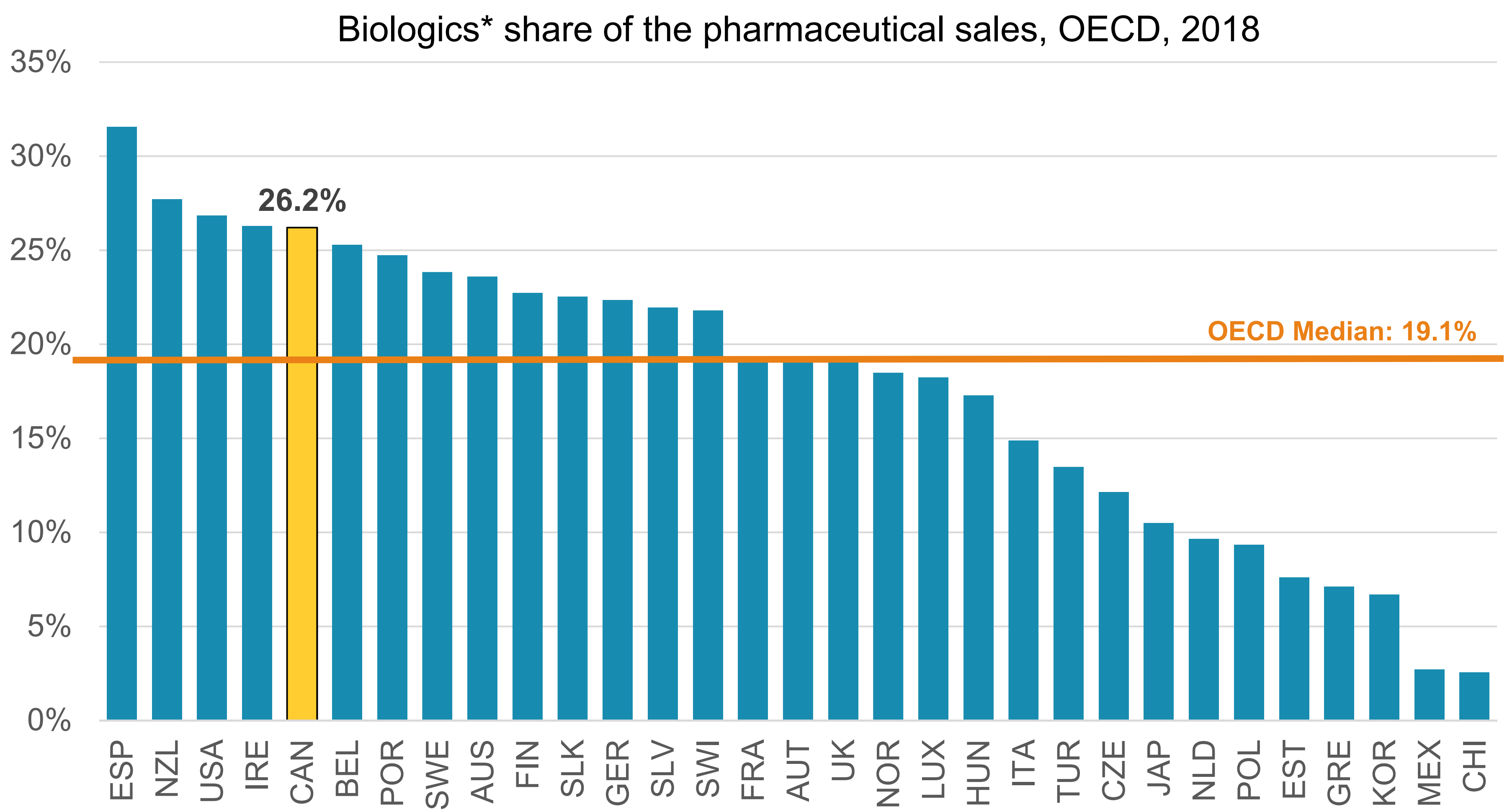
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

Biosimilars in Canada: Current Environment and Future Opportunity

Elena Lungu, Manager
Patented Medicine Prices Review Board, Government of Canada
presentation in
CADTH, April 2019

