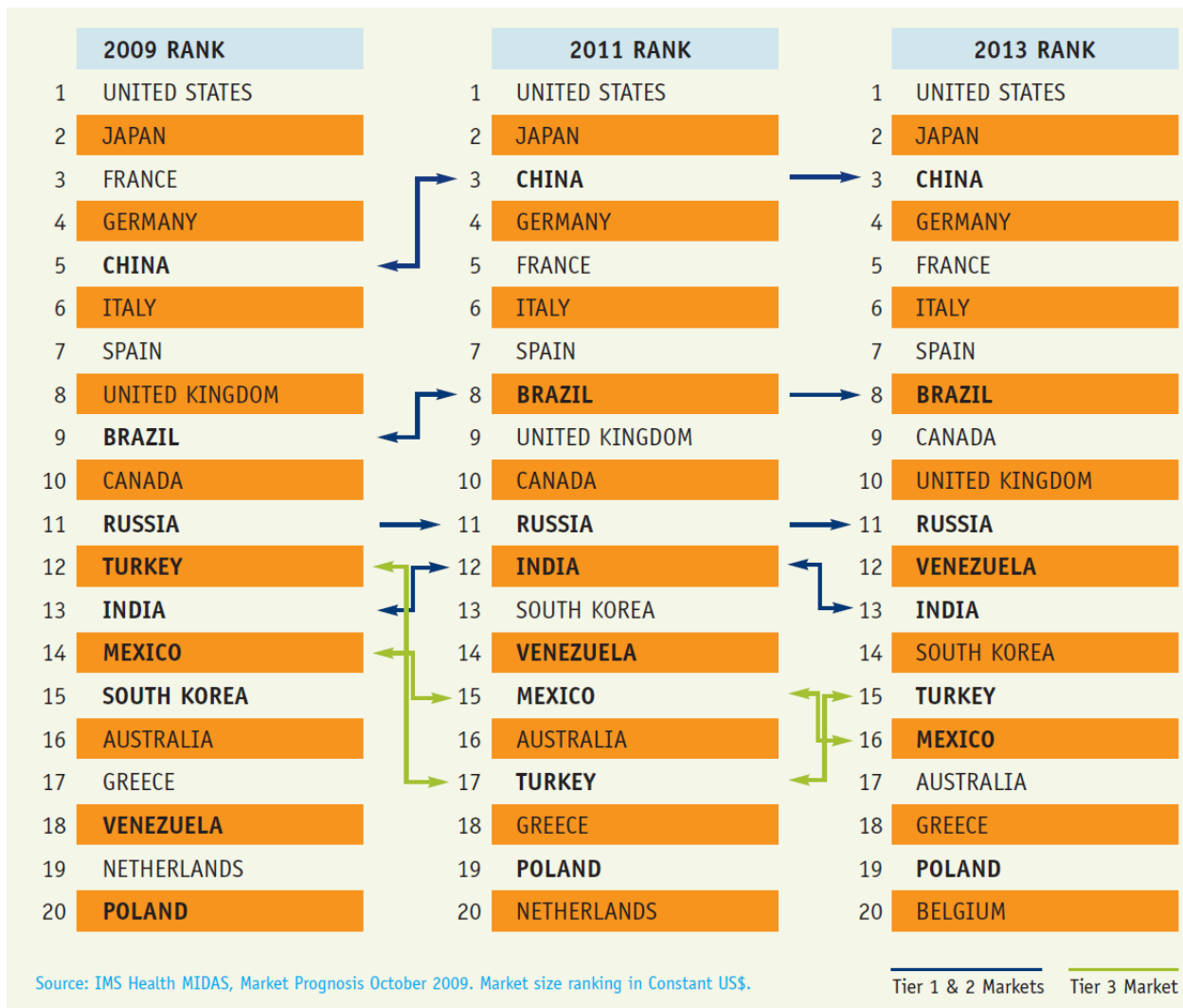


Pricing & Reimbursement in Canada

W. Neil Palmer

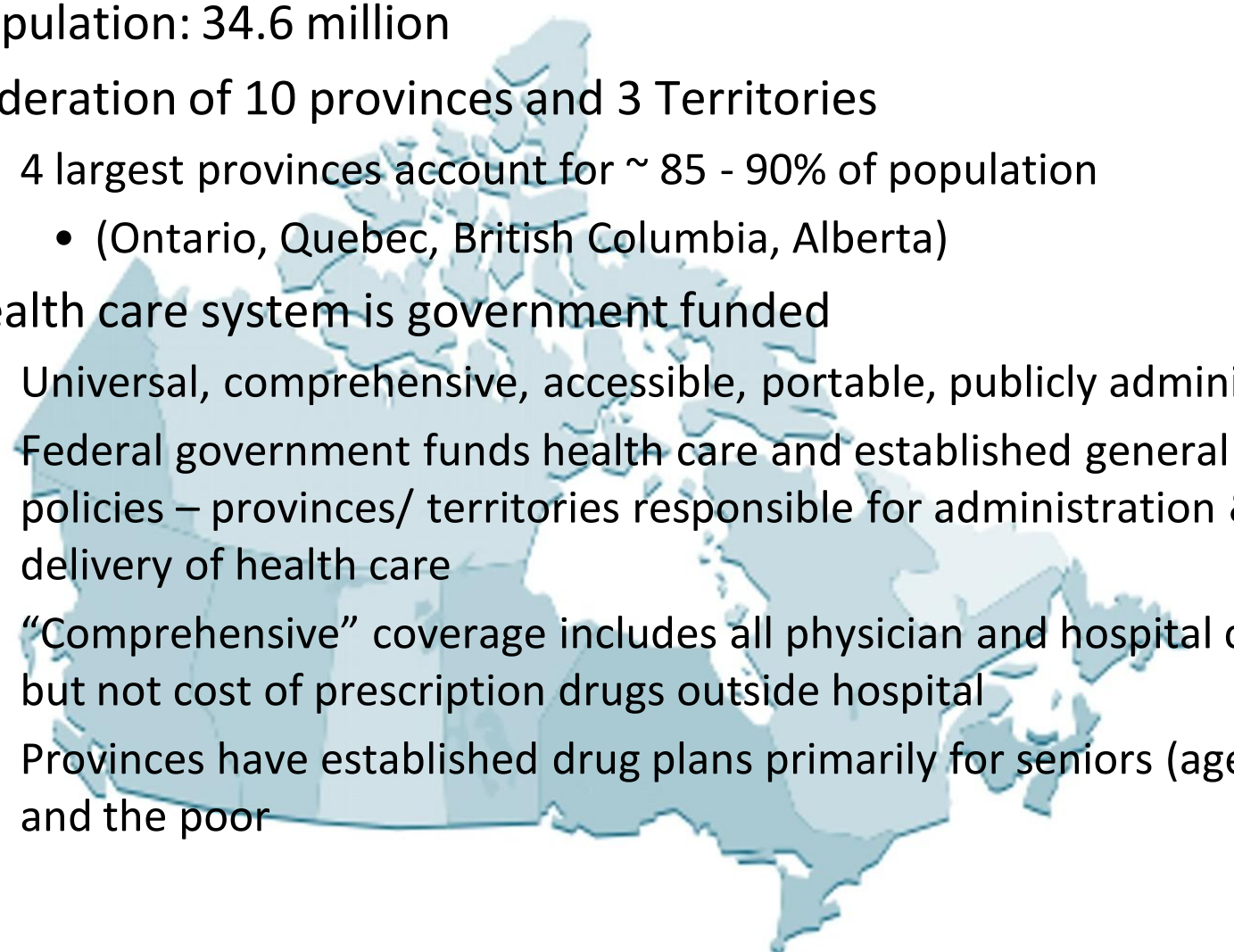
SMi European Pharmaceutical Pricing & Reimbursement
Basel, Switzerland
October 31 – November 1 2011

