Ontario's Generic Pricing Policy: What does it mean for the patented medicines industry?

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What is this?

Background

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% to 50% of brand price
  - Alberta 45% of brand price, B.C moving to 35%
  - Quebec requires the lowest price in Canada
- 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

Summary of Generic Pricing Rules for ON, QC, AB & BC

	Generic Pricing Rule
ON	New (and most existing) generics must be priced at 25% of the original brand list price. Non solid generic drug products may be priced up to 35% of the original brand name drug in recognition of their higher manufacturing costs.
QC	Generic Prices cannot be higher than the price paid by any other provincial drug plan. As such, generic prices in Quebec must effectively match the Ontario price of 25% of the brand list price. The government has introduced transitional measures for manufacturers adjusting to the lower prices over the next 2 years.
AB	New generics must be priced at 45% of the brand list price. The price for existing generic drugs is 56% of the brand list price.
BC	Lower prices for new generics will be phased in over 3 years: 42% of brand list price in Oct 2010; 40% of brand list price in July 2011; 35% of brand list price in April 2012). Under the Pharmacy agreement effective July 28, 2010 to March 31, 2013, the prices of existing generic products will be reduced to 35% of the brand price.

Ontario Generic Pricing

	Ontario's Public Drug Program	Private Payers / Cash paying customers
Date	% of original brand price*	
Up to June 2010	50%	Approx. 65%
July 1, 2010	25%	50%
April 1, 2011	25%	35%
April 1, 2012	25%	25%
April 1, 2013	25%	25%

*Note: Non-solid generic drug products (creams or patches etc) may be priced up to 35% of original brand in recognition of their higher manufacturing costs.
Source: Ont Ministry of Health and Long-Term Care Backgrounder June 7, 2010

http://www.health.gov.on.ca/en/news/release/2010/jun/bg_20100607.pdf

Quebec Generic Pricing

The Conseil du médicament released transitional measures to help manufacturers adjust to the lower generic prices established in Ontario.

Until April 2011

- If the best price in Canada is less or equal to 37.5% of the brand price in Quebec, the price can remain at 37.5%.
- If the best price in Canada is over 37.5% of the brand price in Quebec, the generic price must match the best price in Canada.

From April 2011 to April 2012

- If the best price in Canada is less or equal to 30% of the brand price in Quebec, the price can remain at 30%. If the best price in Canada is higher than 30% of the brand price in Quebec, the generic price must match the best price in Canada.

Effective April 2012

- The price in Quebec cannot be higher than the best price for other provincial drug plans.

Conseil du medicament Quebec Avis aux fabricants de medicaments generiques Nov 5, 2010
http://www.cdm.gouv.qc.ca/site/download.php?f=9d1a15b7c5a3bff5b0abe641ba368933

Alberta Generic Pricing

Reducing generic drug prices is part of phase two of the Alberta Pharmaceutical Strategy, which was announced in October 2009.

New Generics

- Effective October 1, 2009, the price of **new** generic drugs was reduced from 75 per cent to 45 per cent of the price of comparable brand name drugs. A new generic drug is any generic drug added to the Alberta Drug Benefit List after October 1, 2009.