Canada

Biologics – an important segment of the Canadian pharmaceutical market



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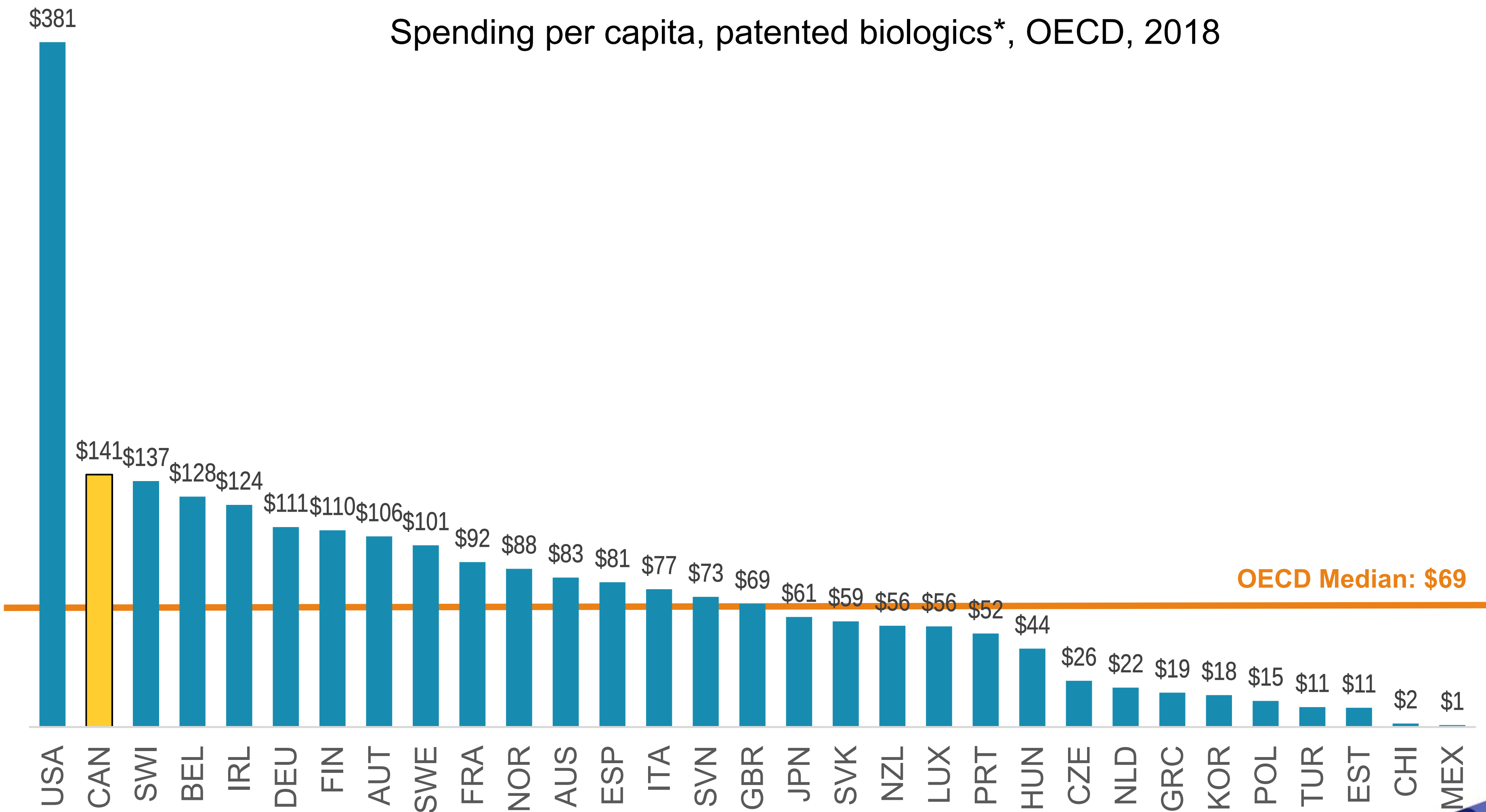
*Includes biologics patented in Canada as of 2017.

Canada has the second highest per capita spending on biologics



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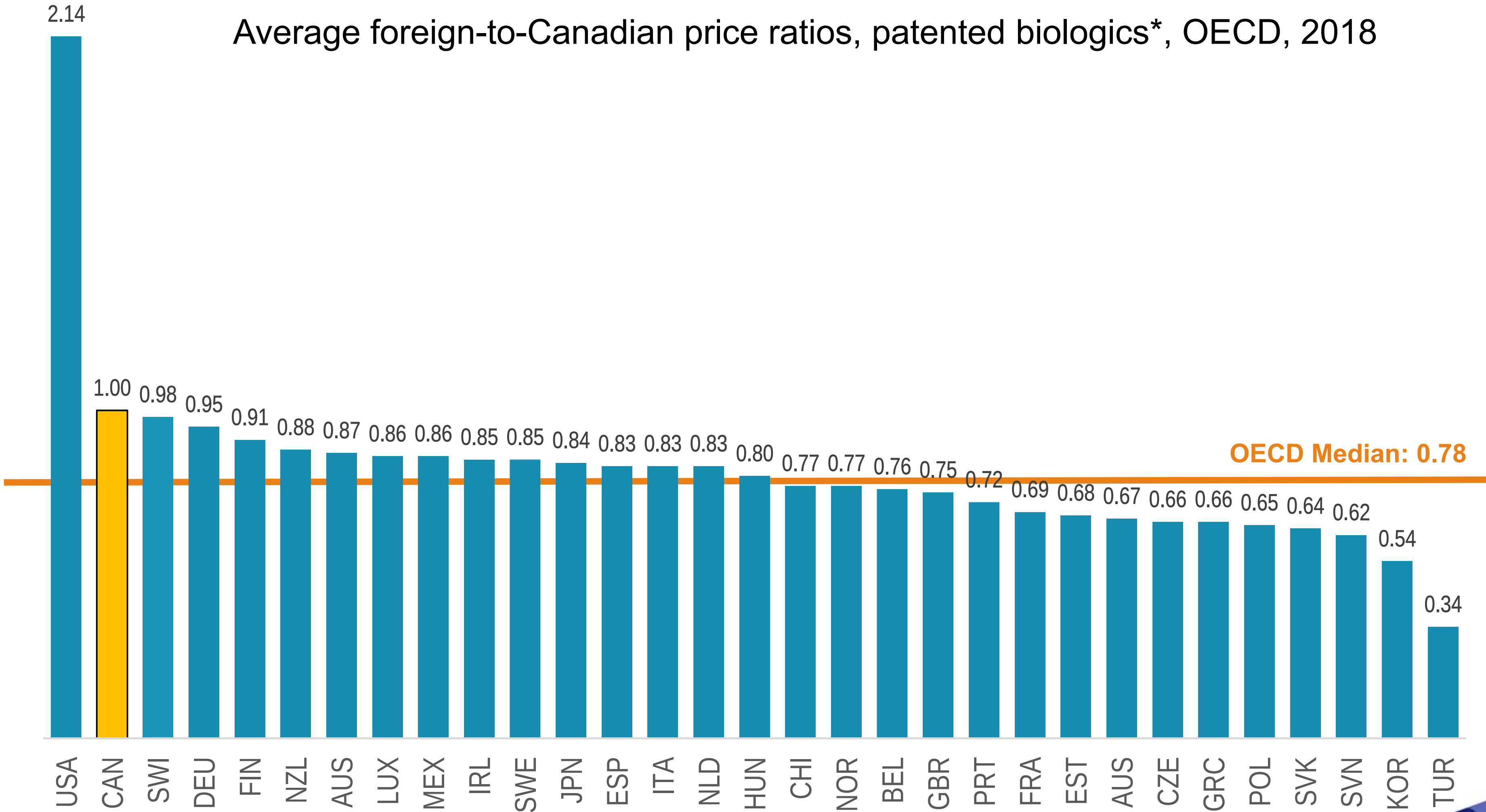
Canada has the second highest prices for biologics



