



Patented  
Medicine Prices  
Review Board

Conseil d'examen  
du prix des médicaments  
brevetés

# **Biosimilars in Canada: Current Environment**



**Jeffrey Menzies, Manager**  
**Patented Medicine Prices Review Board, Government of Canada**

# Conflict of interest disclosure

➤ No conflicts of interest to declare.

# About the PMPRB

Independent, quasi-judicial agency that regulates ceiling prices of all patented drugs sold in Canada.

Created in 1987 as part of a major overhaul of Canada's drug patent regime, which sought to balance competing policy objectives:

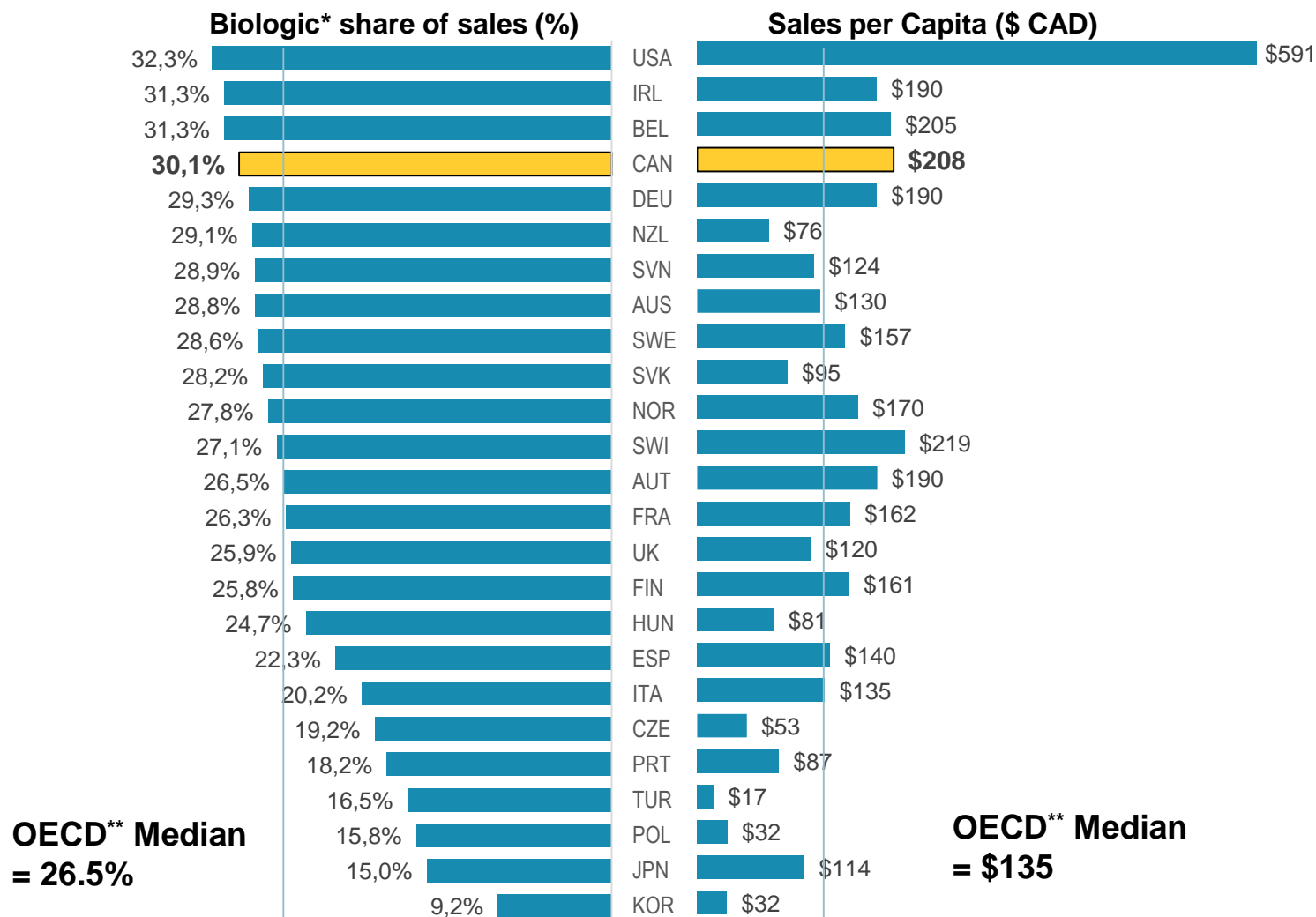
- Strengthen patent protection for drug manufacturers to incentivize pharmaceutical R&D in Canada.
- Protect Canadian consumers by preventing patentees from abusing their patent rights and charging excessive patented drug prices

The PMPRB assesses new medicines for level of therapeutic benefit relative to existing therapies and determines a ceiling price that is based on either:

1. The median international price;
2. The highest price in the domestic therapeutic class, or;
3. A combination of the two.

PMPRB allows CPI increases but never to the point of becoming highest of the PMPRB7.

