Potential Savings from Biosimilars in Canada

The PMPRB is an independent quasi-judicial body established by Parliament in 1987 under the Patent Act (Act), with a dual role:

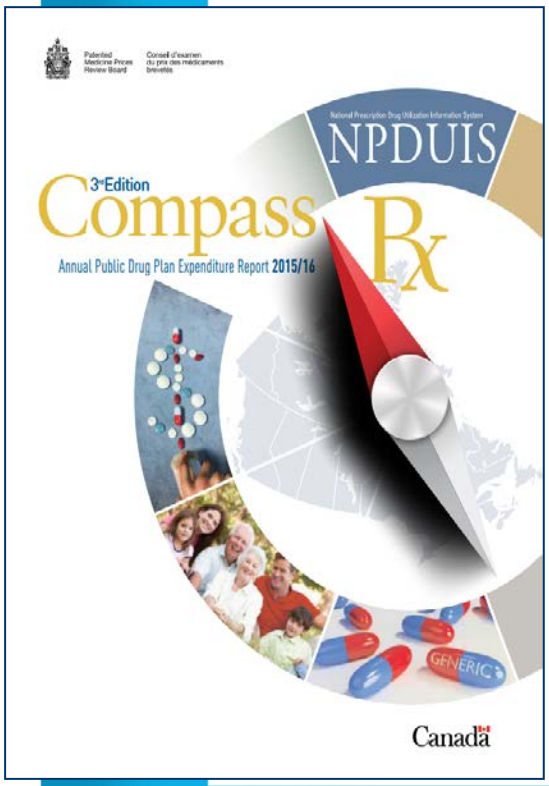
- Regulatory – To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive. The PMPRB was created as part of a major overhaul of Canada's drug patent regime, which sought to balance two policy objectives:
  - The government strengthened patent protection for drugs in an effort to encourage more pharmaceutical industry research and development investment in Canada.
  - Simultaneously, it sought to mitigate the financial impact of that change on Canadians by creating the PMPRB.
- Reporting – To report on pharmaceutical trends of all medicines and on R&D spending by patentees.

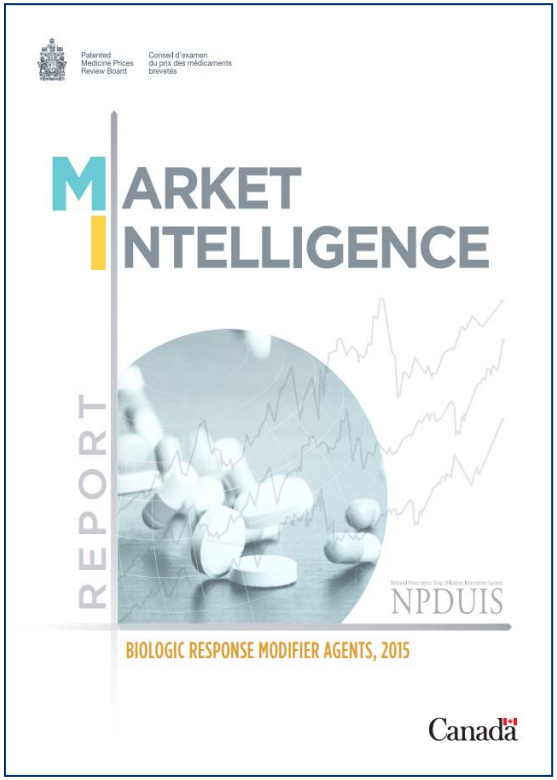
National Prescription Drug Utilization Information System
NPDUIS