Canada: an Important Market



Source: IMS Health: *Pharmerging Shakeup: New Imperatives in a redefined world*

Canada – Quick Facts

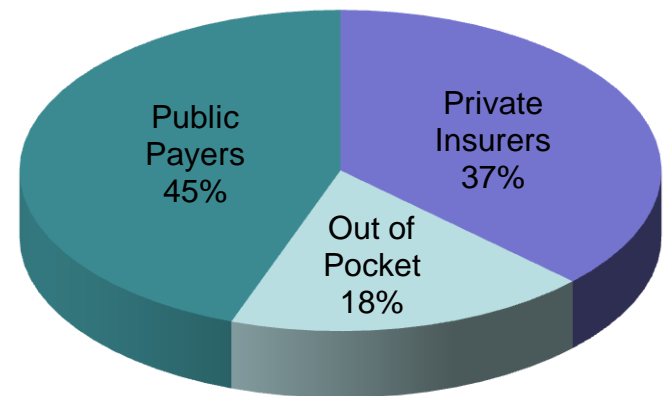
- Population: 34.6 million
 - Federation of 10 provinces and 3 Territories
 - 4 largest provinces account for ~ 85 - 90% of population
 - (Ontario, Quebec, British Columbia, Alberta)
 - Health care system is government funded
 - Universal, comprehensive, accessible, portable, publicly administered
 - Federal government funds health care and established general policies – provinces/ territories responsible for administration & delivery of health care
 - “Comprehensive” coverage includes all physician and hospital costs but not cost of prescription drugs outside hospital
 - Provinces have established drug plans primarily for seniors (age > 65) and the poor
- 

Who pays for prescription drugs in Canada?

- Public (government funded) schemes
 - Federal / Provincial Drug Plans
 - Over 65 years of age, Social assistance, (welfare), High drug costs to Income
 - Hospital in-patients (covered by hospital “global” budget)
 - Cancer products – separate cancer agencies in Ontario and western provinces
 - Vaccines: public health programs
 - Blood products: blood agencies
 - Workers Compensation
- Private insurers
 - Employer sponsored drug coverage for employees and their families
- Consumers / Out of Pocket
 - No coverage / uninsured / underinsured
 - Unemployed, self-employed, small employers
 - Non-reimbursed drugs (e.g., lifestyle drugs)
 - Deductibles / co-payments

% Distribution of Rx Drug Expenditures
Canada 2009

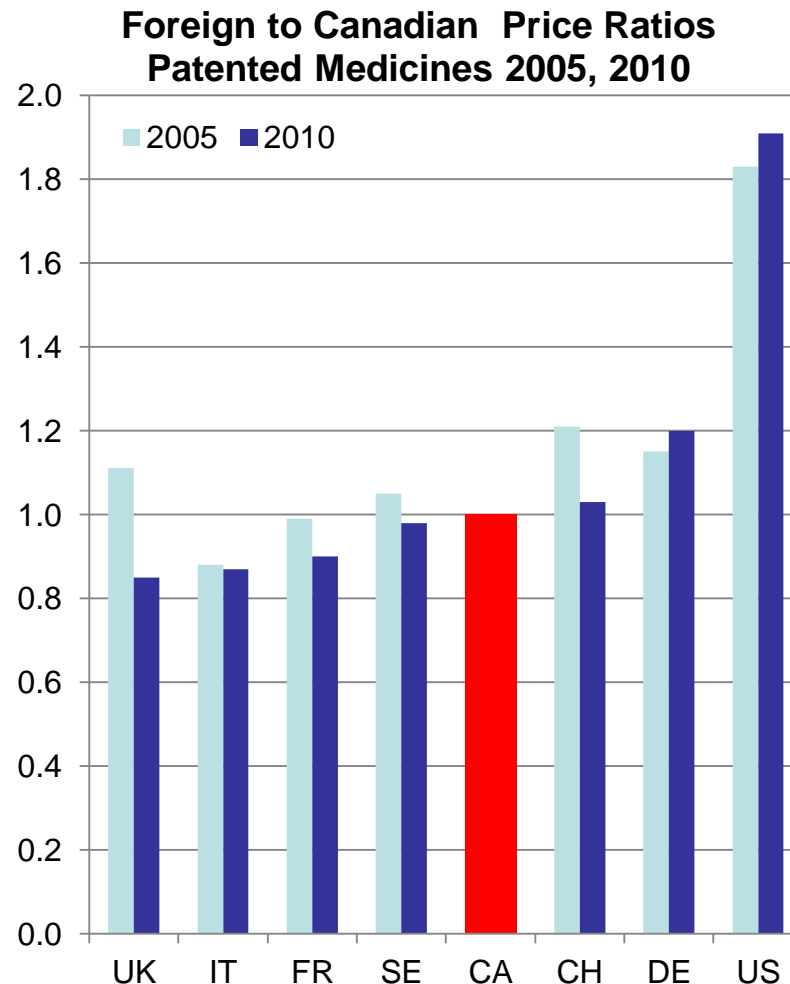
\$25.4 Billion



Source: Canadian Institute for Health Information (CIHI), *Drug Expenditure in Canada, 1985–2009* (Published 2010)

Canadian & international drug prices

- Canada references the US and six European countries (patented medicines only)
- General policy that, on average, Canadian prices should not exceed the median of international prices
- On average, Canadian prices are most similar to Sweden, Switzerland