Existing Generics

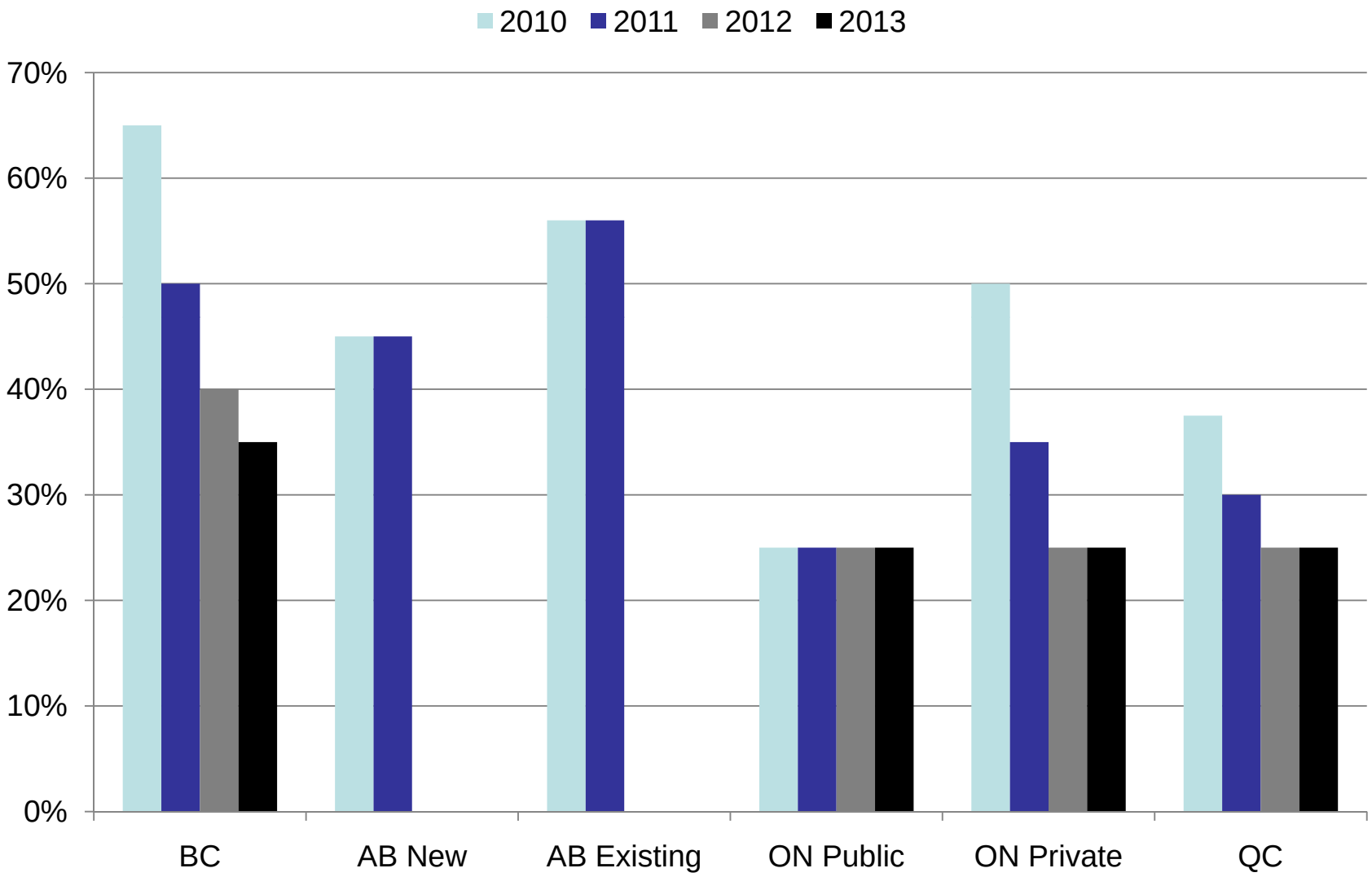
- Effective April 1, 2010 the price of currently available or existing generic drugs will be reduced from 75 per cent to 56 per cent of the price of comparable brand name drugs. Existing generic drugs are generic drugs already included on our Alberta Drug Benefit List as of October 1, 2009.

BC's Pharmacy Agreement Effective 2010 to 2013

- Generic drug prices will be reduced to 35% of brand prices by April 2012
- Increase in PharmaCare maximum dispensing fee
- Investment in new value-added pharmacy services
- Enhanced rural pharmacy funding to support community-based pharmacy

	Status Quo	October 2010	July 2011	April 2012
Existing Generics	65% (average)	50%	40%	35%
New Generics*	50% - 70%	42%	40%	35%

Generic Prices as % of Brand Prices, by Province



Implications of
New Generic Pricing Policies

Market Access Hurdles for New Drugs

Market Access Hurdles		Canada (foreign)	Output
1. Safety **2. Efficacy** **3. Quality**	Required for Market Authorization	Health Canada, (FDA, EMA)	Market Authorization
4. Value	Effectiveness, Cost Effectiveness	CDR/CADTH, (NICE, HAS)	Reimbursement Listing Recommendation
5. Price	Internal & External Price Referencing	PMPRB (Pricing agencies)	Maximum Non-excessive Price
6. Affordability	Budget Impact, Risk Sharing	Drug Plans (Health Ministries)	Reimbursement Decision
7. Local / Regional	Financing/funding	Provinces (PCTs, Regions)	Local Guidelines Funding decision