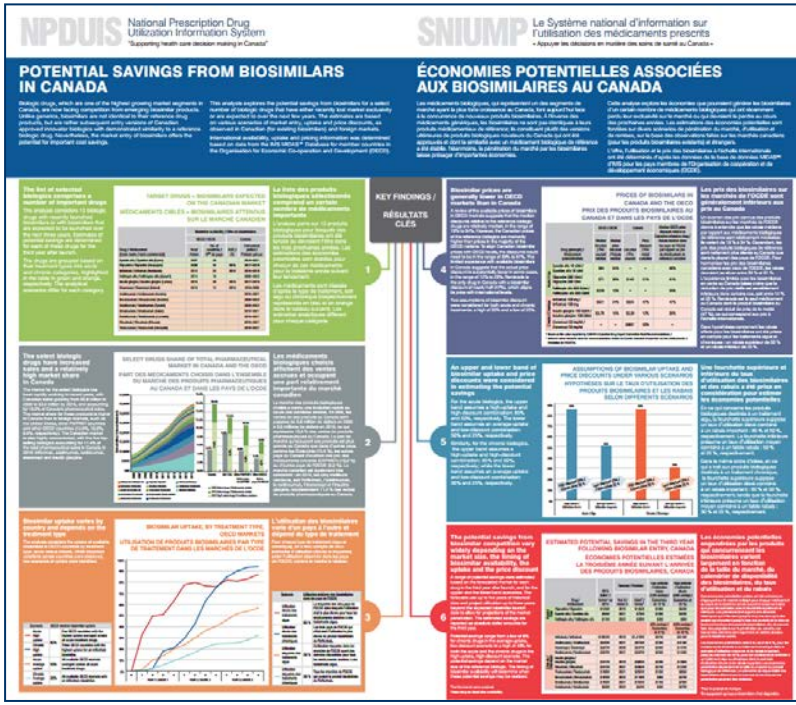
- NPDUIS is a research initiative established by federal, provincial, and territorial Ministers of Health in September 2001, as a partnership between the PMPRB and the CIHI;
- It operates independently from the PMPRB's regulatory activities;
- Pursuant to s.90 of the Patent Act, the PMPRB has the mandate to generate analysis that provides policy makers and public drug plan managers with critical information and intelligence on price, utilization and cost trends.

PMPRB analytical reporting on biologics and biosimilars

- Under the NPDUIS banner and at the request of the jurisdictions participating in the NPDUIS initiative:







Available at: http://www.pmprb-cepmb.gc.ca/en/npduis/analytical-studies

C. Biosimilars savings

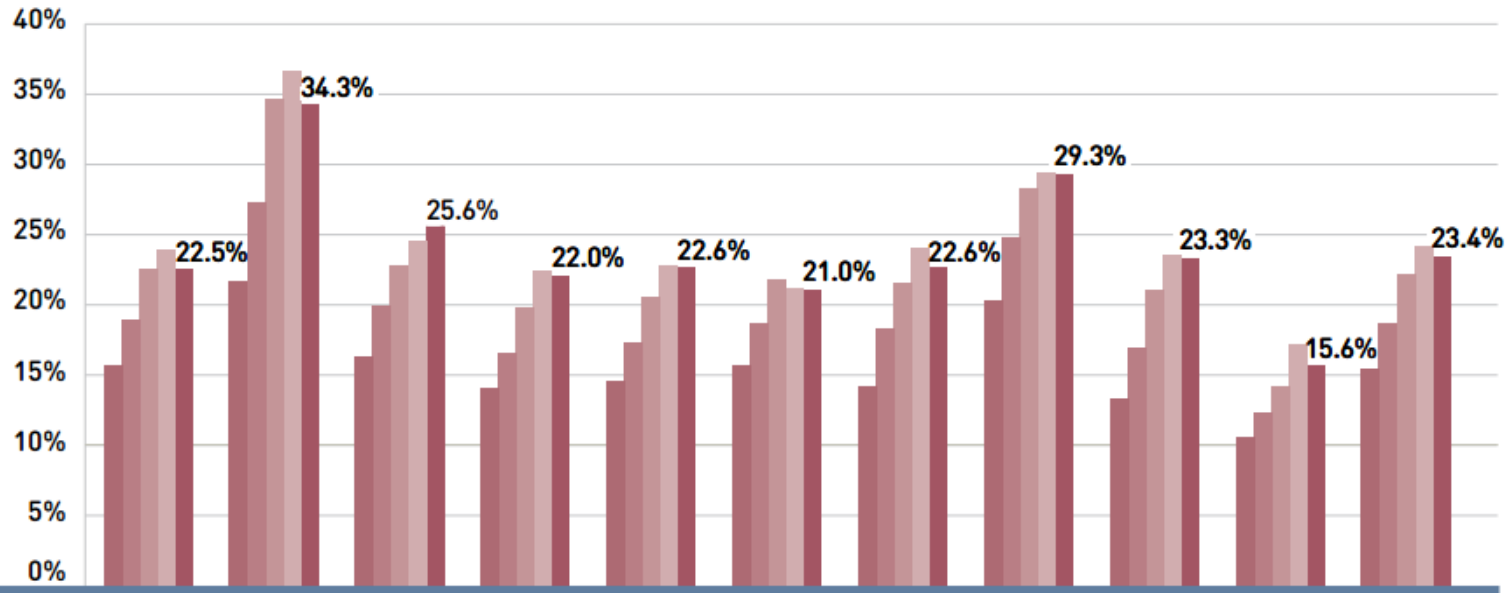
Are a function of:

1. **Importance of drugs (e.g. sales)**
   - Biologics with larger sales have a greater biosimilar saving potential
2. **Timing of biosimilar market entry**
   - Earlier market entry allows for the savings to be realized sooner
3. **Biosimilar uptake (e.g. use)**
   - Increased market penetration of the biosimilar = Greater saving potential
4. **Price discount**
   - Greater price discount = Greater saving potential

Molecule	2016 Canadian sales
Infliximab	$ 1,008M
Adalimumab	$ 649M
Etanercept	$ 337M
Ranibizumab	$ 337M
Insulin glargine	$ 259M
Trastuzumab	$ 251M
Rituximab	$ 241M
Filgrastim	$ 128M
Omalizumab	$ 106M
Bevacizumab	$ 104M
Epoetin alfa	$ 99M
Natalizumab	$ 50M
Follitropin alfa	$ 14M

Biologics growing importance in NPDUIS public drug plan costs

Figure 3.7 Biologic share of total drug costs, NPDUIS public drug plans, 2011/12 to 2015/16

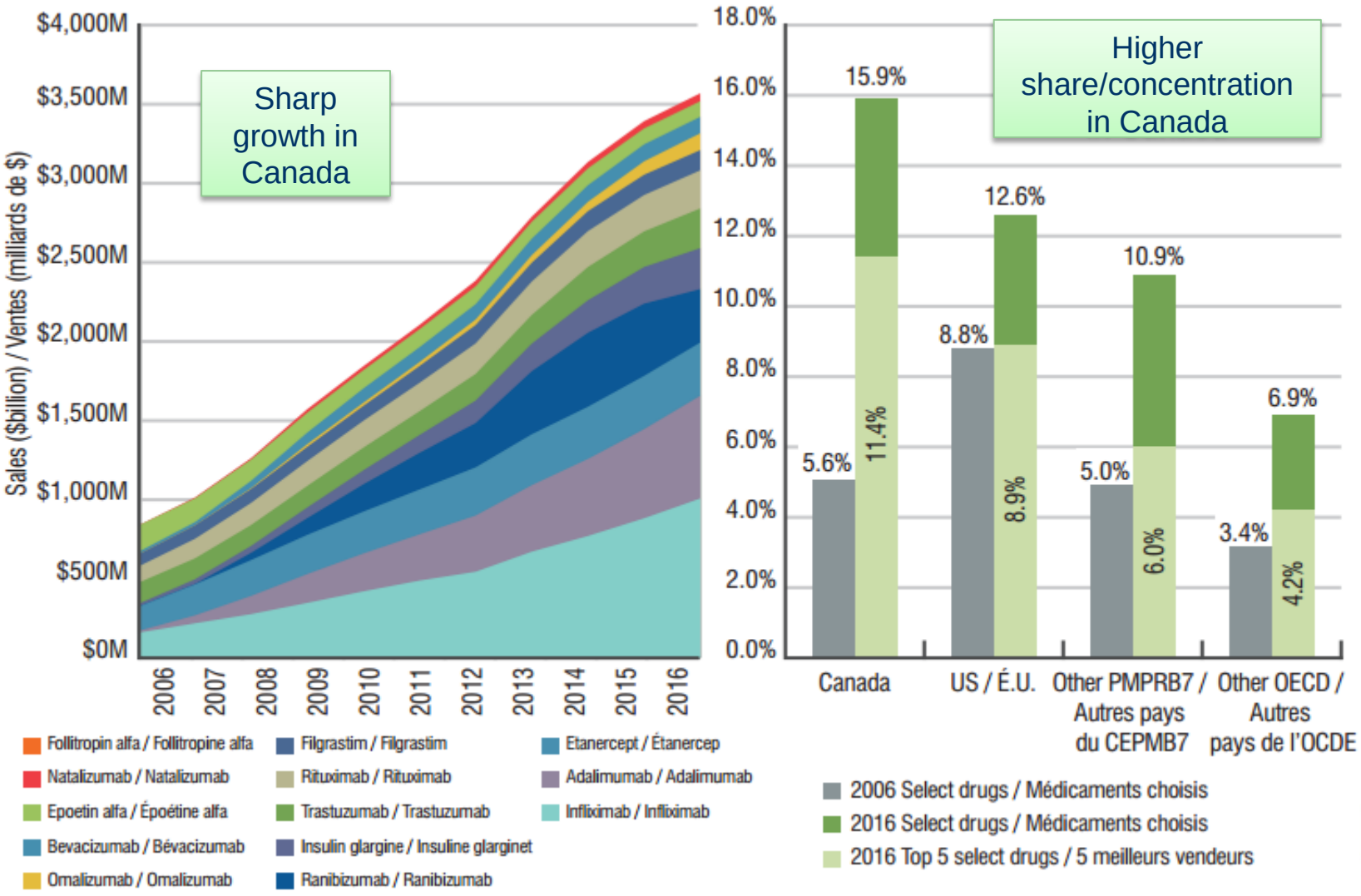


% Growth	BC	AB	SK	MB	ON	NB	NS	PE	NL	NIHB	Total*
2011/12	15.2%	19.4%	16.2%	15.2%	16.3%	12.7%	19.5%	18.4%	22.1%	20.4%	16.6%
2012/13	16.3%	22.2%	17.6%	8.8%	19.6%	7.7%	19.1%	11.4%	16.8%	19.0%	17.9%
2013/14	14.0%	21.7%	19.6%	15.1%	26.0%	7.5%	17.9%	3.8%	10.5%	17.8%	21.0%
2014/15	7.0%	6.1%	11.0%	14.1%	13.8%	-2.6%	9.4%	-3.6%	8.7%	11.8%	11.1%
2015/16	9.7%	3.4%	9.7%	5.4%	11.1%	4.9%	-0.4%	1.4%	0.6%	11.6%	8.9%

Data source: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

Source: PMPRB CompassRx, 3rd edition

Important biologics lost/expected to lose patent protection and face biosimilar competition



Source: MIDAS™ Database, IMS AG. All rights reserved.

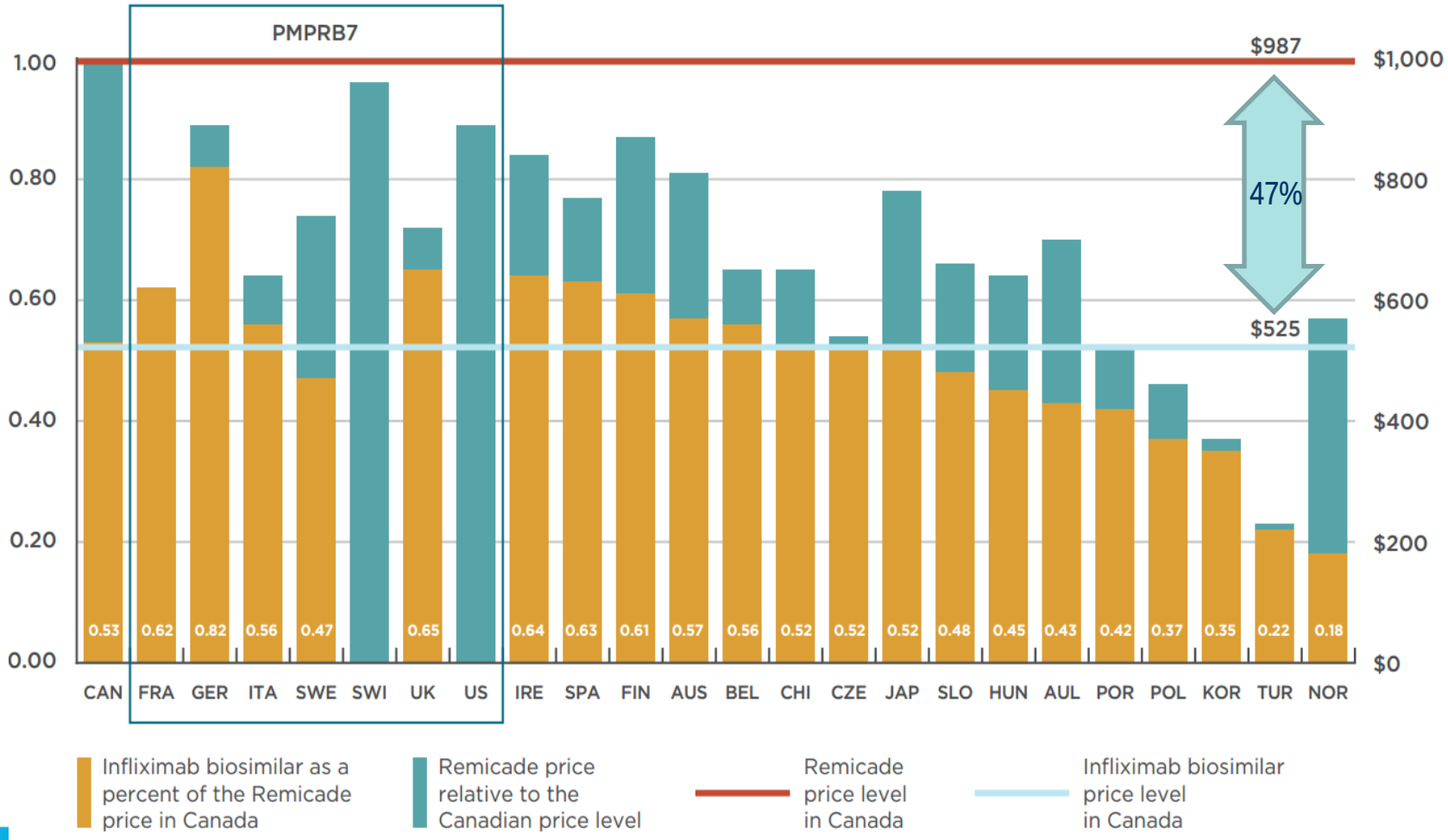
Many foreign markets have earlier biosimilar availability