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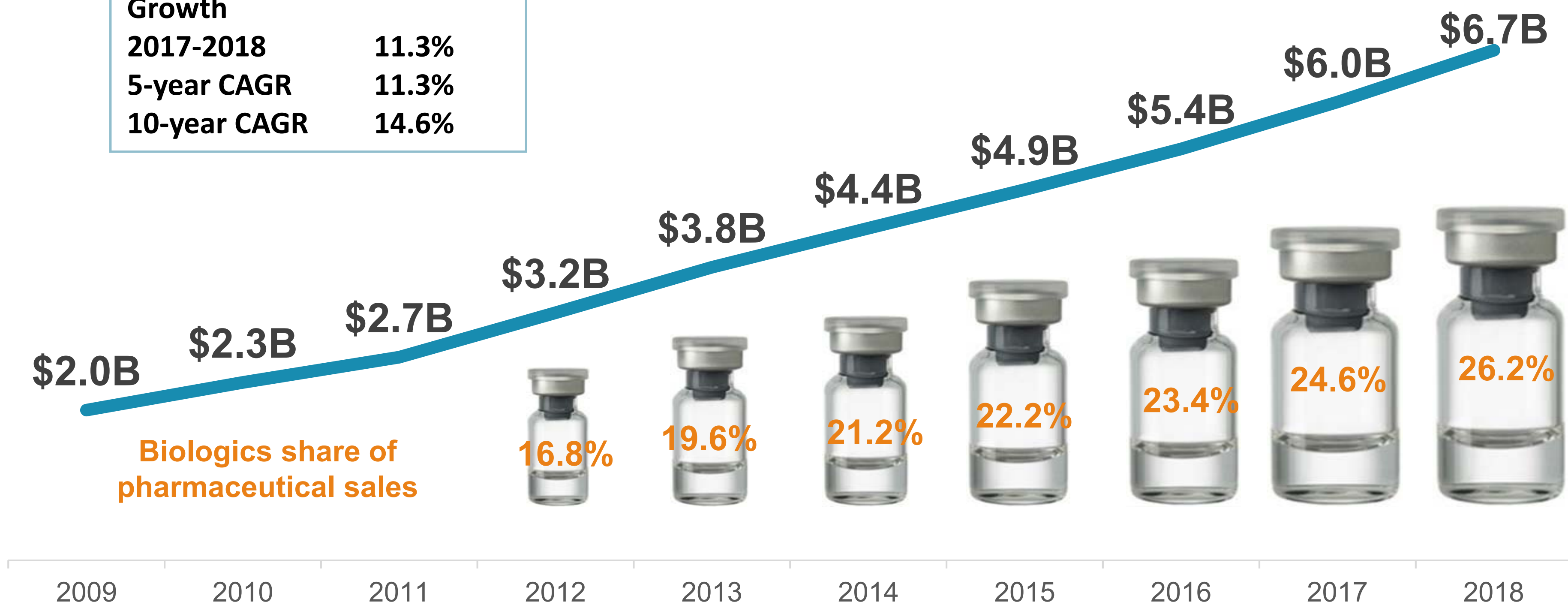
Biologics sales are on the rise, despite biosimilar availability in high-sales areas