# Biologics – an important segment of the Canadian pharmaceutical market



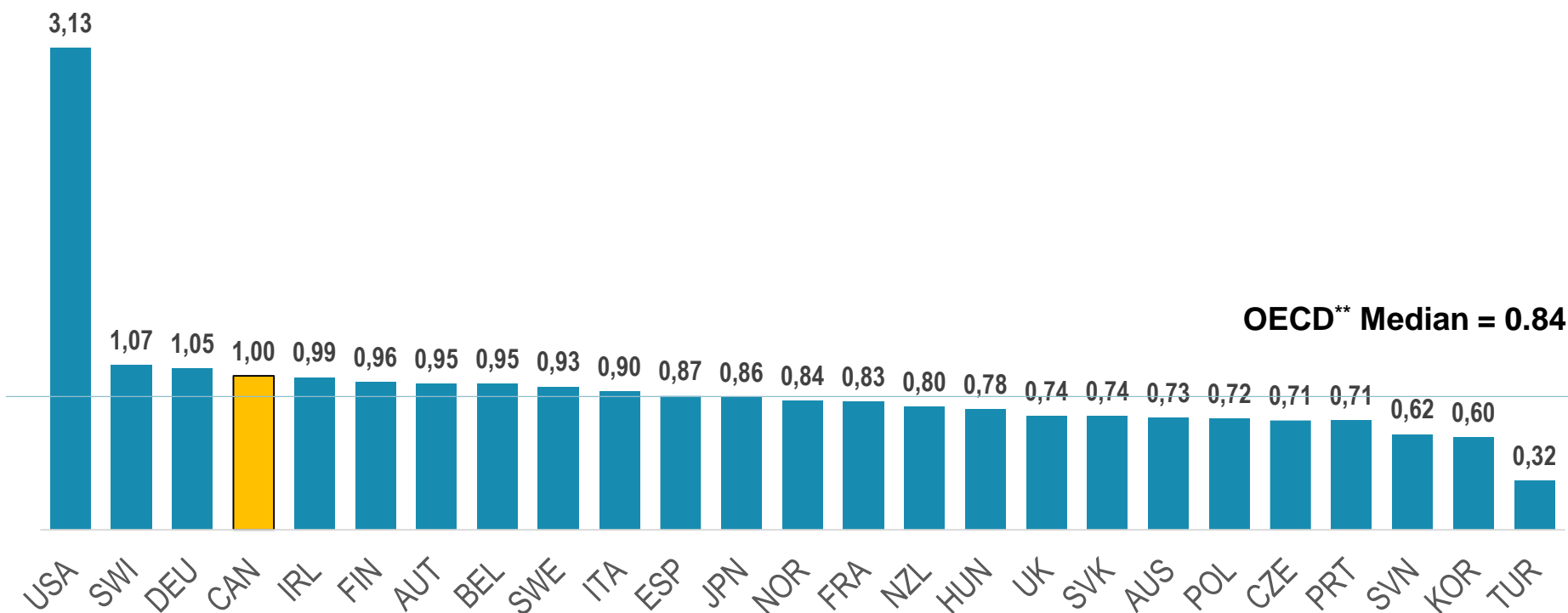
Data source: MIDAS™ Database, prescription retail and hospital markets, 2018, IQVIA. All rights reserved.

\*Includes patented and non-patented biologics in Canada as of 2018.

\*\*Countries with limited sales data were excluded from this analysis.

# Canada has the fourth highest prices for biologics

Average foreign-to-Canadian price ratios, biologics\*, OECD, 2018

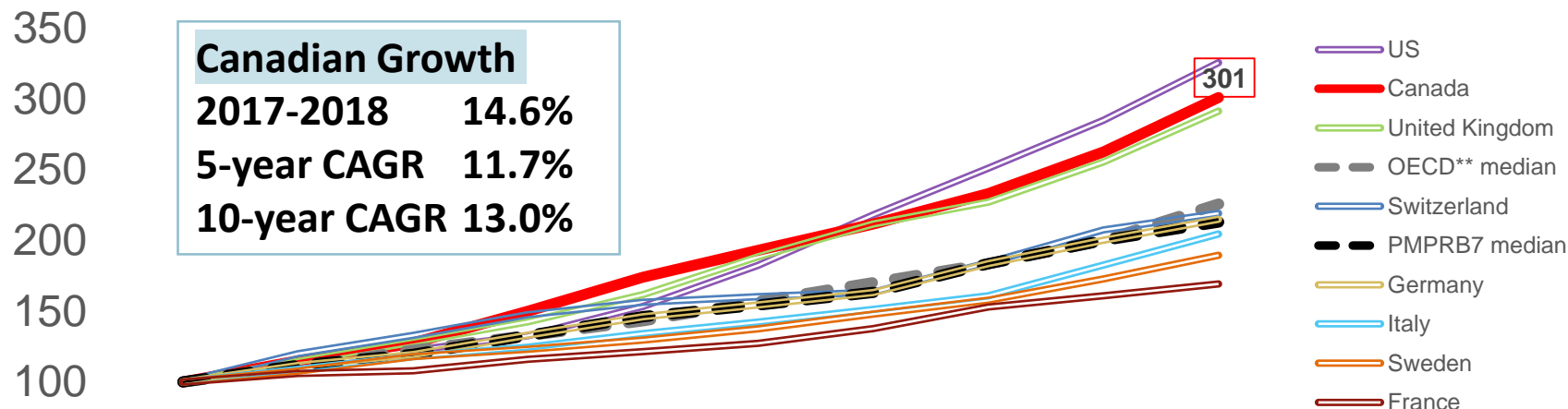


Data source: MIDAS™ Database, prescription retail and hospital markets, 2018, IQVIA. All rights reserved.  
Includes all prescription biologics and insulin biologics in Canada as of 2018. Biosimilar medicines were excluded from the pricing analysis

\*\*Countries with limited sales data were excluded from this analysis

# Biologics sales are on the rise, despite biosimilar availability in high-sales areas

## Biologic\* sales index, Canada and PMPRB7, 2009 to 2018



Trends in Canadian sales, biologics and biosimilars	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
<b>Biologic sales—total (\$)</b>	<b>\$2.6B</b>	<b>\$2.9B</b>	<b>\$3.3B</b>	<b>\$3.8B</b>	<b>\$4.5B</b>	<b>\$4.9B</b>	<b>\$5.4B</b>	<b>\$6.0B</b>	<b>\$6.7B</b>	<b>\$7.7B</b>
Share of pharmaceutical sales (%)	13.5%	15.1%	17.2%	19.9%	22.7%	24.0%	24.7%	25.9%	27.4%	30.0%
Sales per capita (\$)	76.0	86.4	94.9	110.4	126.6	138.9	151.0	164.3	182.9	207.7
<b>Biosimilar sales (M\$)</b>	<b>&lt;0.1</b>	<b>0.1</b>	<b>0.9</b>	<b>\$2.0</b> <b>(0.1%)</b>	<b>\$3.3</b> <b>(0.1%)</b>	<b>\$4.3</b> <b>(0.1%)</b>	<b>\$5.7</b> <b>(0.1%)</b>	<b>\$12.5</b> <b>(0.2%)</b>	<b>\$60.8</b> <b>(0.9%)</b>	<b>\$146.3</b> <b>(1.9%)</b>