Drug / Médicament (trade name / nom commercial)	Biosimilar availability / Offre de biosimilaires			
	OECD / OCDE		Canada	
	Year/ Année	No. of countries / Nbre de pays	NOC / AC	Forecasted period / Période prévue
Epoetin alfa / Époétine alfa (Eprex)	2007	20		2019–2021
Filgrastim / Filgrastim (Neupogen)	2008	26	2015	2017–2019
Infliximab / Infliximab (Remicade)	2012	24	2014	2016–2018
Follitropin alfa / Follitropine alfa (Gonal-f)	2014	18		2020–2022
Insulin glargine / Insuline glargine (Lantus)	2015	20	2015	2017–2019
Etanercept / Étanercept (Enbrel)	2016	12	2016	2018–2020
Adalimumab / Adalimumab (Humira)				2019–2021
Bevacizumab / Bévacizumab (Avastin)				2020–2022
Natalizumab / Natalizumab (Tysabri)				2020–2022
Omalizumab / Omalizumab (Xolair)				2019–2021
Ranibizumab / Ranibizumab (Lucentis)				2019–2021
Rituximab / Rituximab (Rituxan)				2019–2021
Trastuzumab / Trastuzumab (Herceptin)				2019–2021

3. Biosimilar discount

Reference price – biosimilar price

The infliximab experience



Source: Market Intelligence Report: Biologic Response Modifier Agents, 2015, PMPRB, NPDUIS