Source: PMPRB

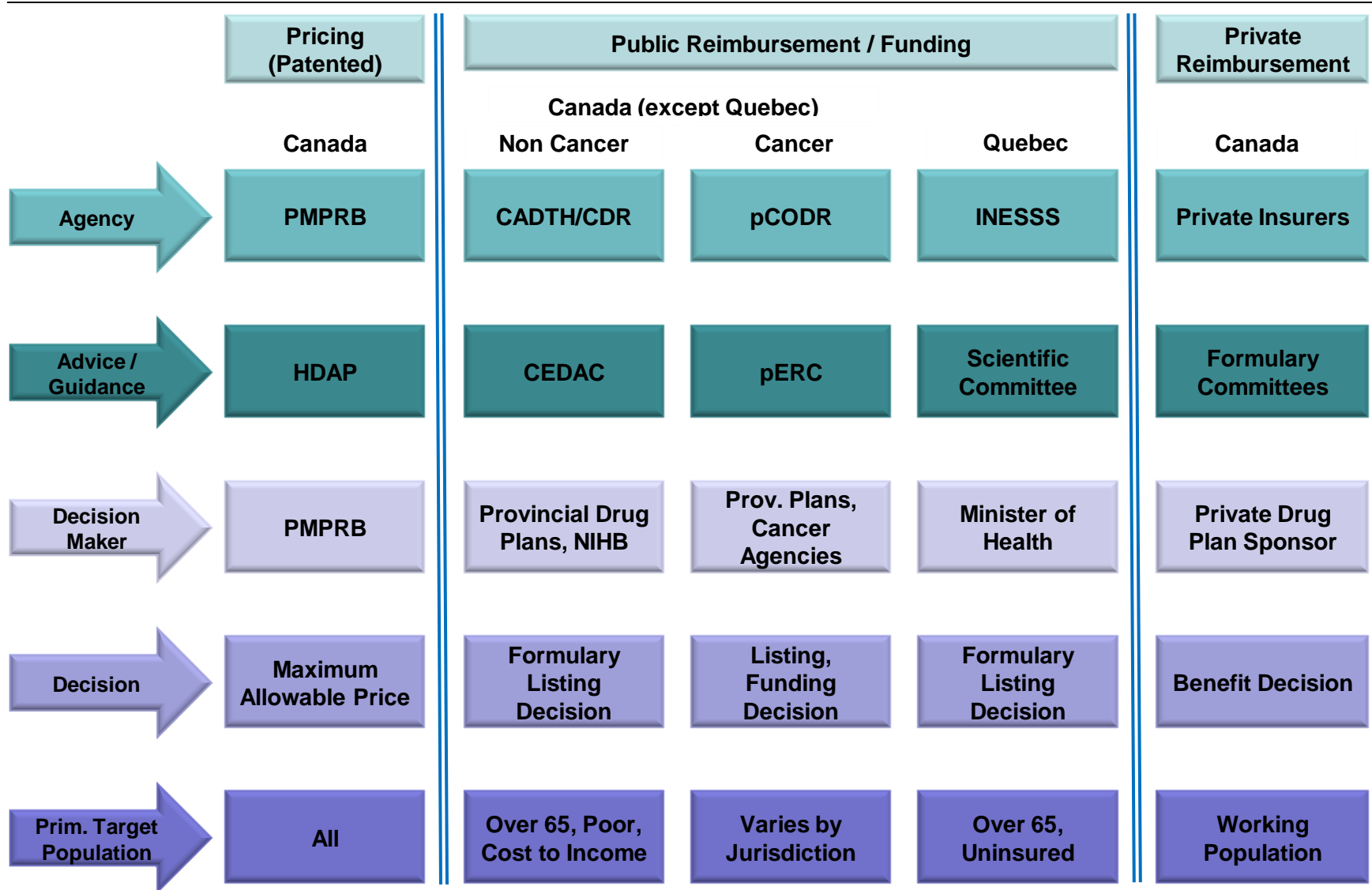
Generic Drug Policies in Canada

- Generic substitution is mandated through provincial legislation and regulations
- Provincial (and most private) drug plans will limit reimbursement to the lowest cost alternative (usually a generic)
 - Exception: Quebec 15 year rule
- Historically, Canadian generic prices have been higher than most other countries
 - And significantly higher than in the US
- Some provinces have explicit policies with respect to pricing levels
 - Ontario 25% of brand price
 - Quebec requires the lowest price in Canada
 - Other provinces: 35% - 45% of brand price
- Strict policies on pharmacist “allowances” have emerged
 - Allowances are payments from generics firms to pharmacists
 - Prior to regulation they were estimated to be ~40% of drug cost

Key P&R / HTA Organizations in Canada

- Patented Medicine Prices Review Board (PMPRB)
- Canadian Agency for Drugs and Technology in Health (CADTH)
 - Common Drug Review (CDR)
 - pan Canadian Oncology Drug Review (pCODR)
- Large provincial drug plans
 - CDR members
 - Ontario Drug Benefit Program
 - British Columbia Pharmacare
 - Alberta Health & Wellness Drug Benefit List
 - Non-CDR
 - Quebec: Le Conseil du médicament [*now part of INESSS*]
- Private drug plans
- Hospitals