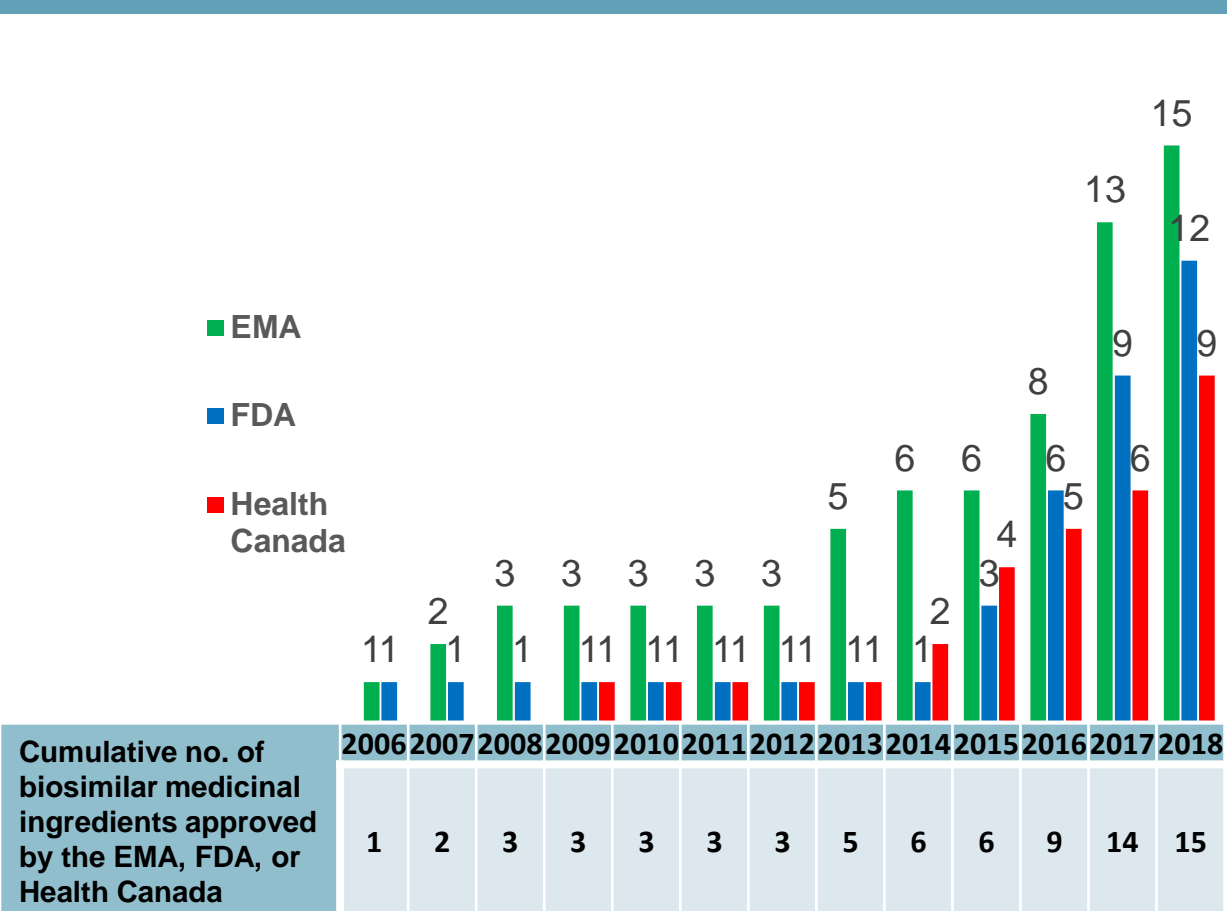
Data source: MIDAS™ Database, prescription retail and hospital markets, 2018, IQVIA. All rights reserved.



\*Includes all prescription biologics and insulin biologics in Canada as of 2018.

\*\* Canada is excluded from the median

Indexed figures are reported in local currency with the sales in 2009 set to a value of 100.

# Biosimilar availability: Canada lags behind Europe



Biologic	 Launch\$	 Launch\$	 Launch\$
Infliximab	Q4-2013	Q4-2016	Q1-2015
Adalimumab	Q4-2018		
Etanercept	Q1-2016		Q4-2016
Trastuzumab	Q2-2018		
Insulin glargine	Q2-2015	Q4-2016	Q1-2016
Rituximab	Q2-2017		
Filgrastim	Q4-2008	Q3-2015	Q2-2016
Bevacizumab			
Epoetin alfa	Q4-2007	Q3-2018	
Insulin lispro	Q4-2017	Q1-2018	
Enoxaparin‡	Q1-2017	NA‡	
Pegfilgrastim	Q4-2018	Q3-2018	
Somatropin	Q2-2006	Q1-2007	Q3-2009
Teriparatide			
Follitropin alfa	Q2-2014		
<b>Total</b>	<b>13</b>	<b>7</b>	<b>5</b>

‡ Enoxaparin (Lovenox) was not approved under a Biologic License Application in the US. While generic versions of this medicine have been approved under the FDA's Abbreviated New Drug Application, they are not considered to be biosimilars in the US and thus are not reflected in this analysis.

Data source: MIDAS™ Database, prescription retail and hospital markets, 2017-2018, IQVIA. All rights reserved.

