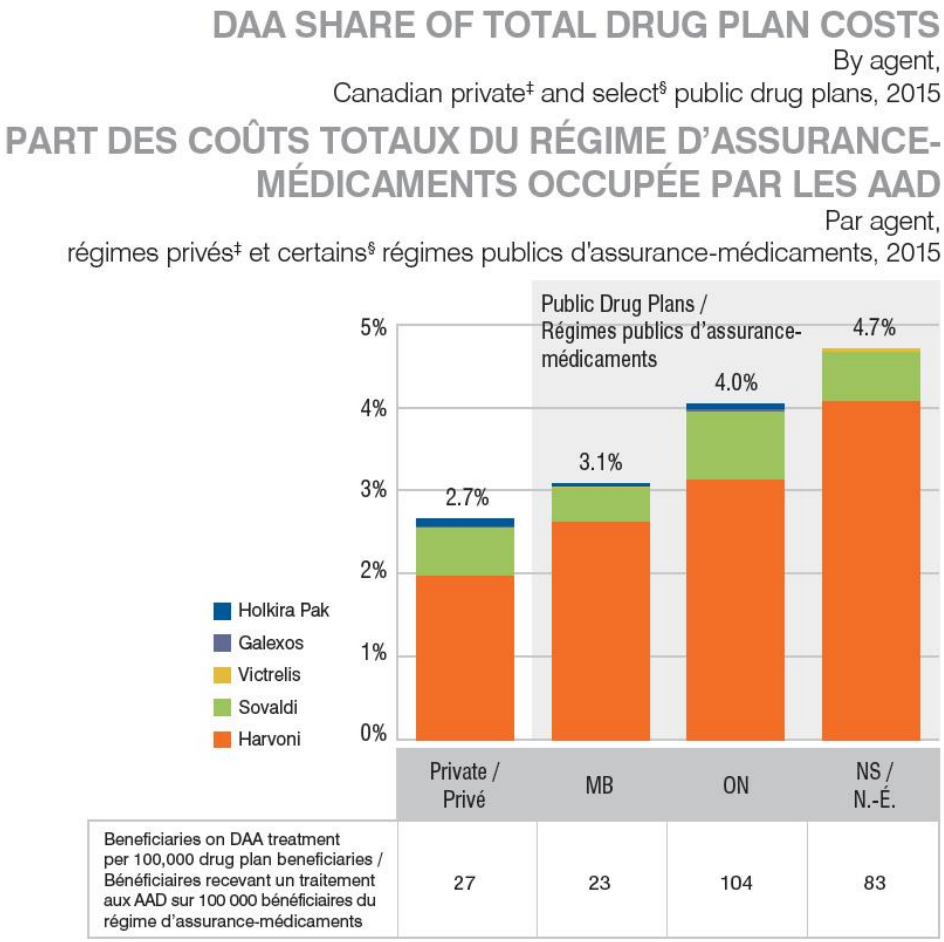
-Increase access to drug treatment options; → **HEALTH CANADA/ Public Programs**

-Achieve lower drug costs and consistent pricing; and → **PMPRB**

-Improve consistency of coverage criteria across Canada → **CADTH/Public Programs**

THE COUNCIL OF THE FEDERATION

Pan-Canadian Pharmaceutical Alliance



Access and *Price Impact* are felt differently across Canadian public drug programs

How do PLAs impact access in different jurisdictions?

PEI: No significant restrictions

ON, BC, AB: F2 or higher liver damage to be eligible

PQ: Scale-back model, down to F0 before 2020

RECALL: pCPA mandate to improve coverage consistency across regions

Data from *PMPRB*

Pan-Canadian Pharmaceutical Alliance

-a priority review procedure exists, and that's appropriate, but who decides the standards?
Examples of timelines

HARVONI®
ledipasvir/sofosbuvir
90 mg/400 mg tablets

CDR: List w/ substantial price reduction
CDR Date: MAR 18 2015
LIST (ON): MAR 23 2015

Time to List: 5 days

ZEPATIER™
(elbasvir and grazoprevir)
50 mg/100 mg tablets

CDR: List w/ clinical criteria or conditions
CDR Date: MAY19 2016
LIST (ON): N/A

Time to List: 6+ Months and counting

Consider *Tivicay* (dolutegravir) for treatment of HIV: over 8 months to list

Data from *pCPA, CADTH*

Pan-Canadian Pharmaceutical Alliance

The ***only*** body in Canada that can:
-execute a critical appraisal of a drug;
-with public affordability as its goal;
-and regulatory teeth with which to negotiate

pCPA does not exist by legislative action
-Convention observed by the Council of the Federation

-Questions of transparency, accountability
-**DOES** use the Patient Input from the CDR
-**DOES** have a seat at the deliberative table during the CDR

...but as Patient Input in the CDR asks nothing of cost, price, or affordability, then HOW does Patient Input inform pCPA negotiations?

Is the pCPA left holding the bag on drug pricing and access?

HCV is testing our ability to achieve consistency across jurisdictions, and to inform complementary processes

Federal/Provincial/Territorial Public Drug Programs

-Ultimate listing decision lies with the Public Payer, despite all previous regulatory processes

-Some jurisdictions duplicate HTA processes; Ontario's CED has reformed that

Is the pCPA making *ad hoc* hepatitis C policy in its PLAs?

-Eligibility restrictions based on cost, not clinical suggestions

-Are there are other parties who can better advise clinical restrictions? PHAC? NGOs?

HCV is testing our ability to have a coherent, communicative, and collaborative system

CTAC

In Summary

HCV is testing our ability to recognize life-savers, get the best price, maintain consistent access, and negotiate collectively

-Are our processes informing one another?

Could PMPRB alert CADTH to a pricing concern?

Could CADTH reintroduce priority review and make comments on price?

Should Health Canada have a say in price?

In Summary

Many countries:
-Review patents, prices, and burden
-Conduct compliance reviews
-Conduct Health Technology Assessment
-Make public listing recommendations in an effort to make access consistent

We do this well, but we can do it better

A discussion of Hepatitis C as an *Acid Test* of Our System

-NOT a declaration that our systems are *broken*

-An advisory that new medicines and revolutions in treatment will continue to test our system

Get social with us!
Joignez-vous à nous!

@CTAC_CAN

/CTAC.CAN

/CTACTALKS

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