



# The Impact of Patent Expiries on Future Drug Spending in Canada

CAHSPR Conference

May 30, 2012

# Outline

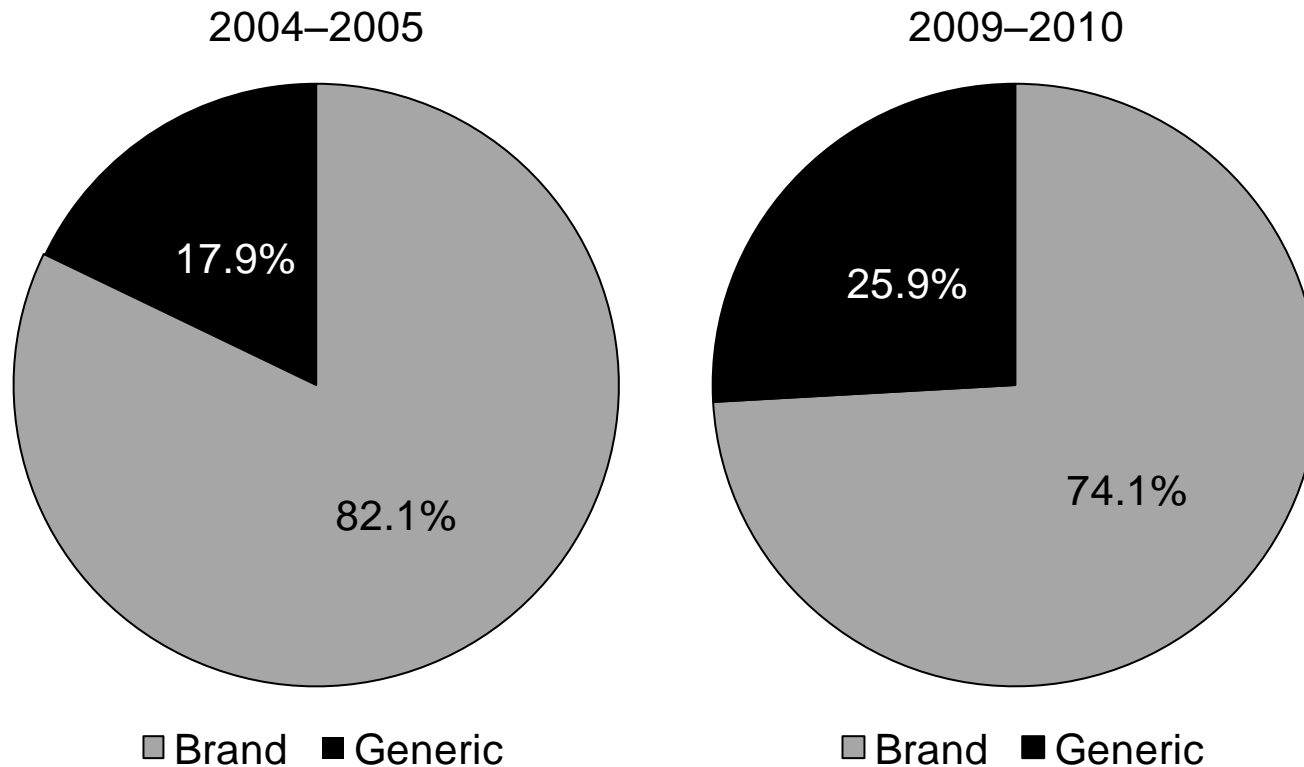
- Background
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# Background

- Generics account for relatively small, but increasing share of drug spending in Canada.
- Generic drug prices in Canada are among the highest in the world.
- Potential savings from generic drugs have become a key issue among Canadian policy-makers.
- Recently, public drug programs in many provinces have reduced the amount they are willing to pay for generic drugs.
- Generic drug prices are regulated to be at most 20% to 56% of brand name prices in most provinces.

# Generic share of spending has increased but remains relatively small

**Percentage Share of Drug Purchases (Drug Stores and Hospitals), Brand Name and Generic, 2004-2005 and 2009-2010**



Source: Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan

# Prices of Generic Drugs in Canada Among the Highest in the World



## Average Foreign-to-Canadian Price Ratios, Generic and Patented Products, 2007

Country	Generic	Patented
Canada	1.00	1.00
Australia	0.90	0.78*
France	0.57	0.81
Germany	0.55	1.00
Italy	0.69	0.78
New Zealand	0.19	0.79*
Sweden	0.38	0.88
Switzerland	0.60	0.82
United Kingdom	0.55	0.88
United States	0.53	1.85

### Notes

\* 2005 figures. Prices compared at purchasing power parities (PPPs).