Pricing & Reimbursement in Canada

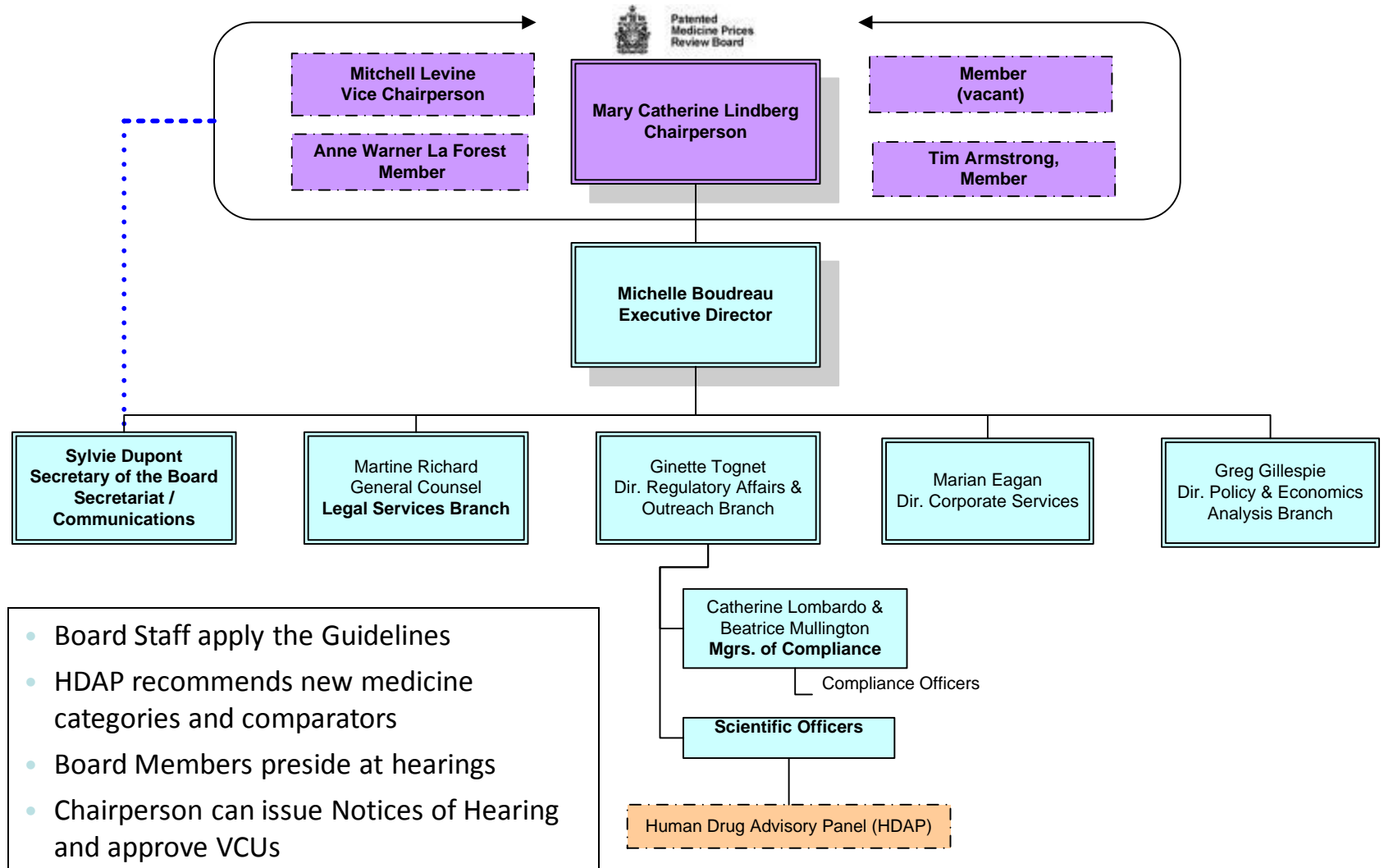


P&R Timeline

Agency	Submission	Decision
PMPRB - Pricing	Pre NOC ok	Initial assessment with 6 months of submission – final decision if appealed can be > 1 year
CDR – HTA assessment (excl Quebec)	Usually Post NOC	Within 7 months of submission
pCODR	Pre-NOC under consideration	Proposed to be 9 – 10 months post submission
Provincial drug plans – listing decision	Assessment post CDR decision	6 months – 1 year post CDR assessment, appeals can take >1 year
Quebec / INESSS	Usually post NOC	6 months, appeals can take > 1 year
Private Drug plans – coverage decision	At NOC	Usually very soon after NOC (most retail Rx drugs) – high cost drugs may take considerably longer

Patented Medicine Prices Review Board (PMPRB)