Trends in patented biologics* sales, Canada, 2009-2018

Growth	
2017-2018	11.3%
5-year CAGR	11.3%
10-year CAGR	14.6%



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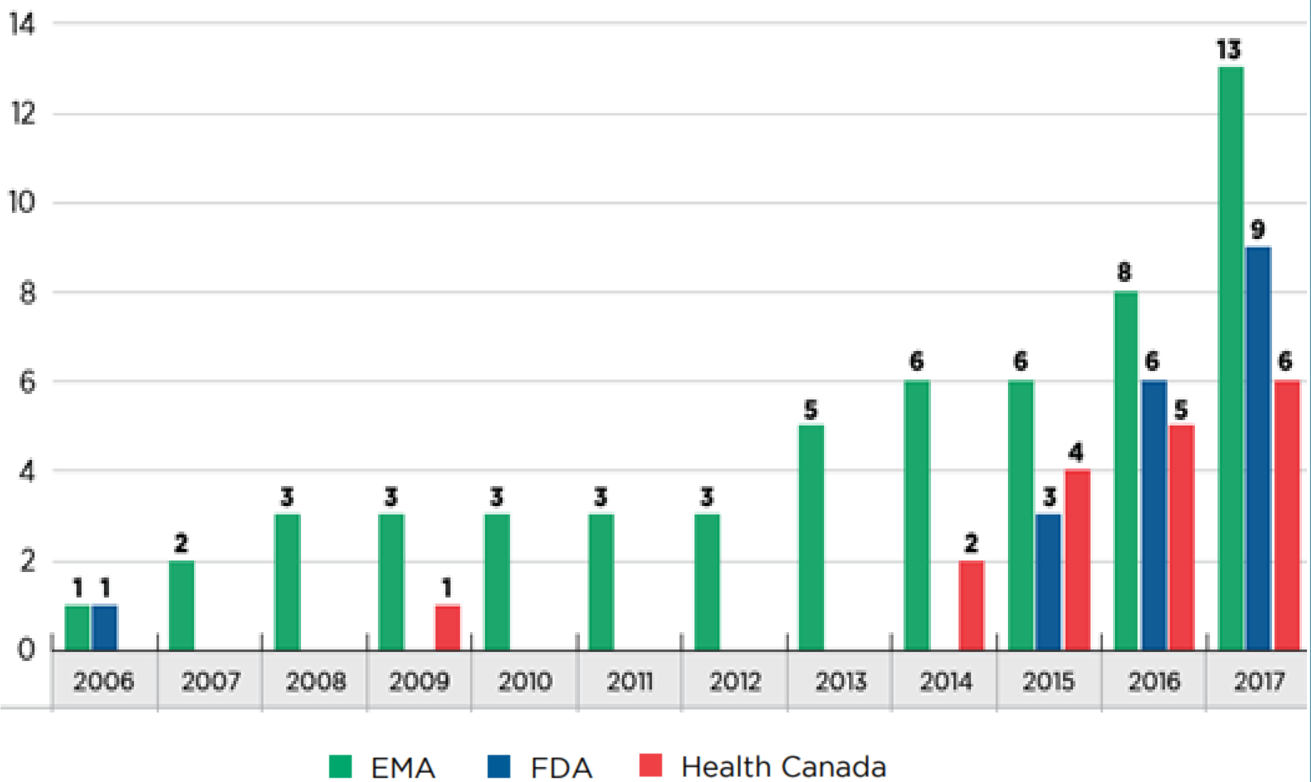
Biosimilar availability: Canada lags behind Europe