### Sources

Generic Prices: PMPRB, *Generic Drugs in Canada: Price Trends and International Price Comparisons, 2007* (Ottawa, Ont.: PMPRB, 2007); Patented Prices: PMPRB, *PMPRB Annual Report, 2007* (Ottawa, Ont.: PMPRB, 2007).

# Canadian Generic Pricing Policies

- Policies implemented/updated by most provinces since 2010.
- Generic drug prices are regulated to be at most 20% to 56% of brand name prices, varying by province.
- In some provinces, policies apply to both public and private markets, in others they apply to public only.

# Data Sources and Methods

# Data Sources

- Canadian Drug Store and Hospital Purchases Audit, IMS Brogan
  - Contains sales volumes of dollars and units of pharmaceutical products purchased by retail pharmacies and hospitals.
  - Dollars represent wholesale or manufacturer prices and do not include dispensing fees or retail markups.
- Drug Product Database, Health Canada
  - Information includes DIN, drug product name, chemical, market date
- Patent Register, Health Canada
  - Information includes DIN, drug product name, patent expiry date



# Method for Assigning Patent Expiry Dates

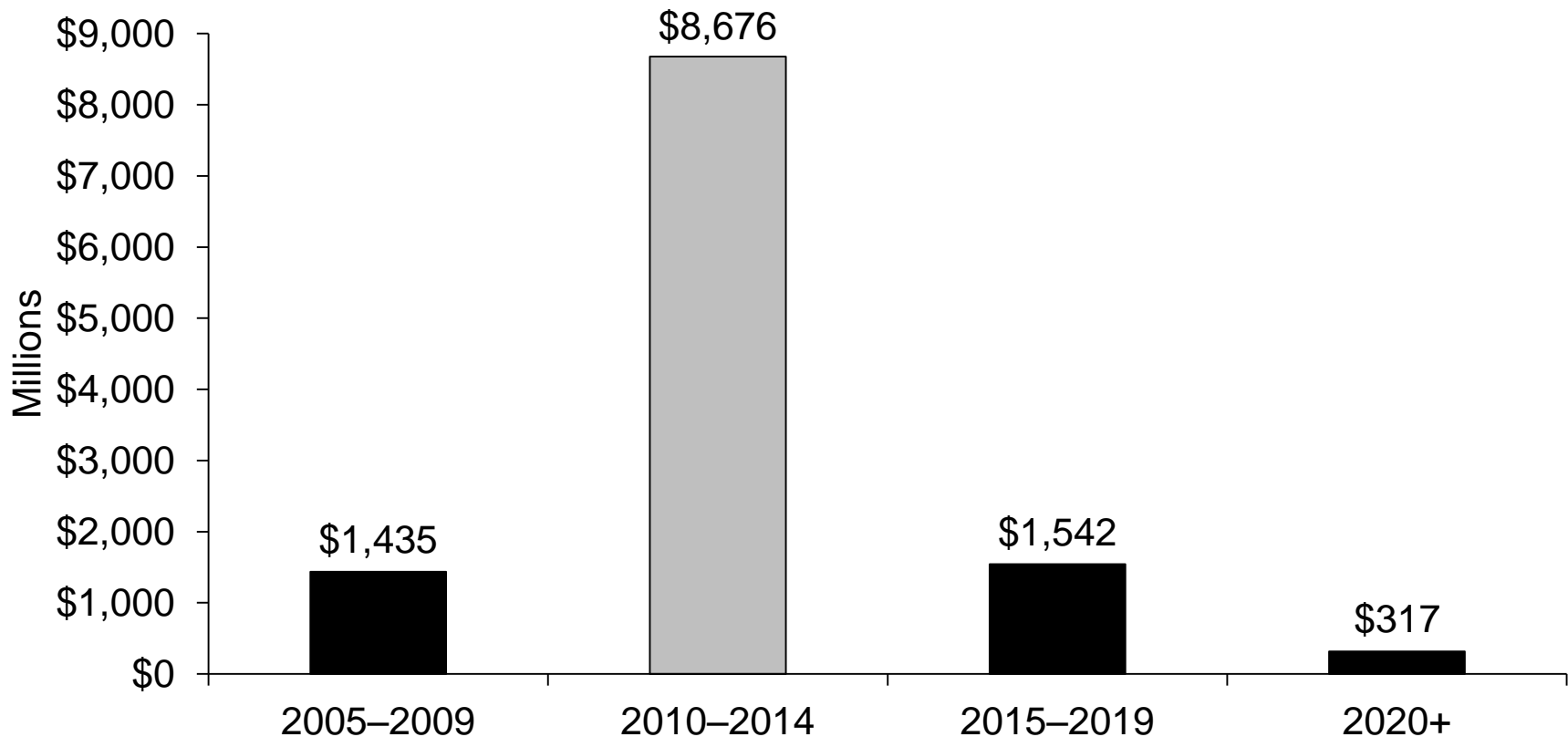
- Not straightforward as multiple patents may apply to a single drug product.
- Comparing generic entry with patent expiries determined earliest patent date was best guess for future expiries.
- If both expired and yet-to-expire patents existed, then:
  - If no generic had come on the market, then the earliest yet-to-expire patent was used to determine patent expiry date.
  - If a generic had come on the market, then the earliest expired patent was used to determine the patent expiry date.
    - Generic versions may enter market before or after patent expiry.
- Expiry dates also validated against news releases, etc., resulting in some case by case changes.