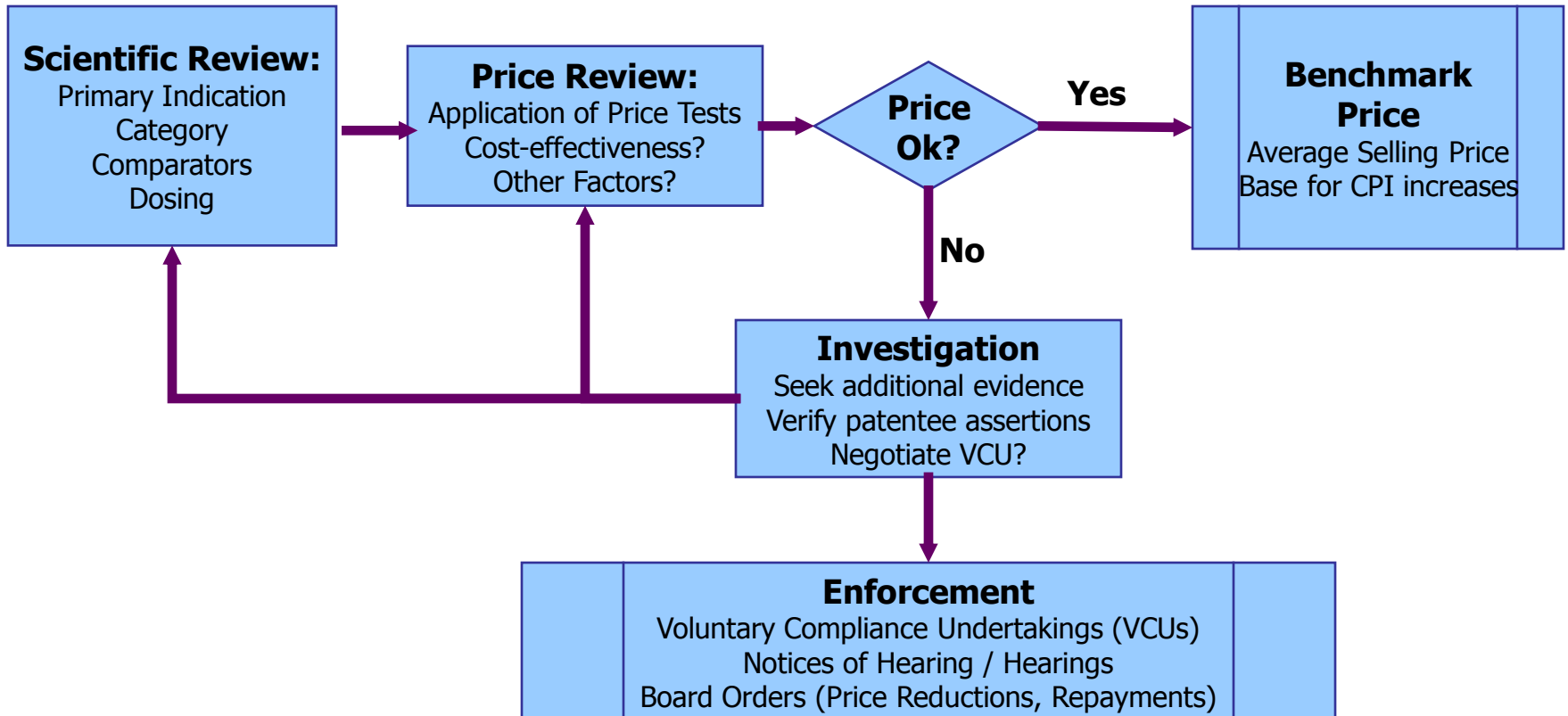
PMPRB Organization Chart



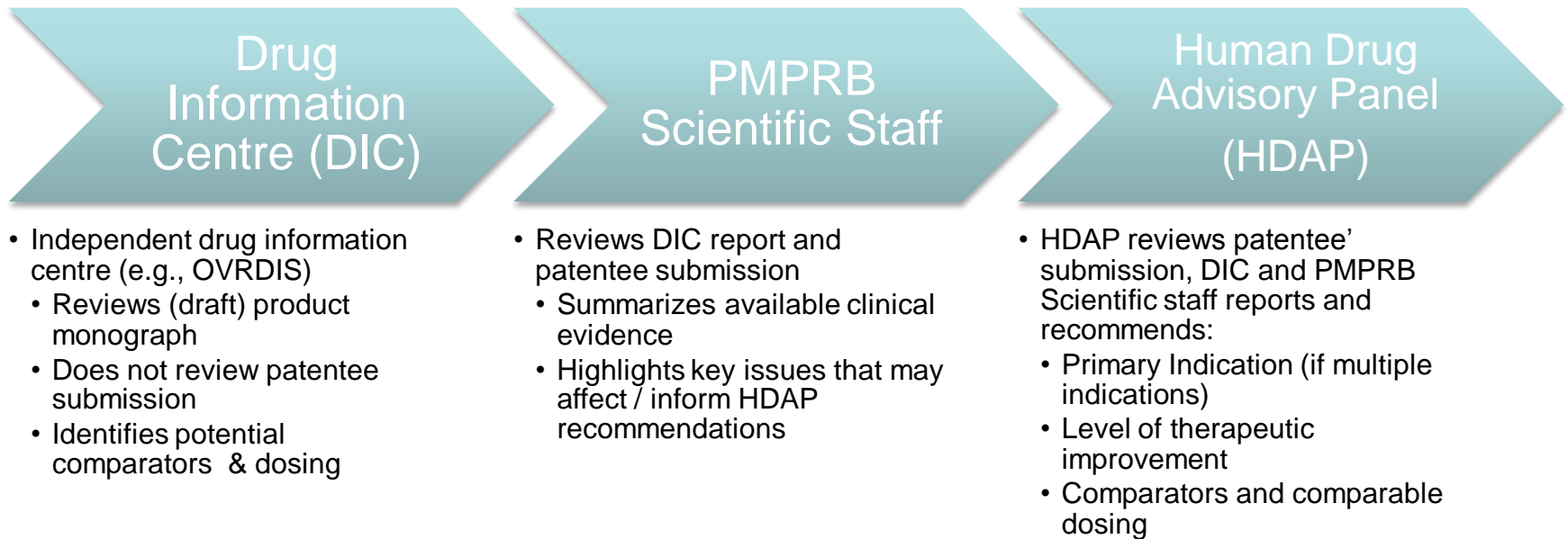
Overview of PMPRB Regulatory Framework

Item	Description	Who can change/amend
<u>Legislation</u> : Patent Act (s 76.1, 79-103)	Empowers the PMPRB, outlines price review factors, penalties for excessive pricing, failing to file information	Parliament
<u>Patented Medicines Regulations</u>	Outlines reporting requirements & PMPRB reference countries	Governor-in-council (federal cabinet)
<u>Board or Court Decisions</u>	Interpretations of the legislation or regulations in the context of particular cases	Subsequent Board or Court decisions (e.g. appeals)
<u>PMPRB Rules of Practice & Procedure</u>	Rules for conducting hearings	PMPRB (but are approved by Governor-in-council)
<u>Guidelines</u>	Excessive Price Guidelines Scientific Review Procedures PMPRB Enforcement Policy	PMPRB (but must consult stakeholders)
<u>Policies</u>	Official PMPRB interpretations of the legislation, regulations, guidelines (these are generally published in the PMPRB Newsletter)	PMPRB
<u>Practices</u>	Un-official interpretations of the legislation, regulations, guidelines	PMPRB staff

PMPRB New Medicine Review Process



PMPRB New Medicine Scientific Review Process



- HDAP is comprised of 6 independent members and meets 4 times per year
- Some new patented medicines will not be referred to HDAP (e.g., line extensions) unless the patentee files a submission claiming therapeutic improvement.
- The HDAP recommendations (including the DIC and scientific staff reports) are generally sent to patentees within one month of the HDAP meeting
- Recommendations can be appealed through re-submissions

PMPRB Price Tests

- New medicine price tests
 - Therapeutic class comparison (TCC) test
 - International price comparison (IPC) test
 - Median
 - Highest
 - Reasonable Relationship (RR) test
- Existing medicine price tests
 - Consumer price index (CPI) test
 - International price comparison (IPC) test
 - Highest
 - Median (re-benchmarking)
- Investigation price tests
 - International therapeutic class comparison test
 - Median of International Price Ratios
 - Median of Comparator International Prices

PMPRB New Medicine Tests

Level of Therapeutic Improvement	Price Test	All Patented Medicines
Breakthrough	Median International Price	Prices of patented medicines can never exceed the International Maximum Price
Substantial Improvement	Higher of: TCC & Intl. Median	
Moderate Improvement	Midpoint of: TCC & Intl Median (but not lower than TCC)	
Slight or No Improvement	TCC or Reasonable Relationship Test	