Generic Pricing & PMPRB

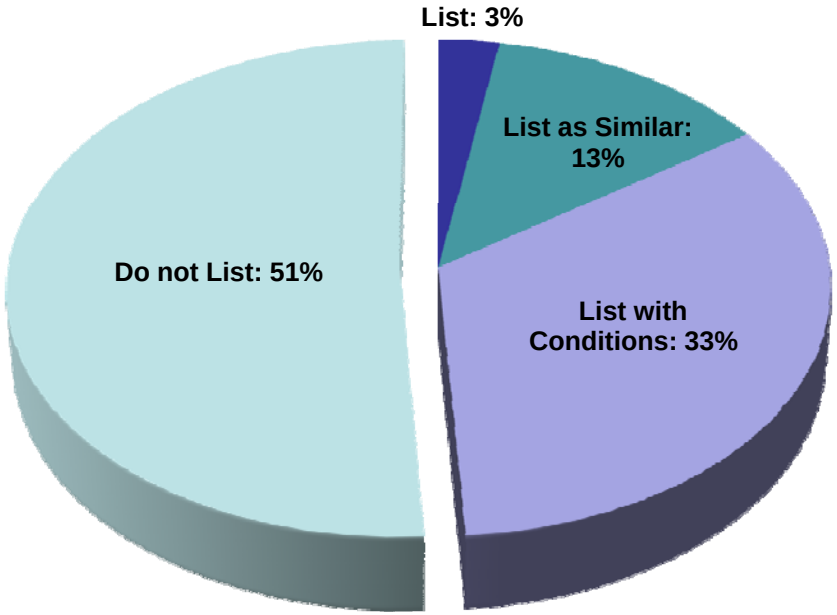
- PMPRB does not generally consider generic prices of comparators in therapeutic class comparisons (unless there is no brand price)
- But...
  - Brand manufacturers may be less willing to continue marketing branded products in the face of significant price differentials
  - Some brand manufacturers have matched generic prices on some products (will this continue?)
  - PMPRB policies (re generic prices) could change in the future if brand prices no longer seem relevant (particularly in therapeutic classes where all drugs have been genericized)

Generic Pricing & CDR recommendations

- Low generic prices will affect health economic models where the key comparator is generic
  - Raises the cost effectiveness bar significantly
  - New drugs will need significantly greater clinical effectiveness to offset much lower generic treatment prices.
- Not clear which generic price that CDR will reference:
  - likely between 25% and 35% of the branded price (range of Ontario and BC)
  - Adds complexity to development (and review) of HE models
- Creates a situation where a new drug could be cost effective in one province but not another
  - however CDR guidance is not province/plan specific

CDR already refuses most new drugs...

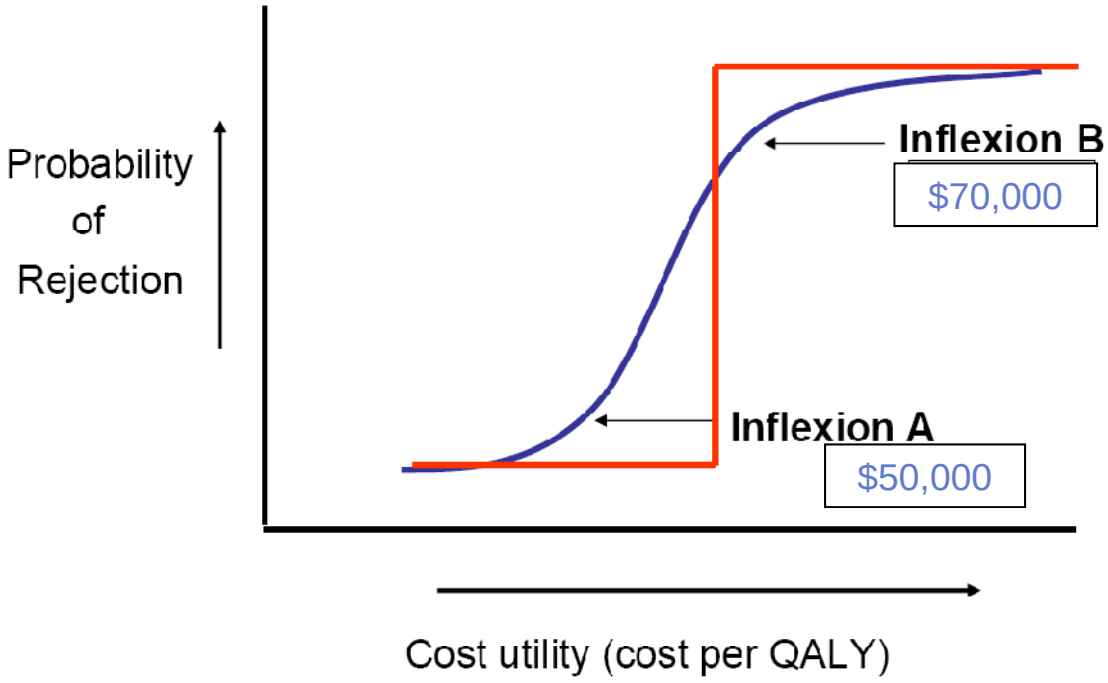
CDR Decisions as of January 2010 (N = 149)