# Results – Spending on Patented Drugs

# Over One-Third of Spending on Drugs with Patents That Will Expire by 2014



**Total 2009 Canadian Wholesales of Patented (or Previously Patented) Drugs, by Year of Patent Expiry, 2005 Onward**



Source: Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan; Patent Register, Health Canada.

# Results Vary Depending on Assumptions Around Future Expiry Dates



## Total 2009 Canadian Wholesales of Patented (or Previously Patented) Drugs, by Year of Patent Expiry, 2005 Onward

<b>Year of Patent Expiry</b>	<b>Percentage of Total 2009 Sales (Earliest Date)</b>	<b>Percentage of Total 2009 Sales (Latest Date)</b>
<b>2005 to 2009</b>	6.3%	6.3%
<b>2010 to 2014</b>	38.2%	20.1%
<b>2015 to 2019</b>	6.8%	16.3%
<b>2020 onward</b>	1.4%	10.2%

Source: Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan; Patent Register, Health Canada.

# Several High-Expenditure Drugs in Canada Have Patents That Have Just Expired or Are About to Expire



**Total 2009 Canadian Wholesales of Drugs With Patents Expiring from 2010 to 2014**

<b>Chemical (Brand Name)</b>	<b>Percentage of Total 2009 Sales</b>
<b>Atorvastatin (Lipitor)</b>	5.5%
<b>Rosuvastatin (Crestor)</b>	2.3%
<b>Infliximab (Remicade)</b>	1.6%
<b>Clopidogrel (Plavix)</b>	1.2%
<b>Esomeprazole (Nexium)</b>	1.2%
<b>Total Value of Patent Expiries</b>	38.2%

Source: Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan; Patent Register, Health Canada.

# Drugs with Patents Expiring After 2014 Account for Lower Proportion of Spending. Biologics Among Largest Expiries.



## Total 2009 Canadian Wholesales of Drugs With Patents Expiring from 2015 to 2019

<b>Chemical (Brand Name)</b>	<b>Percentage of Total 2009 Sales</b>
<b>Ranibizumab (Lucentis)</b>	0.5%
<b>Glatiramer Acetate (Copaxone)</b>	0.4%
<b>Adalimumab (Humira)</b>	0.4%
<b>Oxaliplatin (Eloxatin)</b>	0.4%
<b>Tadalafil (Cialis)</b>	0.3%
<b>Total Value of Patent Expiries</b>	6.8%

Source: Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan; Patent Register, Health Canada.

# Drugs with Patents Expiring After 2014 Account for Lower Proportion of Spending. Biologics Among Largest Expiries.



## Total 2009 Canadian Wholesales of Drugs With Patents Expiring from 2020 onward

<b>Chemical (Brand Name)</b>	<b>Percentage of Total 2009 Sales</b>
<b>Interferon Beta-1A (Avonex)</b>	0.3%
<b>Sunitinib (Sutent)</b>	0.2%
<b>Leuprolide Acetate (Eligard)</b>	0.1%
<b>Sitagliptin (Januvia)</b>	0.1%
<b>Betamethasone &amp; Calcipotriol (Dovobet)</b>	0.1%
<b>Total Value of Patent Expiries</b>	1.4%

Source: Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan; Patent Register, Health Canada.