# Biosimilars are often priced higher in Canada

**Biosimilar prices are generally higher, despite offering comparable discounts, likely due to higher originator prices prevailing in Canada**

Biosimilar	Price in Canada (\$CAD)	Foreign-to-Canadian price ratios		Biosimilar discount relative to reference biologic price*		
		PMPRB7	OECD	Canada	PMPRB7	OECD
Infliximab	535.95	1.09	0.83	45.8%	33.2%	35.5%
Adalimumab					26.4%	34.9%
Etanercept	259.68	0.91	0.82	34.3%	31.1%	30.8%
Insulin glargine	14.31	0.84	0.77	23.6%	16.6%	20.3%
Rituximab					27.5%	28.5%
Trastuzumab					17.6%	27.7%
Filgrastim	166.41	0.61	0.37	21.0% <sup>†</sup>	36.3%	51.4%
Epoetin alfa					34.6%	35.9%
Insulin lispro					17.3%	21.8%
Enoxaparin					22.9%	22.9%
Pegfilgrastim						28.0%
Somatropin	262.42	1.70	1.01	**	28.8%	37.6%
Follitropin alfa					16.93%	20.48%
<b>Sales-weighted average</b>		<b>0.85</b>	<b>0.61</b>	<b>30.0%</b>	<b>26.0%</b>	<b>30.7%</b>

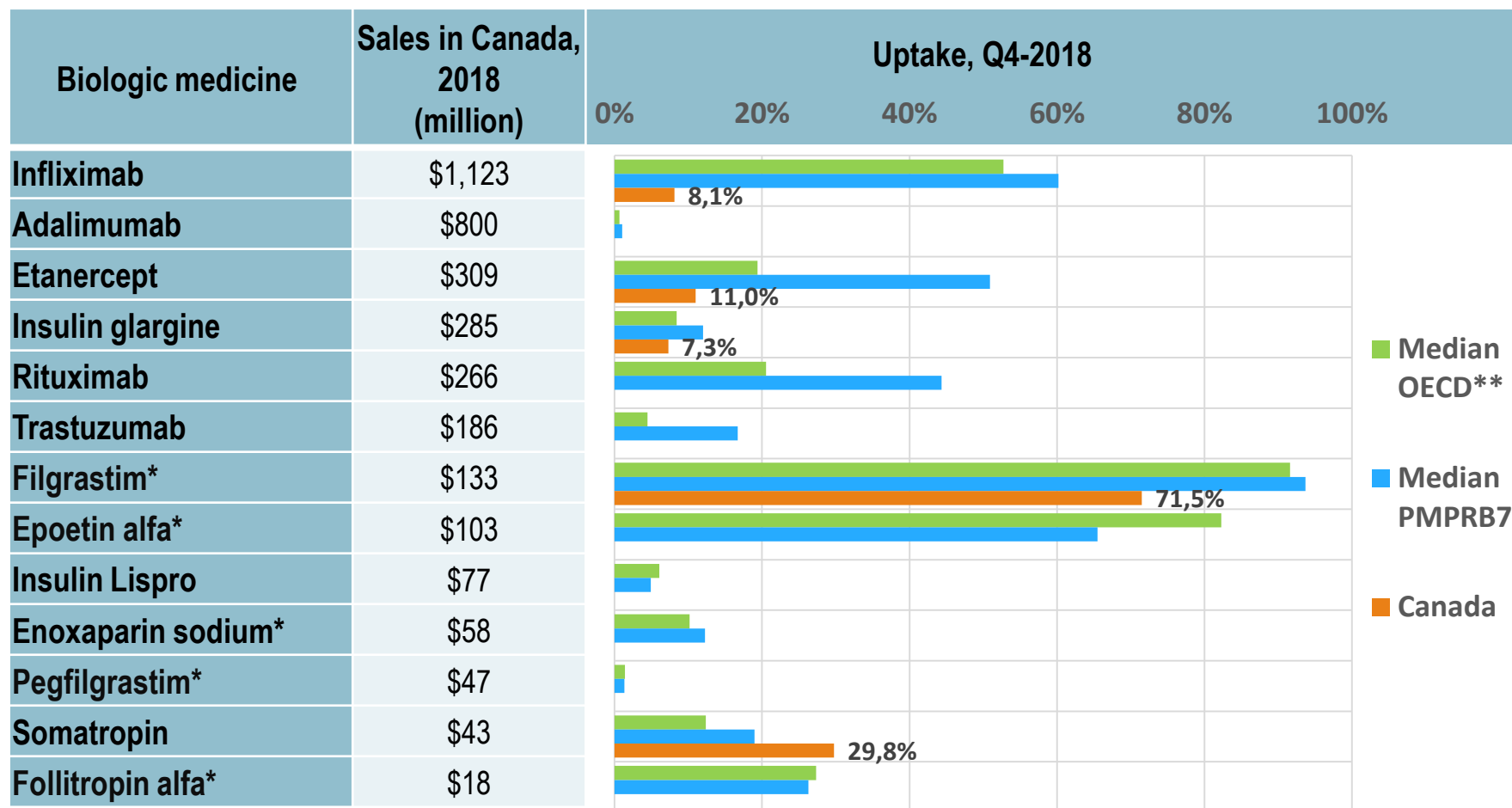
\*The median discounts was calculated based on the price of the biosimilar as of Q4-2018 and the originator in the quarter before biosimilar introduction. Prices and discounts are reported as a sales-weighted average of all available biosimilar forms and strengths unless otherwise indicated.

\*\*The Canadian discount relative to the quarter before biosimilar introduction could not be calculated.

<sup>†</sup> Calculated at the molecule level after adjusting for various strengths.

Data source: MIDAS™ Database, prescription retail and hospital markets, 2018, IQVIA. All rights reserved.