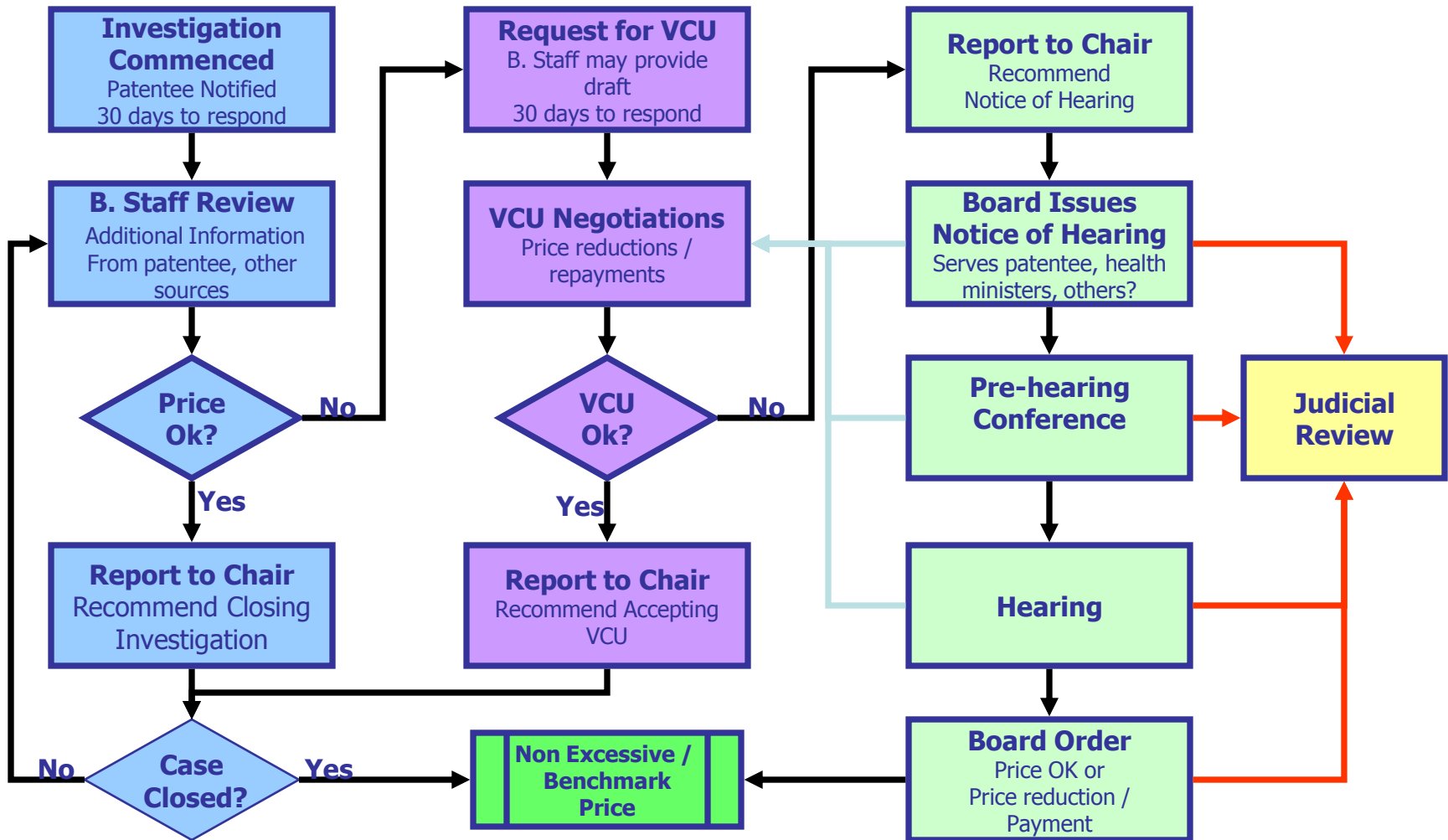
TCC = Therapeutic Class Comparison

- International Therapeutic Class Comparison Test possible in the context of an investigation

Existing Medicines - CPI-Adjustment Methodology

- Prices of an existing patented drug product cannot increase by more than the Consumer Price Index (CPI) as defined by the PMPRB CPI-Adjustment Methodology
 - Note: prices can never exceed the highest international price at any time.
- CPI-Adjustment Methodology involves the following calculations:
 - **Adjusting benchmark prices by the cumulative change in CPI** (CPI-Adjusted Price); and
 - Benchmark periods are up to 3 years prior to the current year
 - **Applying a cap** on the maximum price increase in any one year
 - 1.5 times the forecast change in the annual CPI.
 - 5 percentage points more than forecast CPI in periods of high inflation (over 10%)
 - The **lower** of the results of both calculations will set the Non-Excessive Average Price
 - PMPRB publishes CPI and cap changes on its web site
- PMPRB monitors “**any market**” price changes for each sub market (class of customer, province) but is generally not enforcing “any market” price changes
- **Resetting price after offsetting excess revenues** - when a price reduction below the Non-Excessive Average Price is taken to offset excess revenues the Average Transaction may increase in the next reporting period up to the non excessive price (NEAP) prior to the price reduction.

PMPRB Enforcement Process



Legal Challenges to PMPRB

- Increasingly manufacturers are challenging PMPRB decisions in the courts
 - Leo Labs (Dovobet) – role of free goods in calculating average transaction price
 - PMPRB must take them into account if reported
 - Celgene (Thalomid) – does PMPRB have jurisdiction over prices of named patient (special access program) sales originating outside Canada
 - Yes (supreme court)
 - Pfizer and others... – can PMPRB compel manufacturers to report rebates to provincial governments and other 3rd parties?
 - No
 - Teva NeuroScience (Copaxone) – can the PMPRB make a determination of excessive pricing based on only one of four excessive price factors
 - No – PMPRB must give weight to all excessive price factors

Common Drug Review (CDR)

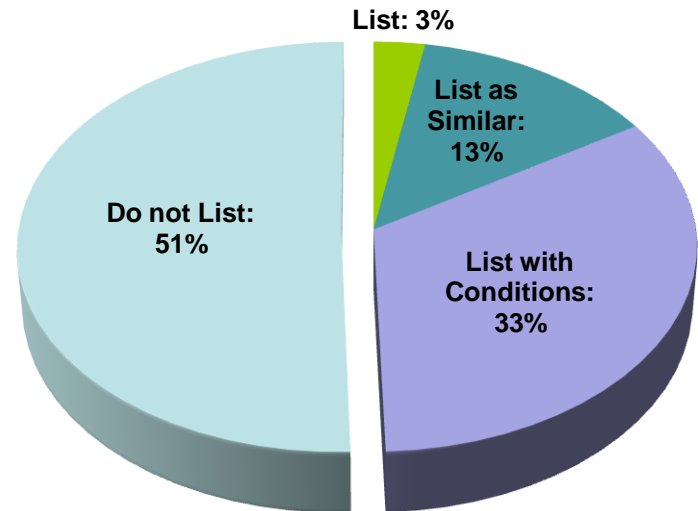
CDR Overview

- The Canadian Agency For Drugs and Technologies in Health (CADTH)
 - Health Technology Assessment (HTA)
 - Canadian Optimal Medication Prescribing & Utilization Service (COMPUS)
 - **Common Drug Review (CDR)**
- The Canadian Agency for Drugs and Technologies in Health developed the Common Drug Review (CDR) process in consultation with the drug plans that participate in the program, the pharmaceutical industry, and the public.