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

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

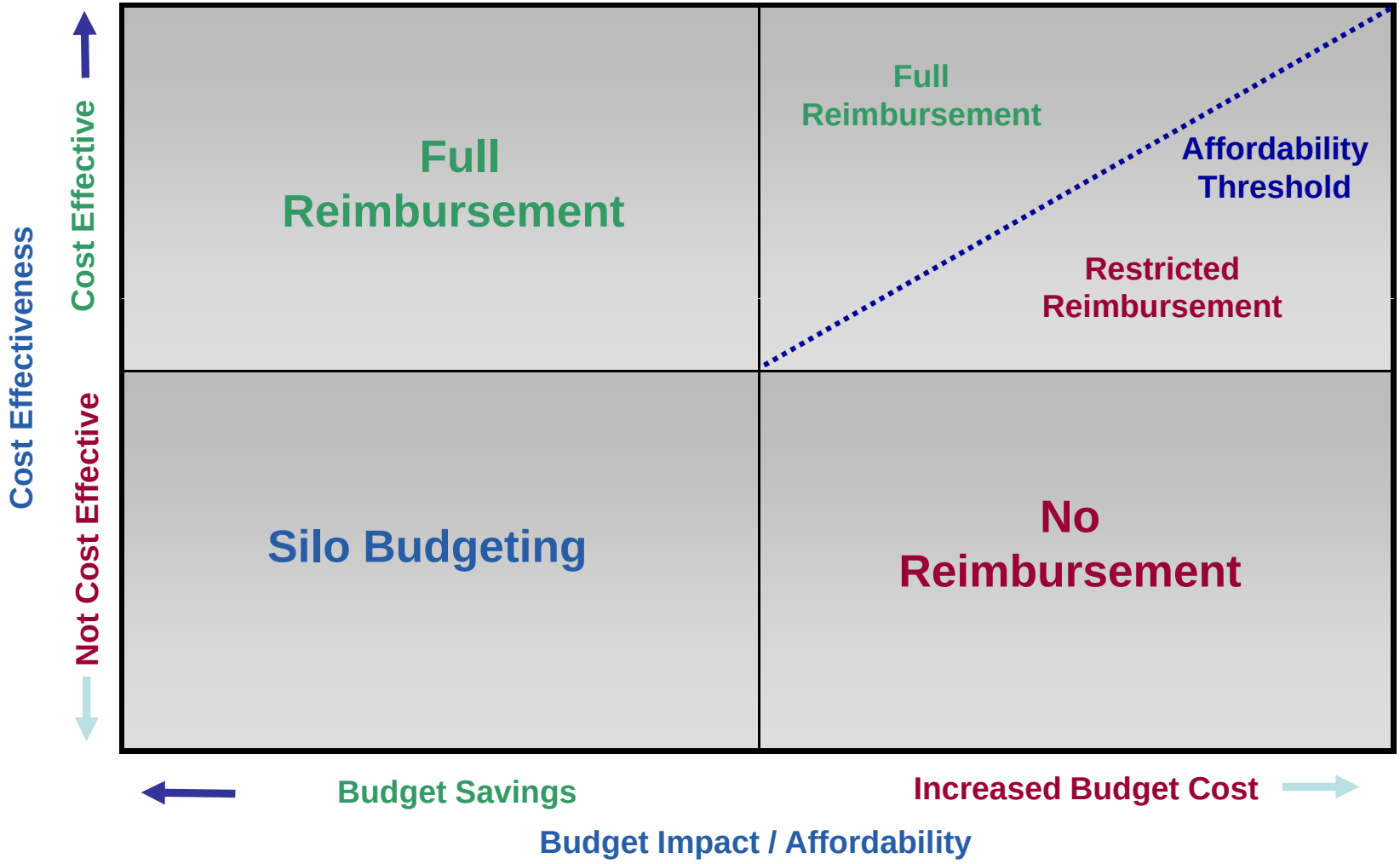


Source: Adapted from Longson C (NICE), *The NICE Health Technology Appraisal Programme (April 2008)*