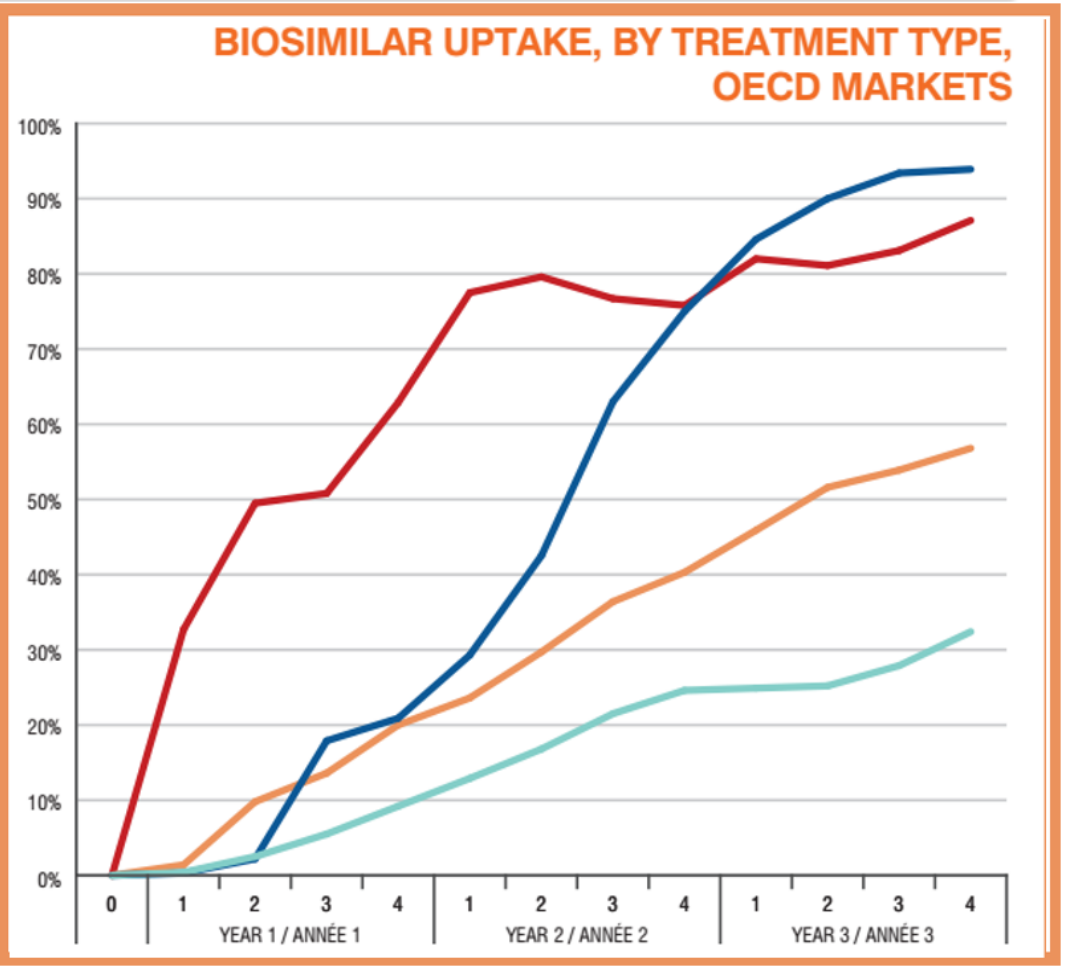
Greater biosimilar discounts would bring Canadian prices in line with OECD medians

	Drug (strength) / Médicament (concentration)	OECD / OCDE		Canada		Median OECD price discount relative to Canadian reference drug / Rabais médian dans les pays de l'OCDE par rapport au prix du médicament de référence canadien
		Median list price / Prix courant médian	Median price discount / Rabais médian	List price / Prix courant	Price discount / Prix réduit canadien	
Acute / Aigu	Epoetin alfa 10 k/ml / Époétine alfa 10 k/ml	$84	34%	–	–	60%
Acute / Aigu	Filgrastim 300 Y/ml / Filgrastim 300 Y/ml	$71	30%	$143	21%	61%
Acute / Aigu	Follitropin alfa 600 IU/ml / Follitropine alfa 600 UI/ml	$228	13%	–	–	59%
Chronic / Chronique	Infliximab 100 mg / Infliximab 100 mg	$521	24%	$525	47%	47%
Chronic / Chronique	Insulin glargine 100 IU/ml / Insuline glargine 100 UI/ml	$3.78	16%	$5.39	12%	39%
Chronic / Chronique	Etanercept 50 mg/ml / Étanercept 50 mg/ml	–	–	$305*	23%	–

* Based on the value reported by CADTH's Canadian Drug Expert Committee Final Recommendations /