# Biosimilar uptake: Canada lags behind Europe



\*Acute biologics

\*\*Canada is excluded from the median

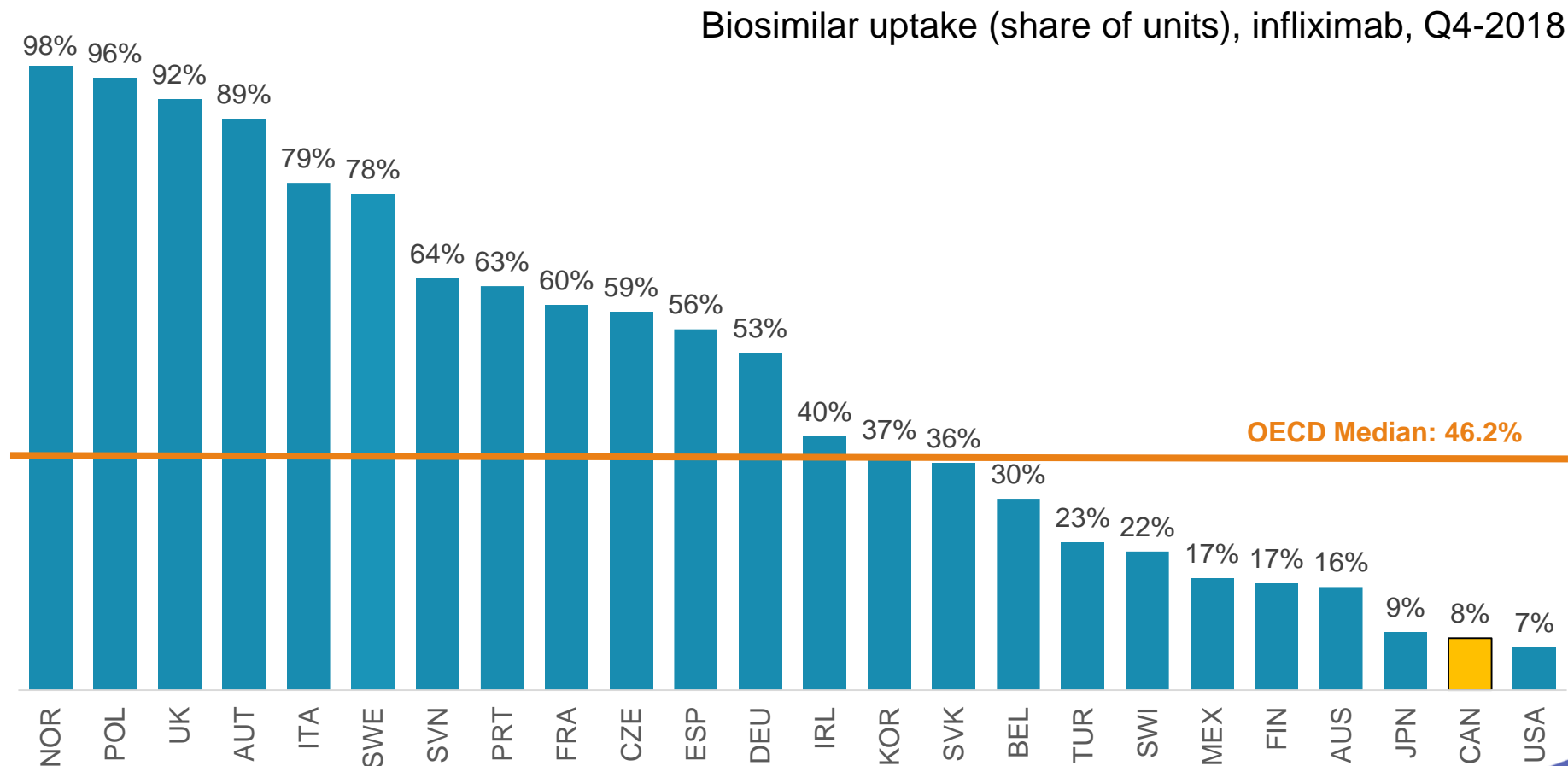
Data source: MIDAS™ Database, prescription retail and hospital markets, 2017, IQVIA. All rights reserved

# Barriers to biosimilar uptake in Canada

- In Canada, biosimilars are not interchangeable with the reference biologic
- Switching from an ongoing biological treatment to an approved biosimilar had not been encouraged in Canada until recently
- Patients and manufacturers of originator biologics are vocal opponents of switching
- Strategies/initiatives undertaken by the manufacturer of the reference biologic that may limit the uptake of biosimilars

# The infliximab experience: biosimilar uptake

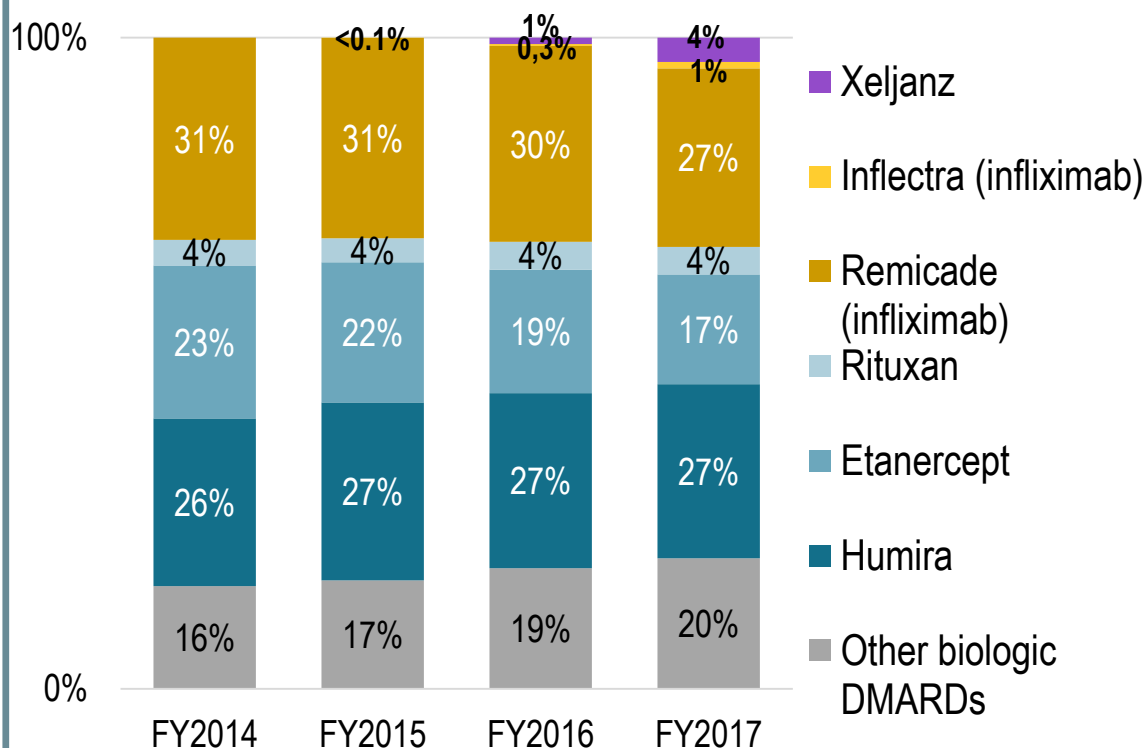
Canada lags behind most OECD countries in terms of the infliximab biosimilar uptake