Cumulative number of biosimilar medicines approved from 2006 to 2017



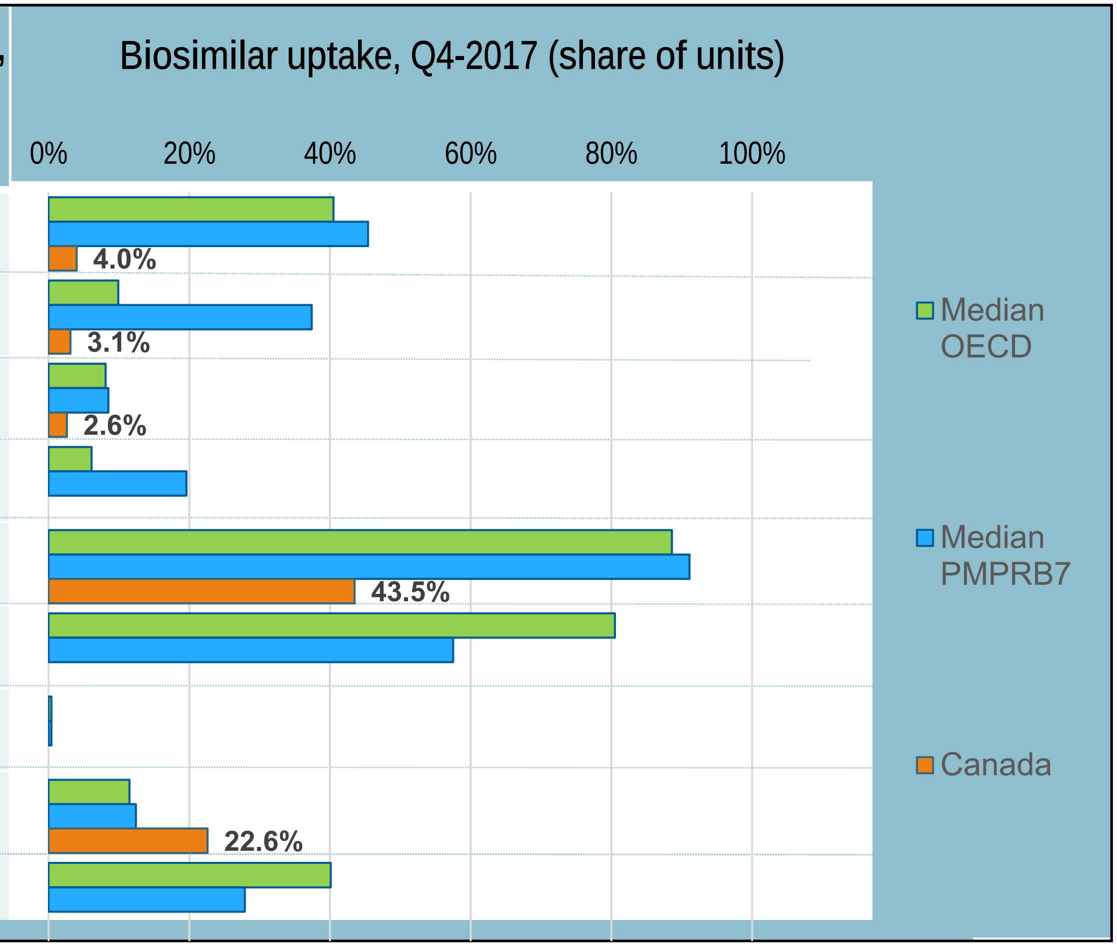
MEDS ENTRY WATCH 2017

Medicine (reference biologic)	First biosimilar sales		
			
Infliximab (Remicade)	Q4-2013	Q4-2016	Q1-2015
Adalimumab (Humira)	Q4-2018	-	-
Etanercept (Enbrel)	Q1-2016	-	Q4-2016
Trastuzumab (Herceptin)	Q2-2018	-	-
Insulin glargine (Lantus)	Q2-2015	Q4-2016	Q1-2016
Rituximab (MabThera/ Rituxan)	Q2-2017	-	-
Filgrastim (Neupogen)	Q4-2008	Q3-2015	Q2-2016
Bevacizumab (Avastin)	-	-	-
Epoetin alfa (Eprex/Erypo; Epogen/Procrit)	Q4-2007	Q3-2018	-
Insulin lispro (Humalog)	Q4-2017	Q1-2018	-
Enoxaparin‡ (Clexane/ Lovenox)	Q1-2017	NA	-
Somatropin (Genotropin)	Q2-2006	Q1-2007	Q3-2009
Teriparatide (Forsteo/ Forteo)	-	-	-
Follitropin alfa (GONAL-f)	Q2-2014	-	-

Data source: MIDAS™ Database, prescription retail and hospital markets, 2017-2018, IQVIA.
*Includes biologics patented in Canada as of 2017.

Biosimilar uptake: Canada lags behind Europe

Biologic medicine	Sales in Canada, 2017 (million)
Infliximab	$1,092
Etanercept	$316
Insulin glargine	$274
Rituximab	$256
Filgrastim*	$128
Epoetin alfa*	$102
Enoxaparin sodium	$61
Somatropin	$39
Follitropin alfa*	$20



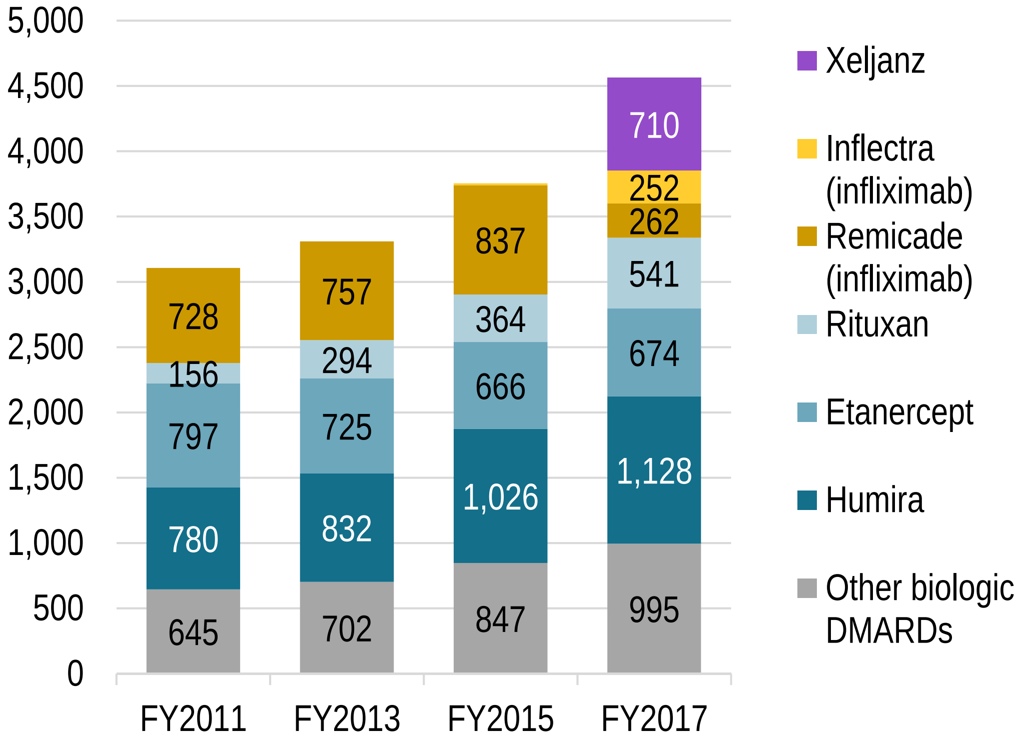
*Acute biologics
Data source: MIDAS™ Database, prescription retail and hospital markets, 2017, IQVIA.