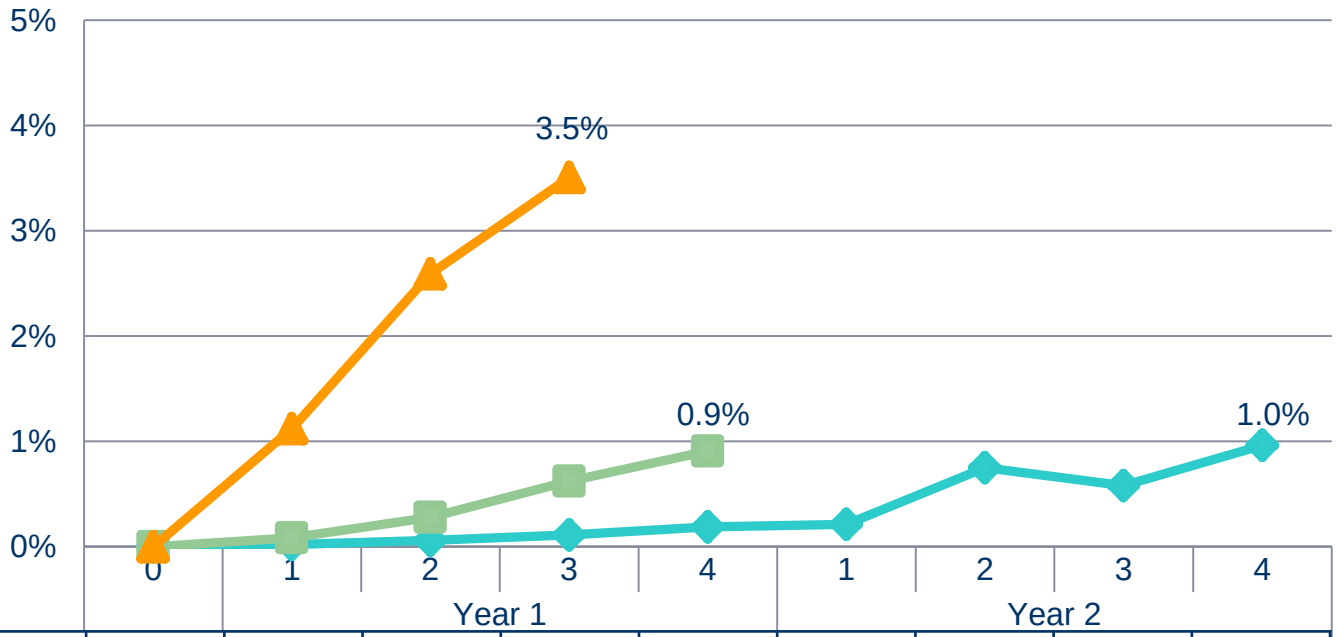
International experience with biosimilar uptake

Scenario	OECD median biosimilar uptake	
Acute High uptake	85%	Five OECD countries with the highest uptake averaged across all acute treatment drugs.
Chronic High uptake		Three OECD countries with the highest uptake for an infliximab biosimilar.
Acute Average uptake	50%	All available OECD markets averaged across all acute treatment drugs.
Chronic Average uptake	30%	All available OECD markets with an infliximab biosimilar.



Modest biosimilar uptake in Canada

Biosimilar share of sales, by molecule, quarterly trends ending Q4-2016



Biosimilars Sales ($M)									
Infliximab	$0.00	$0.03	$0.08	$0.17	$0.30	$0.32	$1.06	$0.85	$1.44
Insulin Glargine	$0.00	$0.04	$0.14	$0.31	$0.48				
Filgrastim	$0.00	$0.26	$0.62	$0.91					

Potential Savings from Biosimilars in Canada

Drug	2016 Sales*	Forecast Year 3	Forecast Sales†	Low discount: 25% Avg. uptake: 50% Low estimate	High discount: 50% High uptake: 85% High estimate
Acute				13% savings	43% savings
Filgrastim	$126M	2019	$145M	$18M	$62M
Epoetin alfa	$99M	2021	$75M	$10M	$32M
Follitropin alfa	$14M	2022	$20M	$3M	$8M
Chronic				8% savings	43% savings
Infliximab	$1004M	2018	$1,210M	$91M	$514M
Adalimumab	$649M	2021	$974M	$73M	$414M
Etanercept	$337M	2020	$347M	$26M	$147M
Ranibizumab	$337M	2021	$337M	$25M	$143M
Insulin glargine	$241M	2019	$306M	$23M	$130M
Rituximab	$241M	2021	$286M	$21M	$122M
Trastuzumab	$180M	2021	$202M	$15M	$86M
Bevacizumab	$104M	2022	$110M	$8M	$47M
Omalizumab	$106M	2021	$184M	$14M	$78M
Natalizumab	$50M	2022	$62M	$5M	$27M