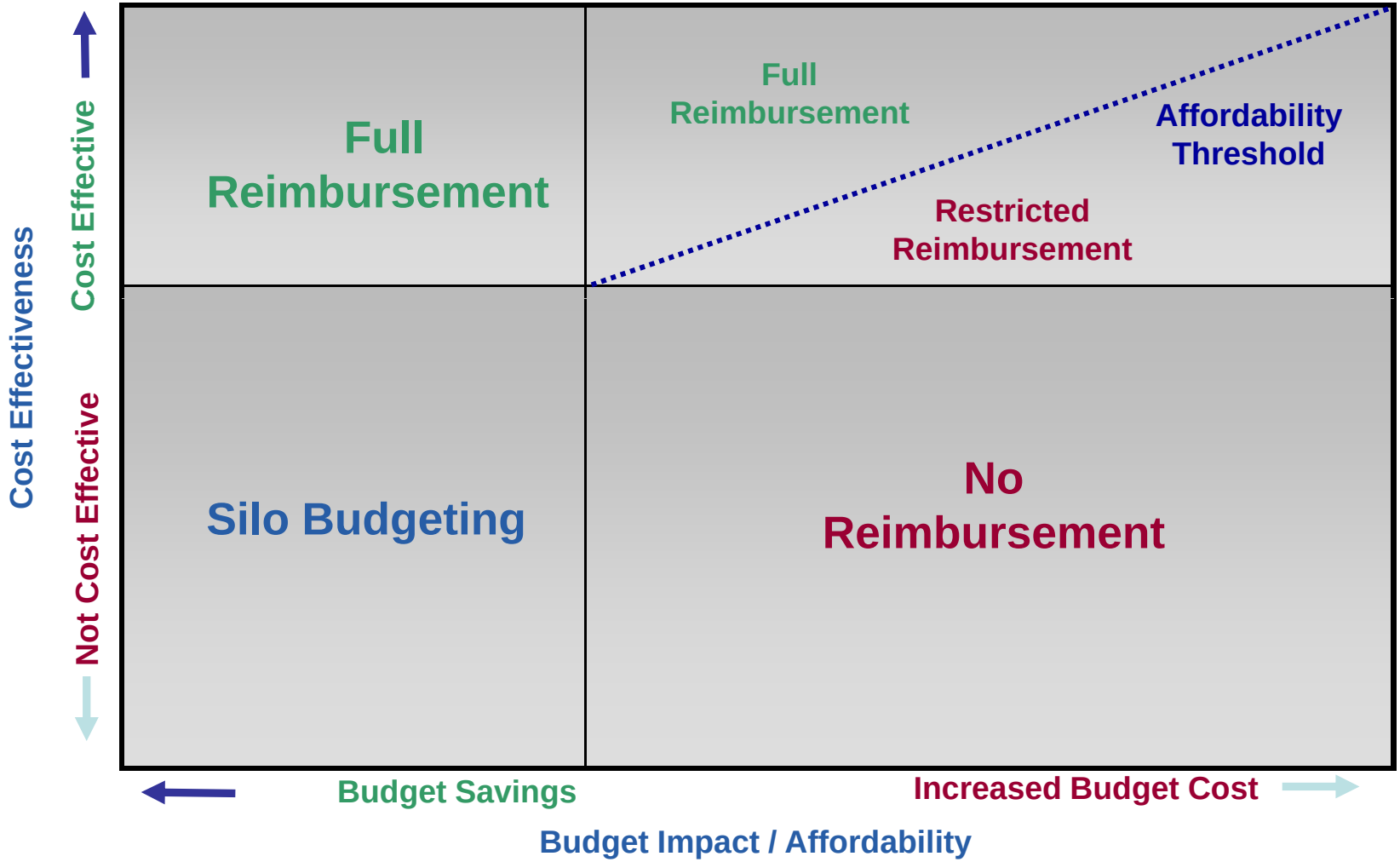
Provincial Drug Plans & Reimbursement Decisions

- Public payers place greater weight on budget impact (affordability) than cost effectiveness
- Low generic prices will affect budget impact assessment (BIA) models where any of the comparators are generic
  - Raises the affordability bar significantly
  - New drugs will need clear rationale to justify the greater budget impact
- Adds complexity to development of BIA models
  - Different generic comparator prices for each province
  - Prices change (decrease) over time in some markets

Tension between Cost Effectiveness & Affordability



Tension between Cost Effectiveness & Affordability (new generic pricing policies)