Fewer patients initiated on infliximab after biosimilar entry

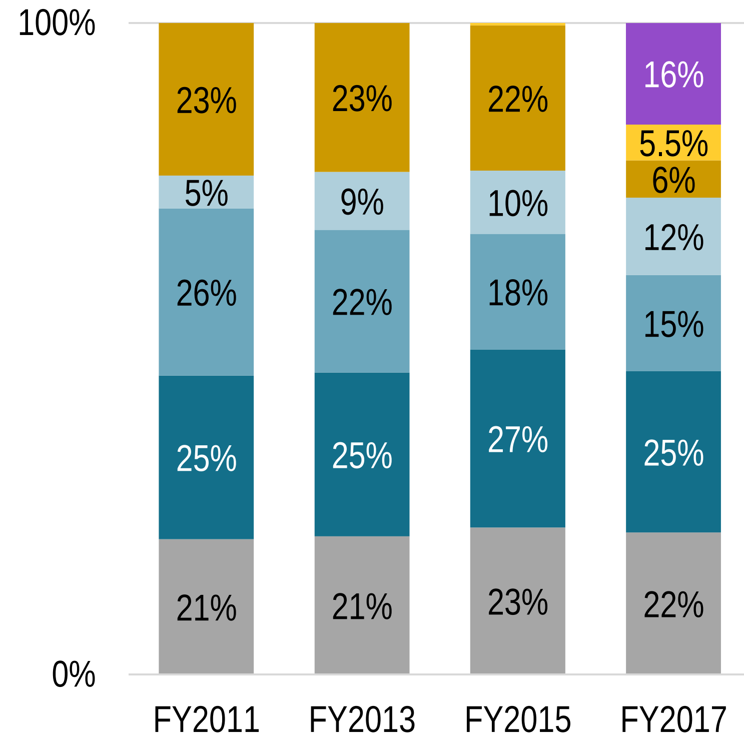
…instead, new patients start on other originator products

Less than half of new infliximab patients were initiated on the biosimilar in 2017

Number of new patients on select DMARDs



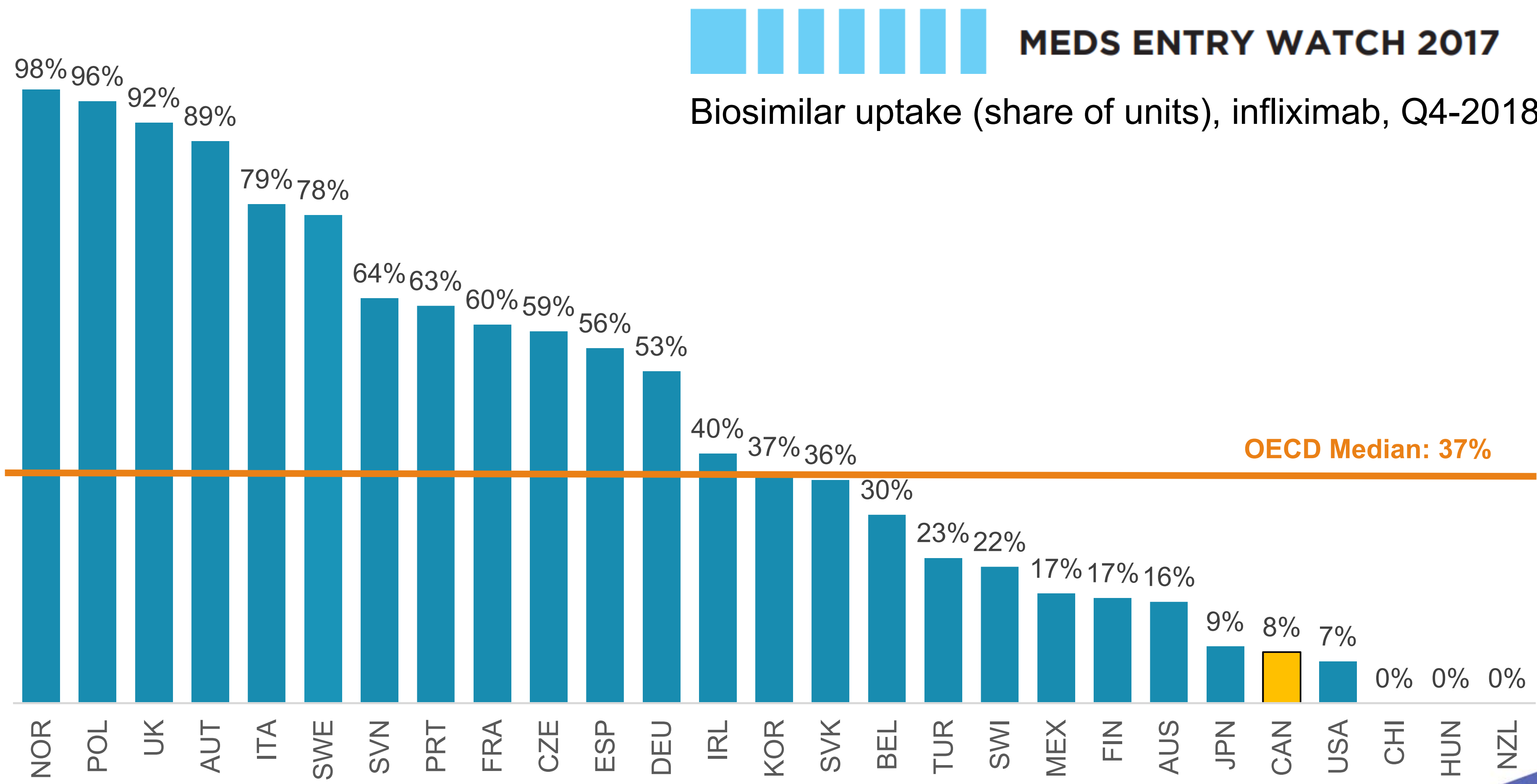
Distribution of new patients by select DMARDs



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

The infliximab experience: the biosimilar uptake

Without switching existing patients and only initiating few new patients on the biosimilars, Canada lags behind all OECD countries in terms of the infliximab biosimilar uptake



Data source: MIDAS™ Database, prescription retail and hospital markets, Q4-2018, IQVIA.