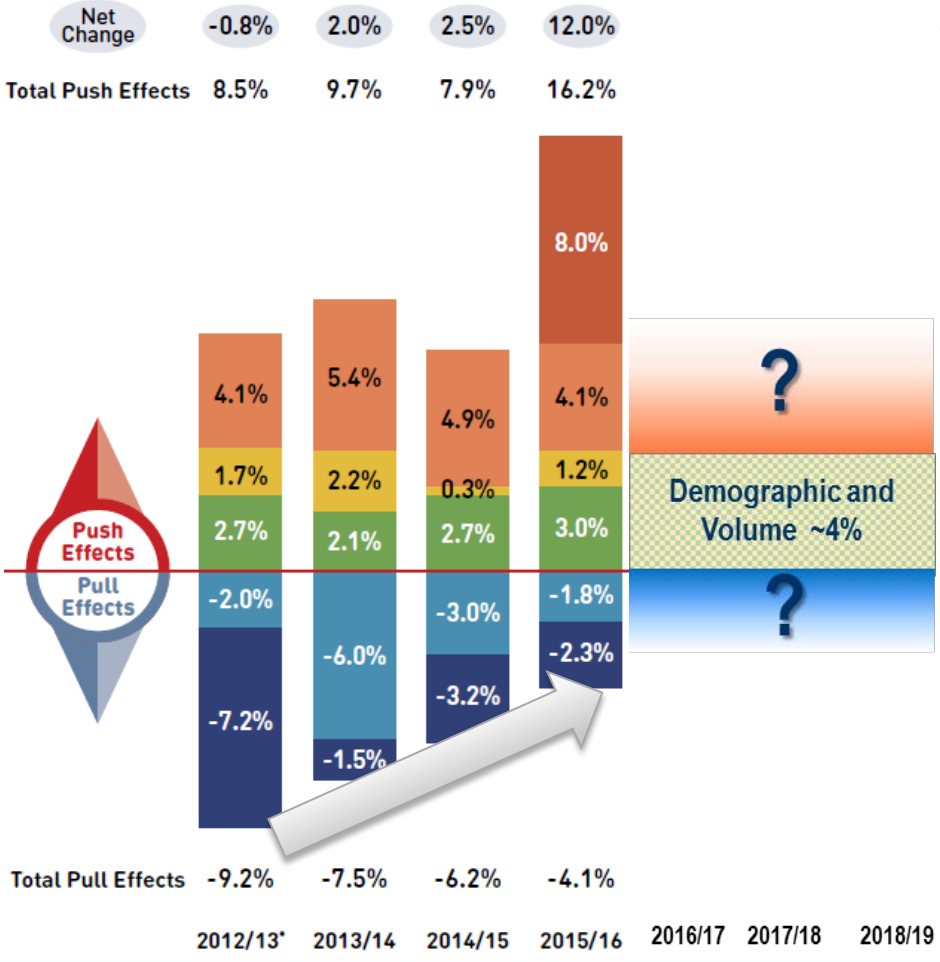
*For the brand name product.

† Assuming no biosimilar availability.

Low discount: 25% Avg. uptake: 30%	High discount: 50% High uptake: 85%
$0.33B	$1.8B

Source: PMPRB poster: *Potential Savings from Biosimilars in Canada, 2016*

Why biosimilar savings matter?



Top patented drugs in NPDUIS public drug plans

Rank	Trade name (Ingredient)	Total†	Marketed years
1	Harvoni (sofosbuvir, ledipasvir)	$455.33	2
2	Remicade (infliximab)	$351.27	15
3	Lucentis (ranibizumab)	$336.60	9
4	Humira (adalimumab)	$226.54	10
5	Advair (salmeterol, fluticasone propionate)	$156.86	17
6	Enbrel (etanercept)	$139.86	15
7	Sovaldi (sofosbuvir)	$124.91	3
8	Lantus (insulin glargine	$124.64	11
9	Cymbalta (duloxetine)	$101.63	8
10	Coversyl (perindopril erbumine)	$100.26	22

Biologic products

†Totals drug cost is in millions

Source: PMPRB CompassRx, 3rd edition

Data source: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

Conclusions

A. Pharmaceutical cycle

- Beyond patent protection period, drug spending on branded products may mean lost opportunities to fund newer treatment options.

B. Canada's experience with biologics

- The relatively higher use of biologics in Canada means Canadians have the most to gain from potential biosimilar savings.

C. Biosimilars savings

- Have been modest to date due to the low uptake.
- At current Canadian price discounts for a number of biosimilars (~25%) and average OECD uptake (30% by 3rd year), the savings would be limited: 8% or tens of millions of dollars for top-selling biologics.
- The price discount of recent biosimilars (15%-23%) has resulted in relatively higher prices in Canada (except for the biosimilar of infliximab);
- Greater biosimilar discounts (30%-60%) would result in closer alignment with OECD price levels and greater saving potential;
  - At the same time, greater biosimilar uptake (e.g. 85%) could results in savings as high as 43%, or hundreds of millions of dollars for top-selling biologics.
- Biosimilars could offer yearly savings of $1.8 billion.