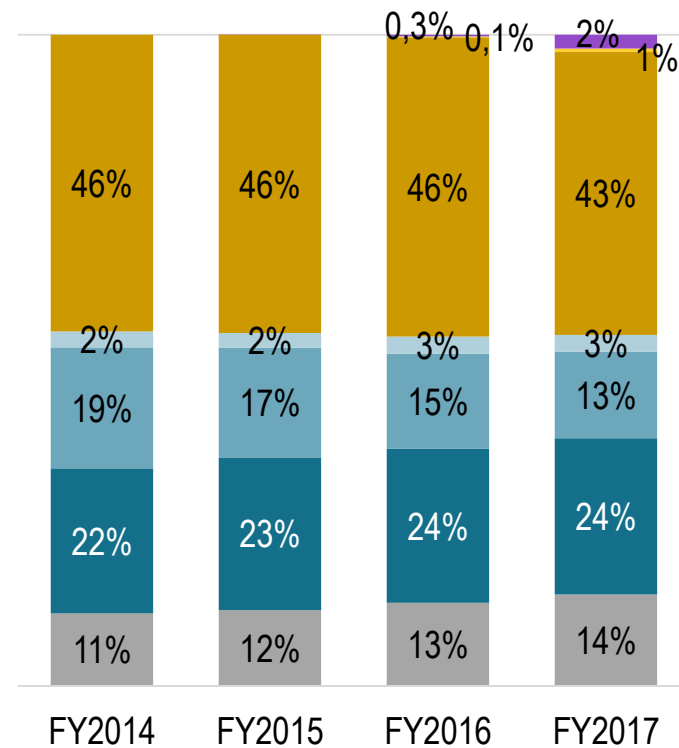
# Only a small fraction of 'experienced' patients have switched to biosimilar versions

Instead, previously treated patients continue to use brand-name versions of the DMARD. There is a missed opportunity for the biosimilar to realize significant savings