Biosimilars are often priced higher in Canada

Biosimilar (highest-selling form and strength)	Price in Canada ($)	Foreign-to-Canadian price ratios		Median foreign prices (CAD)		Discount relative to reference biologic, Q4-2017
		PMPRB7	OECD	PMPRB7	OECD	Canada
Infliximab (inf. dry bottle, 100 mg)	535	1.08	0.93	578	495	45.0%
Etanercept (prefill autoinj, 50 mg/mL, 0.98 mL)	274	0.84	0.87	231	237	30.6%
Insulin glargine (prefill pens, 100 IU/mL, 3 mL)	14.30	0.85	0.77	12.08	11.00	23.9%
Rituximab (infus.via/bot., 10 mg/mL, 50 mL)	-	-	-	1,638	1,524	-
Filgrastim (prefill syrng, 600 y/mL, 0.5 mL)	144	0.61	0.41	88.09	59.52	17.6%
Epoetin alfa (prefill syrng, 40 K/mL, 1 mL)	-	-	-	329	314	-
Enoxaparin (prefill syrng sc, 10 K/mL, 0.4 mL)	-	-	-	3.62	3.62	-
Somatropin (cartridges, 20 IU/mL, 1.5 mL)	308	1.08	0.88	333	272	18.2%
Follitropin alfa (prefill pens, 600 IU/mL, 1.5 mL)	-	-	-	-	-	-
Sales-weighted average		**0.97**	**0.85**			**37.0%**

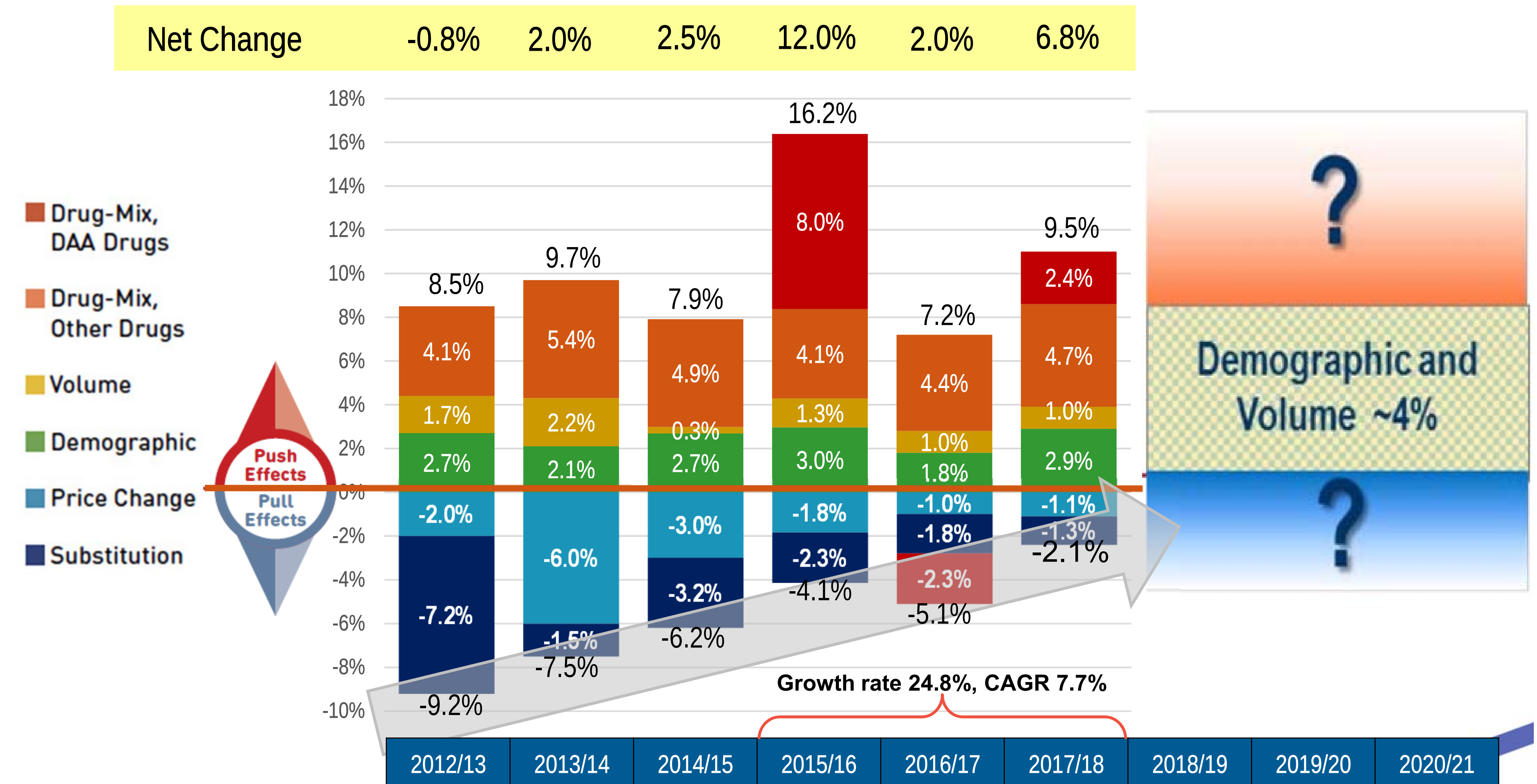
Biosimilar prices are generally higher, despite greater discounts, likely due to higher originator prices prevailing in Canada

MEDS ENTRY WATCH 2017

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

Why biosimilar savings matter?