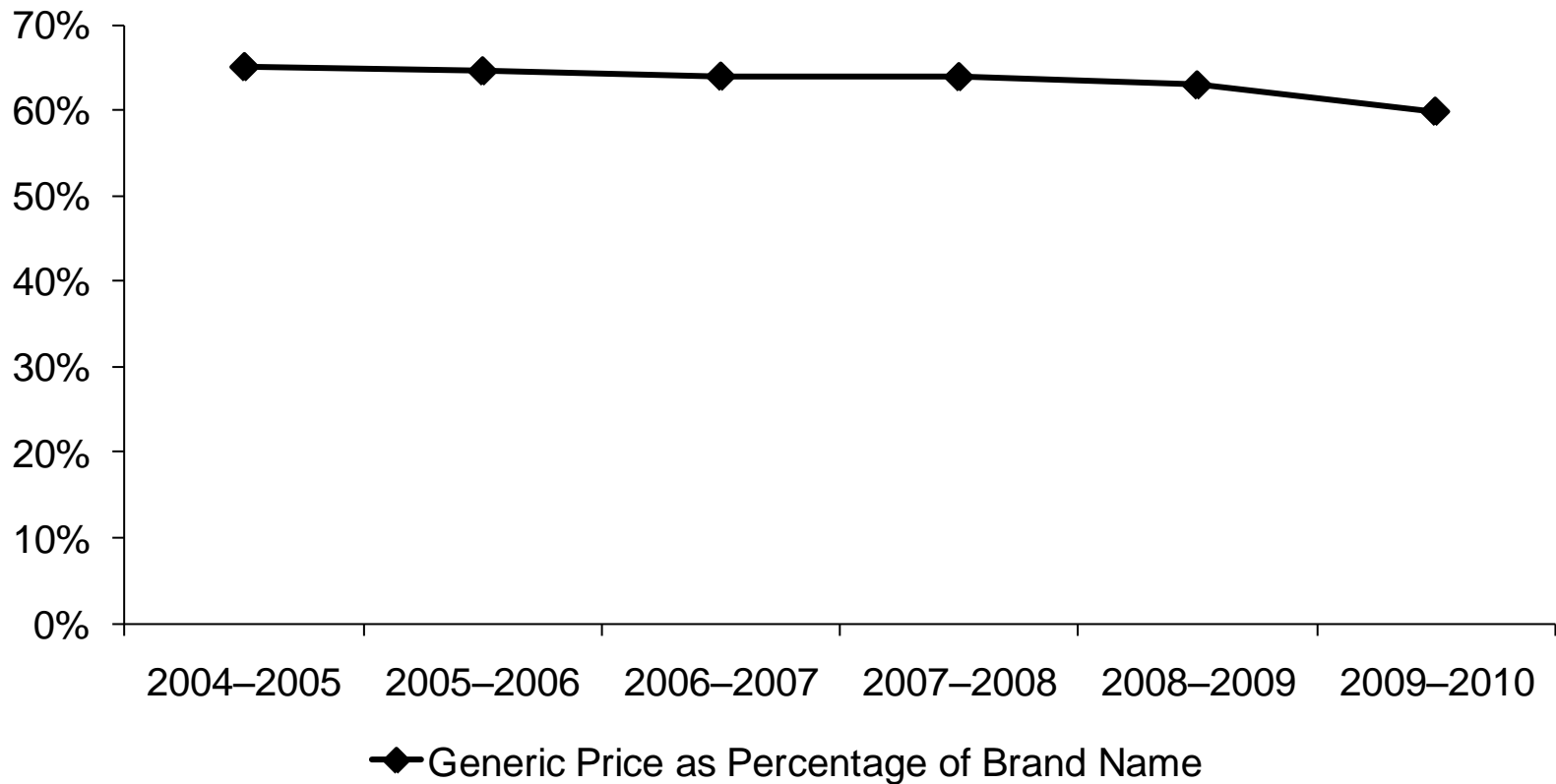
# Results – Potential Savings



# Generic Prices, on Average, Are Approximately 60% of Brand Name Prices



**Average Generic Price as Percentage of Brand Name Prices,  
Top 100 Drugs With Available Generics, 2004–2005 to 2009–2010**



Source: Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan

# Drugs with Patents Expiring After 2014 Account for Lower Proportion of Spending. Biologics Among Largest Expiries.



## Potential Savings from Patent Expiries Based on 2009 Wholesale Spending, by Average Generic Price

Avg. Generic Price as % of Brand Name Price	Potential Savings (\$ Billions)		
	2010-2014	2015-2019	2020+
60%	3.5	0.6	0.1
50%	4.3	0.8	0.2
40%	5.2	0.9	0.2
30%	6.1	1.1	0.2
25%	6.4	1.2	0.2
20%	6.9	1.2	0.3

Source: Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan; Patent Register, Health Canada.

# Results

- Potential savings from patent expiries between 2010 and 2014 range from \$3.5 to \$6.9 billion.
- True savings will depend on impact of pricing policies, particularly on private side.
- Although many people switch to lower-cost generic products following a patent expiry, other factors can offset potential savings. These include:
  - Patients who continue taking the brand name product following patent expiry.
  - Increased use of other patented products within the same drug class.
  - Patients starting on a generic who were not previously taking the brand name product.

# Conclusion

- Majority of savings to come in short-term.
- Generic pricing policies increase potential savings, but do not result in long-term reduction in spending growth.
- Savings due to patent expiries may not be available, at least not to same degree, for biosimilars.
  - Uncertainty as to the regulatory requirements, manufacturing processes and pricing for “generic” versions of biologics.