Distribution of existing patients by select DMARDs

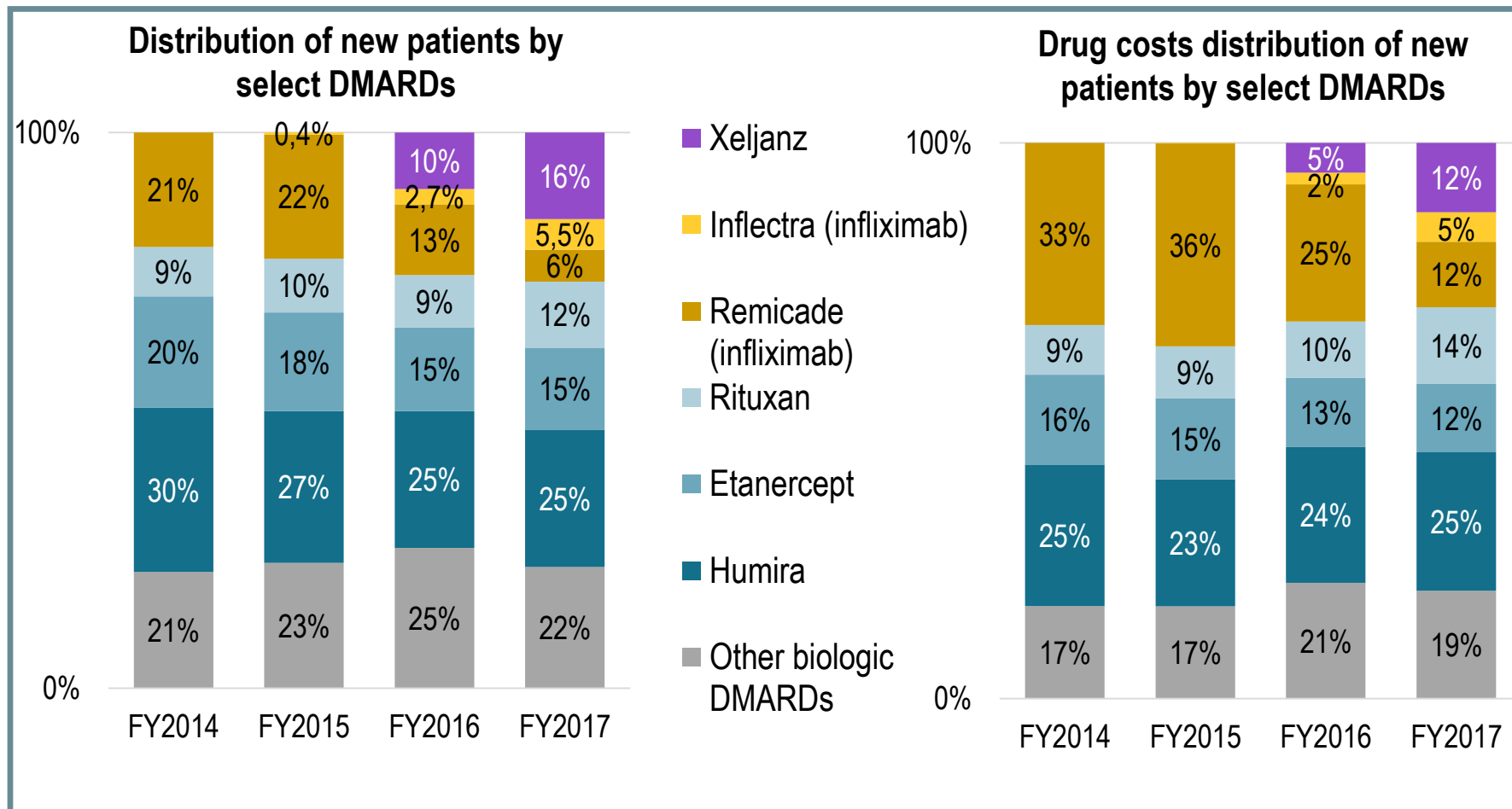


Drug costs distribution of existing patients by select DMARDs



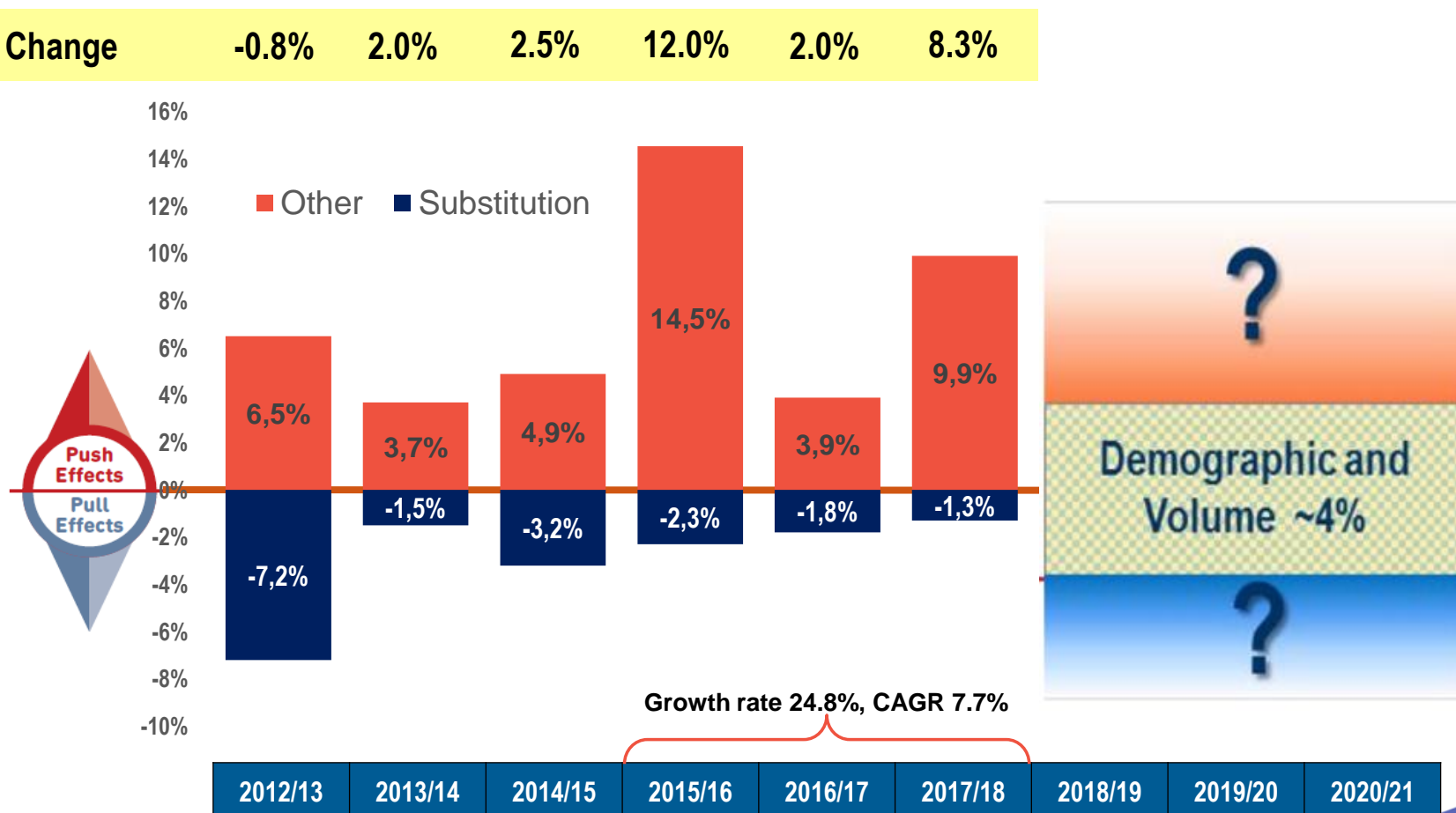
# Barrier to entry: Brand-name DMARDs have been able to maintain market share of new patients despite biosimilar availability

As a result, other brand-name products have gained significant market share in this class – highlighting the missed opportunity for the biosimilar to establish itself in the new patient space