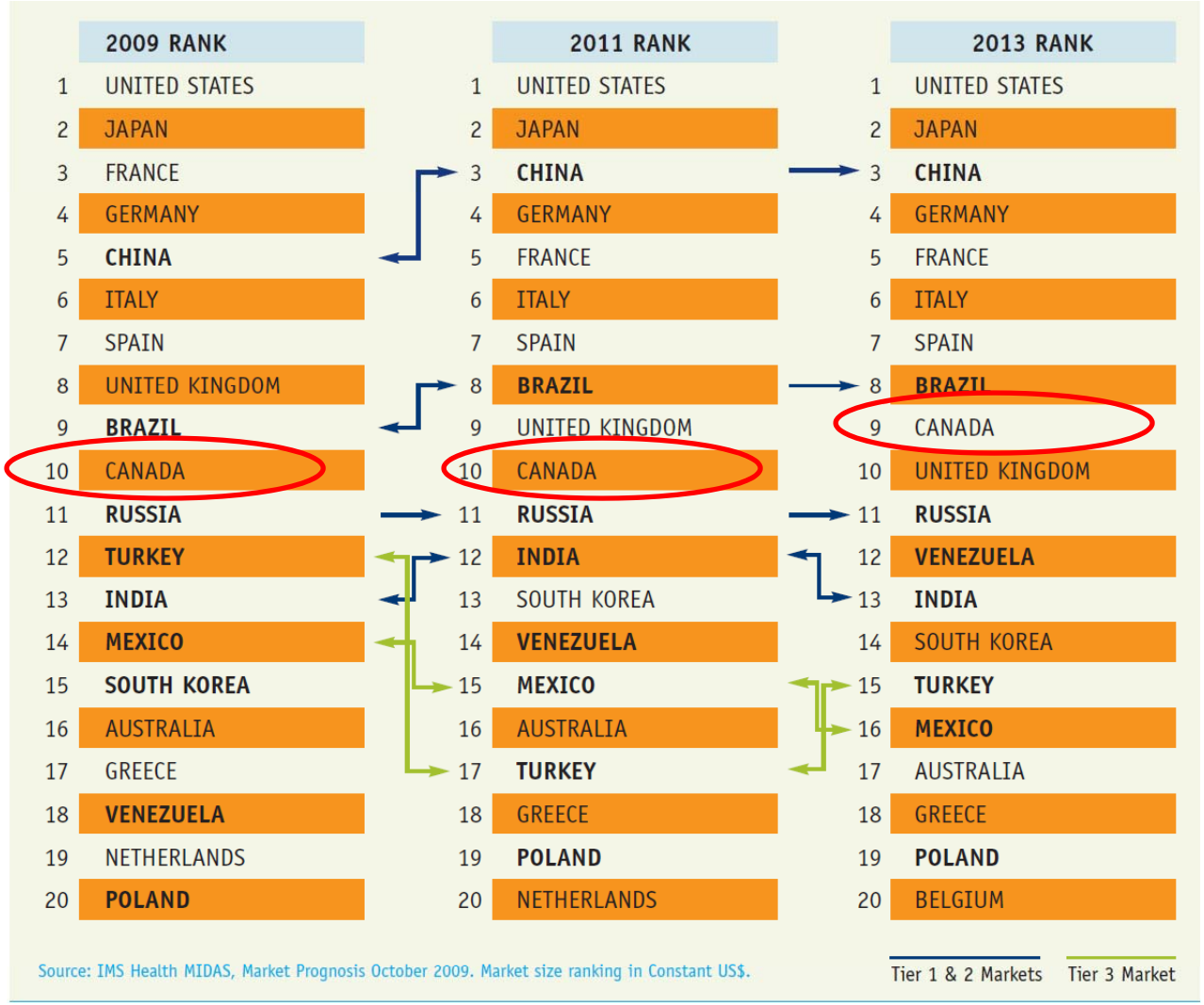


Listing (risk sharing) agreements

- Financial / utilization
  - Price volume agreements
  - Rebates
  - Discounts
  - Contracting (tendering, sole source)
- Financial risk sharing
  - Expenditure
  - Patient utilization caps
- Outcomes risk sharing
  - Pay for performance
    - Treatment response, treatment outcome
  - Trial periods
- Performance monitoring /Post hoc assessments
- Disease management programs to foster appropriate use
- R&D, investment commitments

Outlook

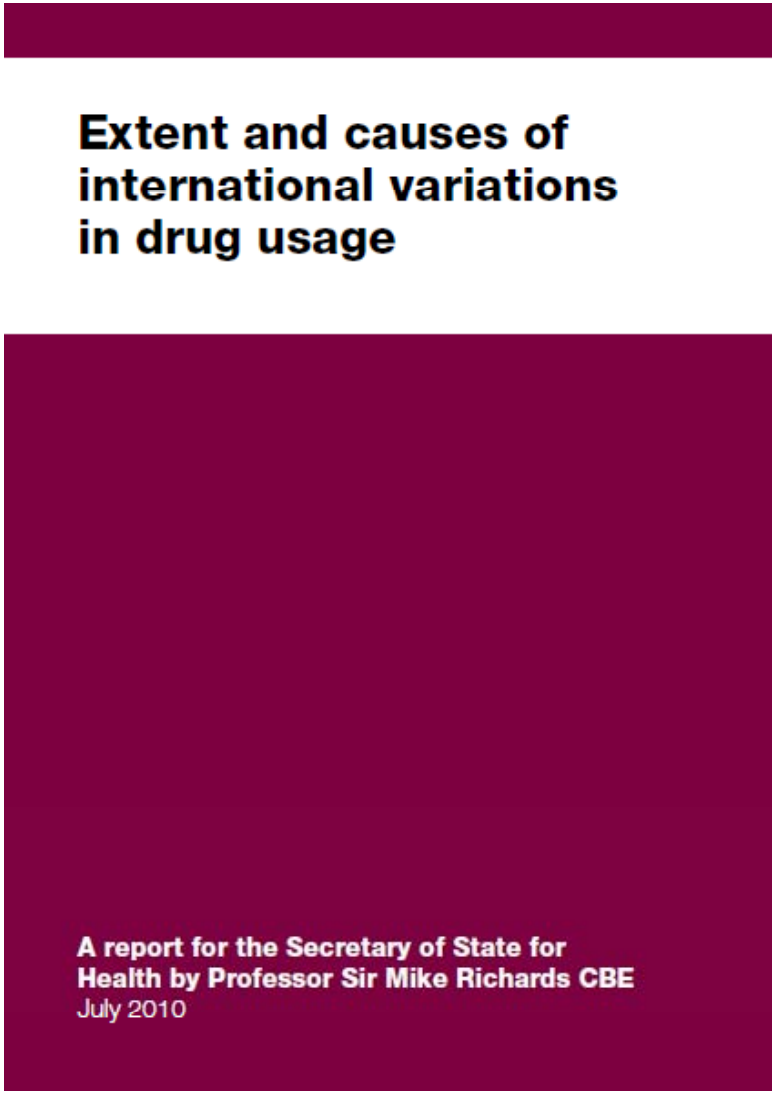
Why Canada is an Important Pharma Market