CADTH and Common Drug Review (CDR)

- The CDR reviews new drugs and provides formulary listing recommendations to all publicly-funded drug benefit plans in Canada except Quebec
- The CDR Directorate oversees clinical and P/E reviews but not budget impact (each drug plan reviews BI)
- Each plan independently advises manufacturer of its listing decision and coverage status of the drug.
 - Affordability / budget impact are the key factors for the drug plans
- The pan-Canadian Oncology Drug Review (pCODR) reviews and provides recommendations for cancer drugs

CDR Decisions as of August 2011 (N = 180)



**The majority of new drugs are refused by CDR
Those with a positive recommendation usually have restrictions – provincial plans generally follow CDR recommendations**

Comparison of CDR and SMC Final Recommendations

(86 drugs reviewed by both CDR and SMC as of August 2011)

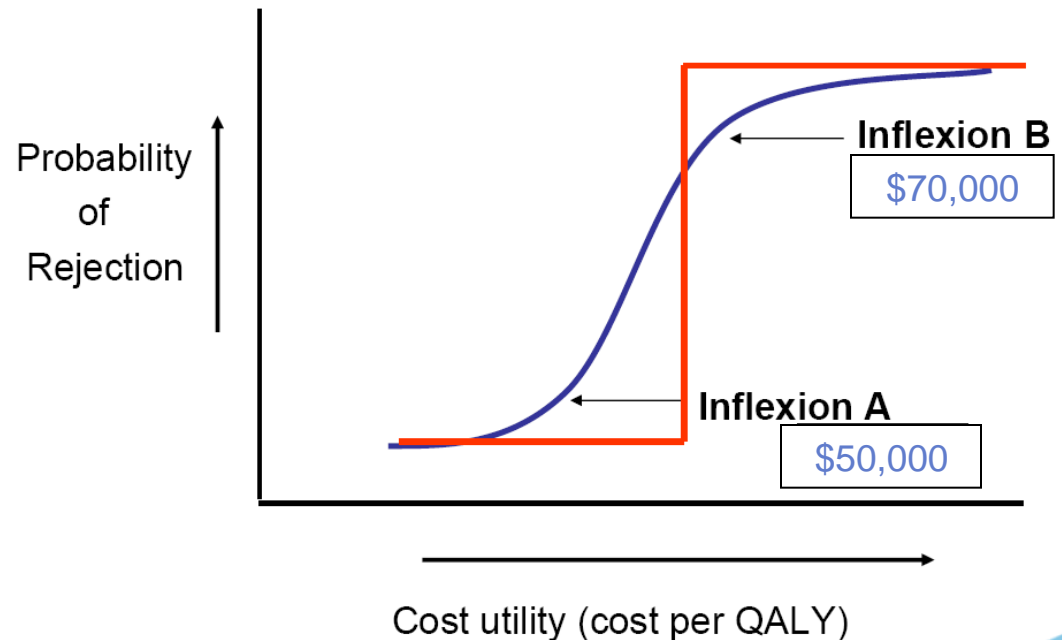
Recommendation	% Distribution of Recommendations (N=86)	
	Canada (CDR)	Scotland (SMC)
List / Accept	1.2%	31.4%
List / Accept with Restrictions	51.2%	47.7%
Do not List / Not recommended	47.7%	20.9%
Total	100.0%	100.0%

- Scottish Medicine Consortium (SMC) is far more likely than the Canadian CDR to recommend new drugs be publicly funded.
- Analysis suggests that CDR is unconvinced that new products offer incremental value when older, less expensive alternatives are available.
- CDR tends to rely more on cost comparison to an established comparator rather than cost-utility analysis (\$/QALY)
- These results are consistent with other studies that concluded that CDR is more restrictive than decisions made by other HTA agencies.

Source: Canadian Agency for Drugs and Technology in Health (CADTH), Scottish Medicines Consortium (SMC)

Canada / CDR: Cost effectiveness ICER thresholds

- There is no official incremental cost effectiveness ratio (ICER) threshold in Canada
 - Probability of rejection increases quickly above \$50K/QALY
 - Rejection almost certain above \$70K/QALY
- The threshold for oncology drugs and drugs for rare disease may be moving higher
- However, most CDR recommendations do not reference an ICER threshold



Source: Adapted from Longson C (NICE), *The NICE Health Technology Appraisal Programme (April 2008)*

CDR New Initiatives

- CADTH organizational changes
- Expanded public involvement
- Therapeutic Reviews
- Subsequent Entry Biologics
- Pre-NOC reviews
- Peer review process
- Transparency

Drug Funding & Reimbursement

Hospital Drugs

- Drugs used within hospitals (inpatients) are funded as part of the hospital “global budget”
 - Provinces fund hospitals and each hospital manages its pharmacy budget
- Hospital pharmacy and therapeutics (P&T) committees decide which drugs will added to the hospital formulary
 - Additions to the hospital formulary must be initiated by a hospital physician
 - Manufacturers provide hospital formulary kits to support the P&T review process
- Hospital buying groups (e.g., HealthPro, MedBuy) issue tenders and negotiate discounts/rebates on behalf of member hospitals
- Quebec is the only province that has a province wide hospital formulary (liste des établissements)
 - Listed drugs must be funded within Quebec hospitals

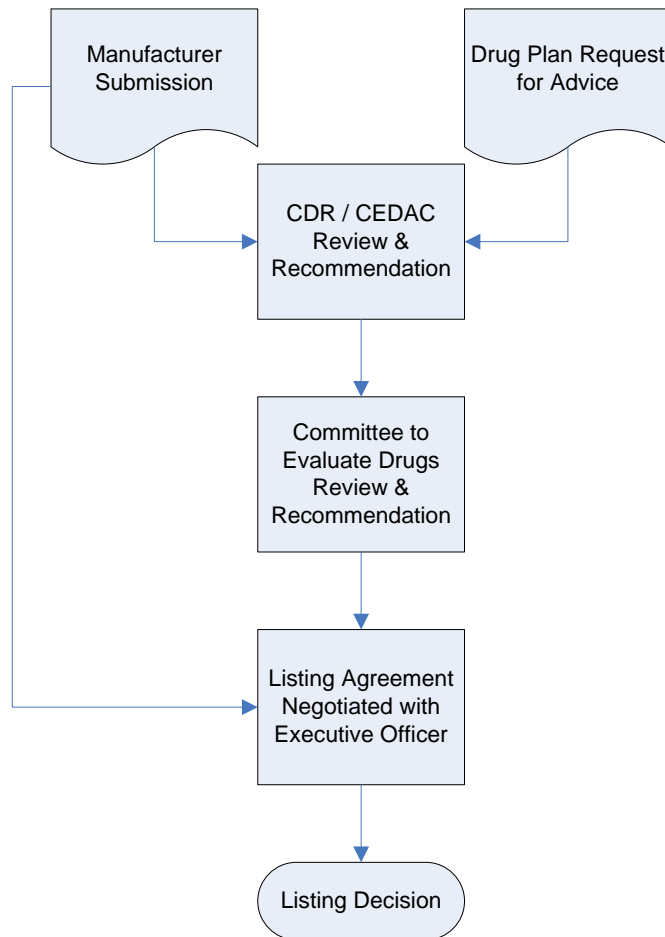
Private Drug Plans

- Private drug plans typically cover working Canadians and are generally sponsored by employers.
- Most (80 - 85%) private drug plans cover all prescription drugs with the exception of “lifestyle” drugs (e.g., weight loss, smoking cessation, erectile dysfunction), hospital only drugs, vaccines and very expensive therapies.
- Some drugs may require prior authorization
 - Expensive drugs (biologics)
 - Drugs that could be used for “lifestyle purposes (e.g., Wellbutrin, Revatio)
- Most private plans feature annual deductibles, co-payments (often 20%) and may feature annual or lifetime limits
- Public plan listings can influence private plan coverage and physician prescribing
 - A small minority of private plans maintain formularies that mirror the provincial plan formulary.
 - Physicians are more likely to prescribe a therapy that they know is covered by the provincial plan even if the patient only has private (or even no) coverage .
 - In Quebec, private insurers are required to provide coverage for all products listed on the provincial formulary