# Why biosimilar savings matter?

## Cost drivers in select Canadian public drug plans

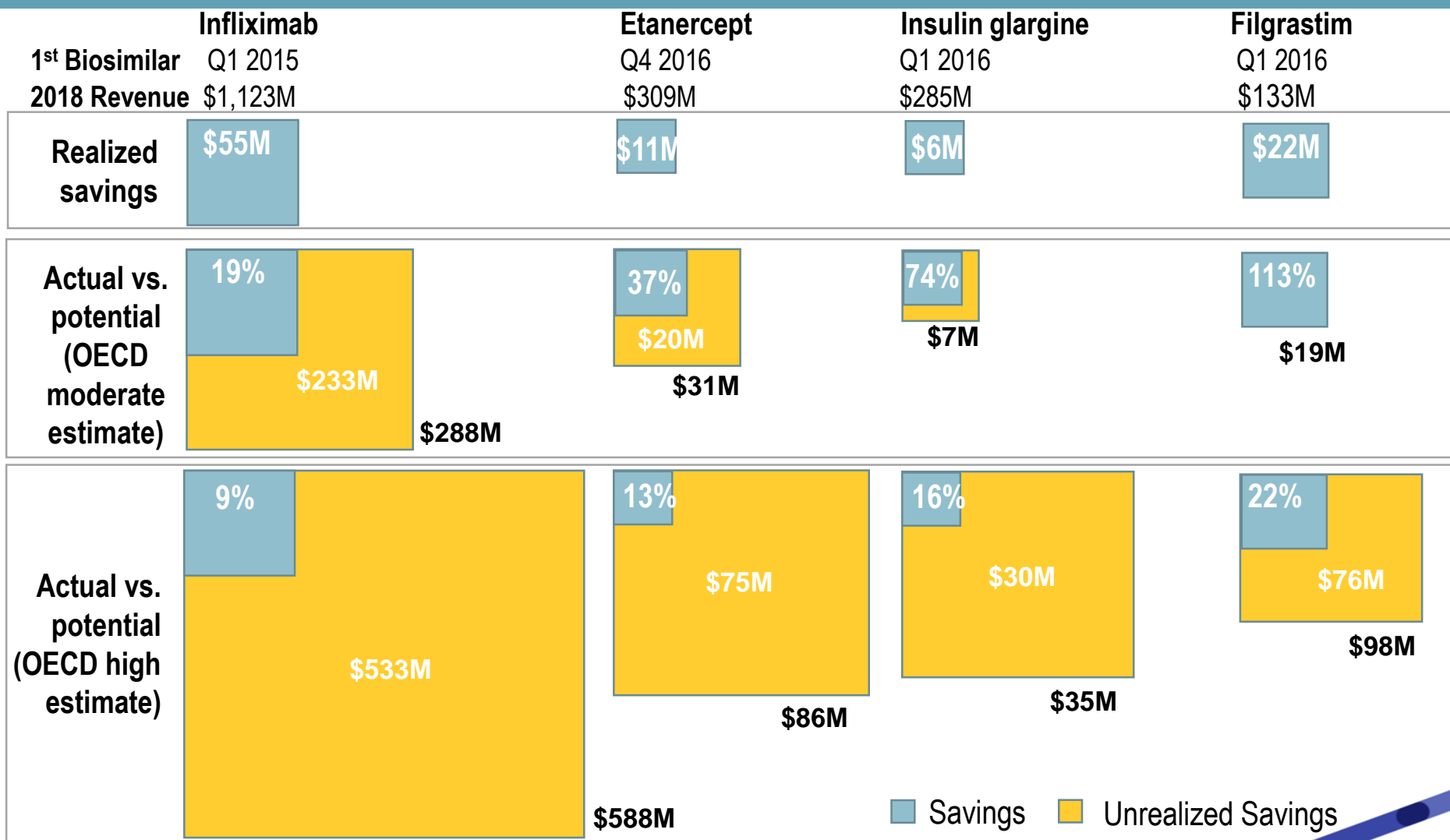


Note: Drug costs include markups.

The other category is the net effect of the following: drug-mix, volume, demographic, and price changes.

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

# Canadian savings only a fraction of their potential



# Potential Savings of new biosimilars

Molecule	2018 Canadian sales	First Biosimilar Availability			2023 Forecast	Potential Savings in 2023	
		NOC	Launch Status	Anticipated Launch	Sales†	OECD moderate estimate	OECD high estimate
Ranibizumab	\$317M	-		2020	\$372M	54M (14.6%)	\$201M (54.2%)
Rituximab <sup>c</sup>	\$266M	April '19		2020	\$283M	40M (14.2%)	\$83M (29.2%)
Trastuzumab <sup>c</sup>	\$186M	May '19	Jun '19		\$194M	\$39M (20.2%)	\$83M (43.0%)
Bevacizumab <sup>c</sup>	\$118M	April '18	Aug '19		\$130M	\$26M (19.8%)	\$54M (41.4%)
Insulin Lispro	\$77M	Nov '17		Q4-2019	\$96M	\$3M (3.4%)	\$12M (12.8%)
Pegfilgrastim	\$47M	April '18	Feb '19		\$22M	\$4M (17.9%)	\$13M (61.7%)
<b>Total Savings (2023)</b>	<b>\$1,011M</b>				<b>\$1,097M</b>	<b>\$167M (15.2%)</b>	<b>\$447M (40.7%)</b>

# Conclusions

- **Canada has relatively high spending and prices of biologics compared to other OECD countries**
- **Canadian biosimilar availability and uptake lags behind Europe**
- **Some biosimilar prices are markedly higher in Canada than internationally**
- **Biosimilar savings have been minimal in Canada, well below international norms**
- **Given the cost pressures, payers depend on biosimilar savings to fund new and innovative therapies and expand drug coverage**



Patented  
Medicine Prices  
Review Board

Conseil d'examen  
du prix des médicaments  
brevetés

# THANK YOU

Patented Medicine Prices Review Board



Jeffrey Menzies

Manager, NPDUIS

Patented Medicine Prices Review Board / Government of Canada

[Jeffrey.Menzies@pmprb-cepmb.gc.ca](mailto:Jeffrey.Menzies@pmprb-cepmb.gc.ca) / Tel: 613-288-9576

Canada 