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

International variations in drug usage..

Professor Sir Mike Richards



Country rankings – cancer drug utilization

By launch timeframe (Richards 2010)

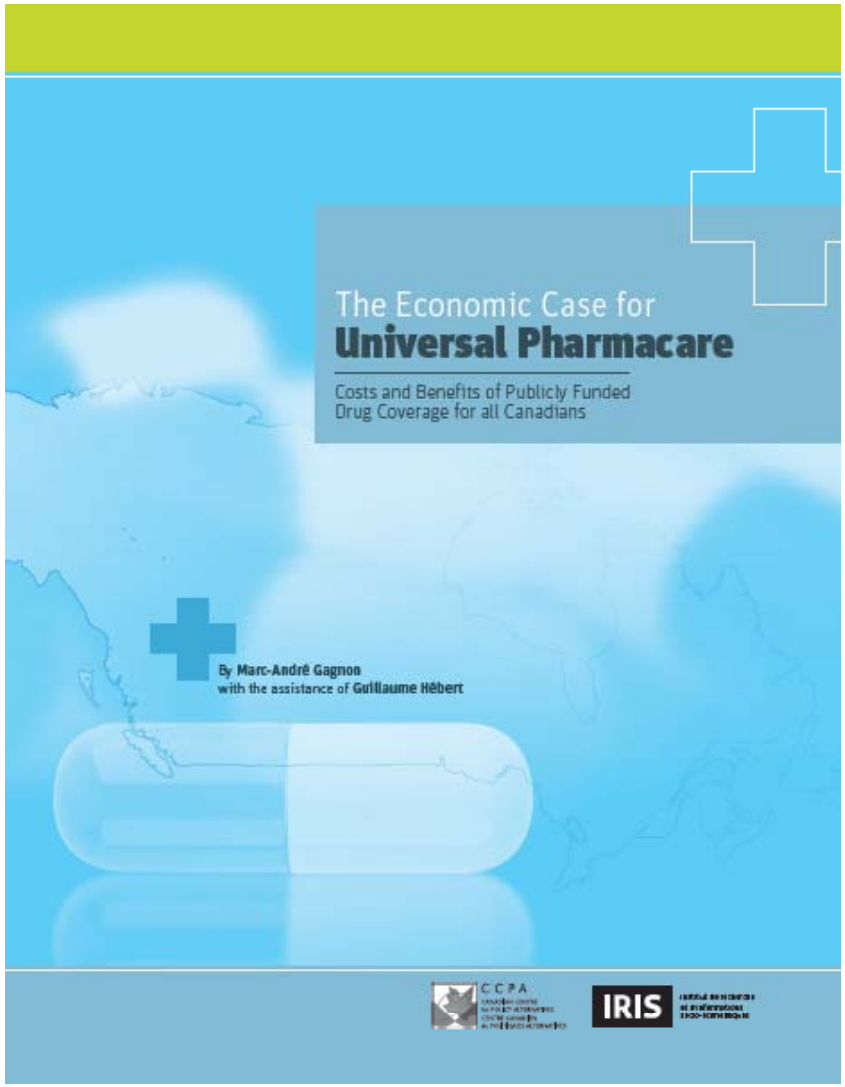
Rank	Within Last 5 years	6-10 years ago	More than 10 years
1	France	France	France
2	Austria	Denmark	Italy
3	USA	Switzerland	Spain
4	Germany	Austria	Germany
5	Spain	Spain	Switzerland
6	Switzerland	Italy	Austria
7	Denmark	Germany	Denmark
8	Sweden	USA	USA
9	Italy	UK	Sweden
10	Norway	Australia	UK
11	Australia	Sweden	Canada
12	UK	Canada	Norway
13	Canada	Norway	Australia
14	New Zealand	New Zealand	New Zealand