Public Drug Plans

- Public reimbursement in Canada is through provincial and federal drug benefit plans that are typically targeted at:
 - seniors (65+)
 - the poor
 - individuals with high drug costs relative to income.
- Listing on provincial drug plans is particularly important for drugs prescribed predominantly to seniors or for expensive drugs.
- Each plan maintains a formulary or drug benefit list of drugs eligible for reimbursement.
- Drugs are added to the formularies on the basis of recommendations of :
 - the Common Drug Review (CDR) (except Quebec) and
 - the respective provincial therapeutic committees
- The CDR reviews
 - most new single source drugs
 - new indications
 - new combination drugs

Ontario Reimbursement Review Process



- As part of the Common Drug Review (CDR) process the Canadian Expert Drug Advisory Committee (CEDAC) assess the clinical and cost effectiveness and issues a “Canadian” listing recommendation
- The Ontario Committee to Evaluate Drugs (CED) assesses the CEDAC recommendation and issues an Ontario listing recommendation
- The Executive Officer (EO) negotiates a listing agreement with the manufacturer that reflects or improves on the listing recommended by the CED
 - “price” agreements are the most common (generally confidential rebates tied to claims)

Recent Changes to Canadian HTA Procedures

- pCODR – the pan Canadian Oncology Drug Review replaces JODR
 - Oral oncology drugs to be reviewed by CADTH
 - IV oncology drugs to be reviewed by Program for Evidence Based Care (McMaster University)
 - Submissions accepted beginning August 2011
- INESSS – *Institut nationale d'excellence en sante et service sociaux*
 - Merges the current Conseil de medicament that reviews drugs and the Quebec HTA agency AETMIS
 - Implications to listing recommendations and decision making process for drugs still unclear although there is a requirement that recommendations be implemented quickly
 - www.iness.qc.ca

Product Listing Agreements

Listing agreements in Canada

- British Columbia
 - Listing agreement is often a precondition for reimbursement
 - Some kind of financial consideration in all agreements
 - Proposed savings should be primarily to drug budget

- Alberta
 - Agreements will become a requirement for listing – potential agreements include:
 - Price volume
 - Utilization management
 - Coverage with evidence development
 - Health research capacity development

Source: Jeffcott G, What do public drug plan managers want from industry agreements?, PRA May 2008;
Alberta Health October 2009

Listing agreements in Canada (continued)

- Quebec
 - Limited opportunities for listing agreements
 - Risk sharing agreements can be proposed only after a drug is listed (i.e. listing is a precondition)
 - Financial agreements are required for price increases
- Ontario
 - Listing agreement are a condition of listing
 - Must include provisions to monitor utilization
 - Must address concerns from CED / CEDAC reviews (particularly pricing / cost-effectiveness)
 - Education and disease management programs can be used to support utilization objectives but not to replace firm financial commitments

Source: Jeffcott G, What do public drug plan managers want from industry agreements?, PRA May 2008

Important elements in Canadian listing agreements

- **Quantifying value**
 - The preferred approach is a financial commitment that is easily calculated based on volumes, expenditures or objective performance measures
- **Addressing uncertainty**
 - Clinical and financial
- **Ease of administration**
 - Direct payments to the plan are preferred – free goods to offset non-responders can be difficult to monitor
- **Addressing concerns of expert committees**
 - Inappropriate use, duration of treatment, patient sub-groups, etc
- **No new clinical data**
 - New data needs to be reviewed / assessed by the therapeutics committee and won't be considered in a listing agreement
- **Monitoring and evaluation against objectives**
 - Commitment to evaluate the performance of the agreement against clear objectives and reassess, adjust or renegotiate if necessary

Summary: Canadian listing agreements...

- Clear, easily calculated financial commitments are preferred as they address both cost-effectiveness and budget impact concerns
- Clinical effectiveness is a prerequisite for negotiating agreements
- Agreements can be for useful addressing payers concerns that theoretical benefits may not materialize in a real world setting
- Provincial drug plans have demonstrated a willingness (eagerness?) to enter into non-transparent agreements to expedite patient access to new therapies and at the same time contain costs
- Industry has embraced the new reimbursement environment although there are some misgivings that drug plans may take advantage

Summary

Outlook for Canadian P&R

- Pricing / PMPRB:
 - PMPRB price Guidelines are becoming more complex, uncertain in application
 - High Canadian dollar putting downward pressure on prices
 - Price cuts in reference countries add to the pricing pressure
- HTA / Common Drug Review
 - Expected to continue to recommend only 50% of new drugs
 - Confidential listing agreements make cost effectiveness analysis more challenging
 - Cooperation with other HTA agencies
- Payers / Provincial Drug Plans
 - Will continue to embrace listing agreements and non-transparent pricing for branded drugs
 - Lower prices for generics – impact on cost effectiveness of branded drugs

Thank You

Biography



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Neil Palmer is President and Principal Consultant of PDCI Market Access Inc (PDCI), a pricing and reimbursement consultancy founded as Palmer D'Angelo Consulting Inc (PDCI) in 1996. In addition to PDCI, Neil has worked with RTI Health Solutions, the Patented Medicine Prices Review Board (PMPRB), the Health Division of Statistics Canada and the research group of the Kellogg Centre for Advanced Studies in Primary Care in Montreal. He has more than 20 years of experience in pharmaceutical pricing and reimbursement and is a frequent speaker at pharmaceutical conferences in North America and Europe.

PDCI Market Access (PDCI) is a leading pharmaceutical pricing and reimbursement (P&R) consultancy based in Ottawa and Toronto. Established in 1996, the firm features a senior team of bilingual market access professionals with extensive experience assisting clients navigate the complex P&R challenges facing Canadian pharmaceutical manufacturers. PDCI develops successful P&R strategies and prepares comprehensive submissions to CDR, pCODR, public & private payers and the PMPRB. The firm's senior consultants facilitate meetings with CDR/payers/PMPRB, negotiate product listing agreements (PLAs) and resolve pricing compliance issues with the PMPRB. PDCI maintains databases of international pharmaceutical prices and provincial drug claims and costs..