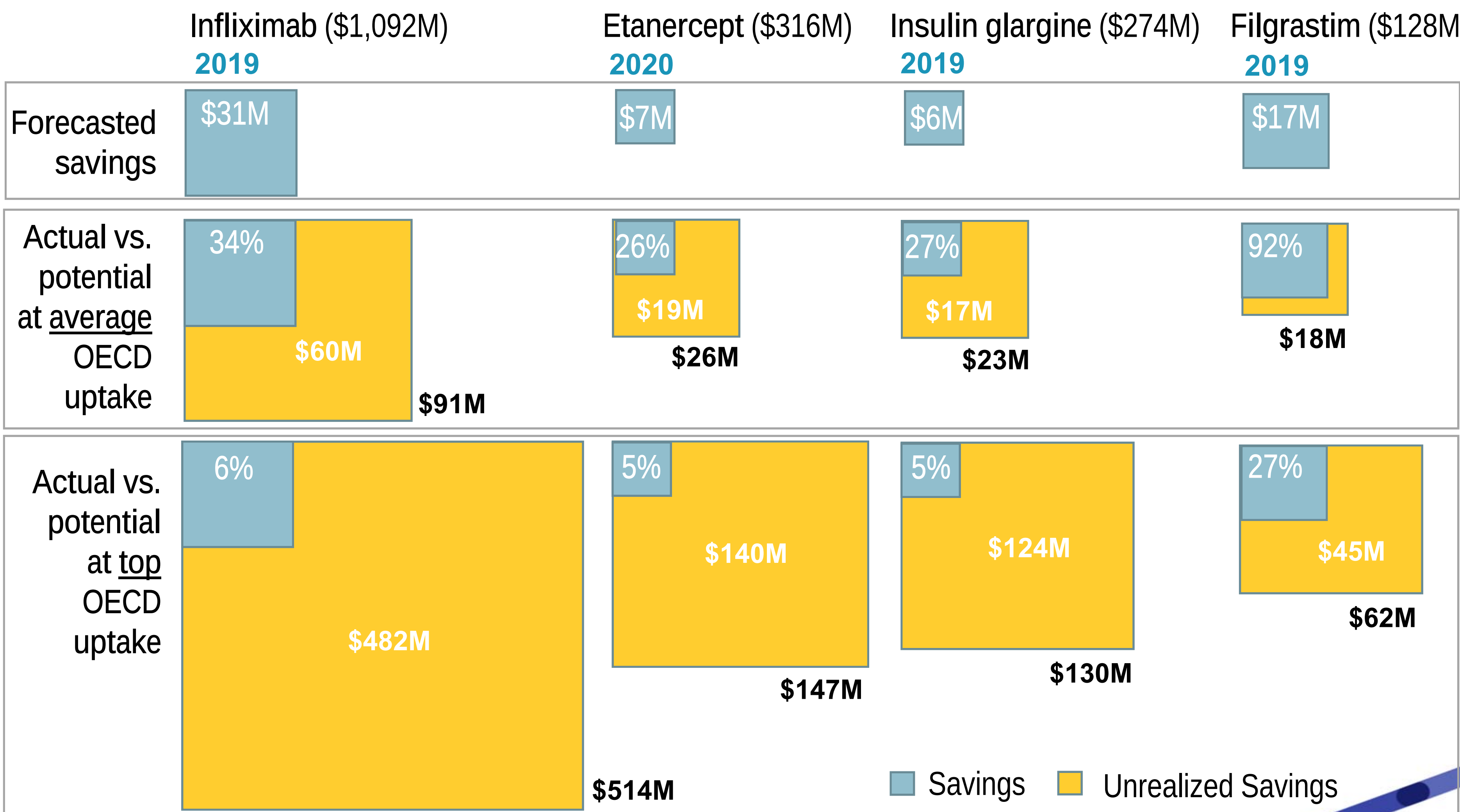
Cost drivers in select Canadian public drug plans



Note: Drug costs include markups.

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

Canadian savings only a fraction of their potential



Data source: MIDAS™ Database, prescription retail and hospital markets, IQVIA.

Recent developments in Canada

- **Biosimilar industry association:** announces the introduction of Patient Support Programs to be launched in 2019
- **HTA:** CADTH streamlined the biosimilar review process (Feb 2018), with fewer submission requirements, shortened review period, etc.
- **Price negotiation:** pCPA Policy on Biologics and Biosimilars (Sept 2018) aims for parallel processes with the HTA, requires price transparency and considers the implementation of tiered listing and switching
- **Public payers:**
  - Preferential reimbursement: generally applies to biosimilars for treatment-naïve patients (e.g., Remicade) – those on reference biologic do not have to switch; Quebec only reimburses the lowest priced version of infliximab
  - Tired reimbursement: implemented by Manitoba – new patients required to try two Tier 1 products before being reimbursed for a Tier 2 product; Tier 1 biologic products have been determined to be the most cost-effective
- **Private payers:**
  - Preferential reimbursement: e.g., Green Shield Canada opened its biosimilar transition program to any sponsor who wishes to take part (Dec 2018); patients that do not switch to the biosimilar pay the difference out of pocket

Conclusions

- Canada has the second highest spending on biologics in the OECD, and pays the second highest prices
- Canadian biosimilar availability and uptake lags behind Europe
- 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
- Canadian biosimilar industry, HTA, price negotiators, and payers are taking steps towards greater market penetration of biosimilars: Patient Support Programs, streamlined and transparent processes, preferential reimbursement, transitioning, and tiered reimbursement

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THANK YOU

Patented Medicine Prices Review Board

Elena Lungu

Manager, Policy Development

Patented Medicine Prices Review Board / Government of Canada

Elena.Lungu@pmprb-cepmb.gc.ca / Tel: 613-288-9602

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