Economic case for universal pharmacare

CCPA
CANADIAN CENTRE
for POLICY ALTERNATIVES

<u>Recommendation</u>

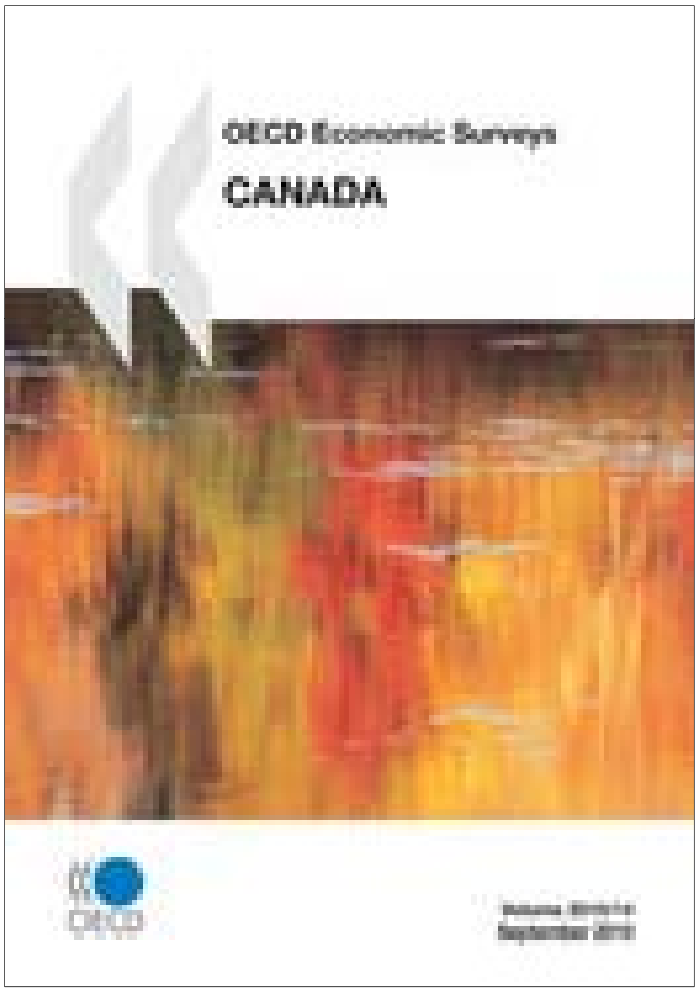
- Universal Pharmacare
- 1st Dollar Coverage
- “New Zealand” model would save billions



OECD Report

Healthcare System Recommendations

- Allow private insurance for core services and mixed public-private contracts for doctors
- Pharmaceuticals, home and therapeutic care should be integrated into the core public package.
- Revenues could be raised and excess demand curbed by implementing capped patient co-payments and deductibles.



Source: OECD, OECD Economic Surveys: Canada, 2010

Outlook for branded drugs (in the new low price generic environment)

- Pricing / PMPRB:
  - Little immediate impact for most patented drugs
- Common Drug Review
  - Will likely recommend fewer new drugs absent lower brand prices or increase in ICER thresholds
  - Confidential listing agreements make cost effectiveness analysis more challenging
- Provincial Drug Plans
  - Provinces will eventually all establish generic pricing policies at 25% of brand price
  - Lower prices for generics will exacerbate budget impact of new drugs
  - Will continue to embrace listing agreements and non-transparent pricing for branded drugs

Implications for brand manufacturers

- In a genericized therapeutic class - options
  - Do not launch
  - Launch with listing agreement with drug plans (financial offsets)
  - Focus on restricted listing (treatment failures) or niche markets not well served within the class
  - Forego public reimbursement (focus on private market)
  - Develop compelling clinical/cost effectiveness arguments, engage patient advocacy
- Most manufacturers will not invest in genericized classes:
  - With little prospect for full reimbursement, even products that offer a moderate may not be developed, launched
  - Manufacturers will invest in classes where generic risk is not imminent

Thank You

Biography

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Neil Palmer is President and Principal Consultant of PDCI Market Access Inc (PDCI) a leading 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 is a leading pricing and reimbursement consultancy with engagements covering Canada, Europe, the US, Latin America and Asia. Established in 1996, the firm has wide-ranging experience assisting clients with pricing, reimbursement and market access as well as pharmaceutical policy and economic research projects. PDCI also maintains extensive databases of international pharmaceutical prices and Canadian drug claims and costs. Headquartered in Ottawa, PDCI features a senior team of market access professionals complemented with a global network of expert consultants in pricing & reimbursement and health economics.