Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

CHARTBOOK

National Prescription Drug Utilization Information System

NPDUIS

Biologics in Canada

Part 1: Market Trends, 2018

Canada

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PMPRB Reporting

About the PMPRB

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body established by Parliament in 1987. The PMPRB has a dual regulatory and reporting mandate: to ensure that prices at which patentees sell their patented medicines in Canada are not excessive; and to report on pharmaceutical trends of all medicines and on research and development spending by patentees.

The NPDUIS Initiative

The National Prescription Drug Utilization Information System (NPDUIS) is a research initiative established by federal, provincial, and territorial Ministers of Health in September 2001. It is a partnership between the PMPRB and the Canadian Institute for Health Information (CIHI).

Pursuant to section 90 of the *Patent Act*, the PMPRB has the mandate to conduct analysis that provides decision makers with critical information and intelligence on price, utilization, and cost trends so that Canada's healthcare system has more comprehensive and accurate information on how medicines are being used and on sources of cost pressures.

The specific research priorities and methodologies for NPDUIS are established with the guidance of the NPDUIS Advisory Committee and reflect the priorities of the participating jurisdictions, as identified in the NPDUIS Research Agenda.

Disclaimer

NPDUIS operates independently of the regulatory activities of the Board of the PMPRB. The research priorities, data, statements, and opinions expressed or reflected in NPDUIS reports do not represent the position of the PMPRB with respect to any regulatory matter. NPDUIS reports do not contain information that is confidential or privileged under sections 87 and 88 of the *Patent Act*, and the mention of a medicine in a NPDUIS report is not and should not be understood as an admission or denial that the medicine is subject to filings under sections 80, 81, or 82 of the *Patent Act* or that its price is or is not excessive under section 85 of the *Patent Act*.

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Introduction

Biologic medicines are an important segment of the global pharmaceutical market. In Canada, sales of biologics reached $7.7 billion in 2018, placing Canada among the top-ranked countries in the Organisation for Economic Co-operation and Development (OECD) in terms of per capita spending.

Given the high use and cost of biologics in Canada, biosimilars offer an opportunity for significant cost savings. However, despite being on the market for over a decade, the savings from biosimilars have yet to be fully realized.

This analysis examines the market dynamics of biologics in Canada and compares Canadian and international trends in sales, pricing, and biosimilar uptake.

This overview of the biologic space sets the stage for the second publication in this two-part chartbook series. *Biologics in Canada. Part 2: Biosimilar Savings, 2018* uses recent Canadian and international trends to expose the current and future cost savings that could be realized through increasing the uptake and/or lowering the prices of biosimilars in Canada.

Background

Biologics are a high-growth segment of the pharmaceutical market. Sales of biologic medicines in Canada have tripled over the last decade, increasing by 14.6% in the last year alone. Canadian approved biologics also demonstrated a strong growth internationally, with median OECD sales for these medicines almost doubling over the same time period.

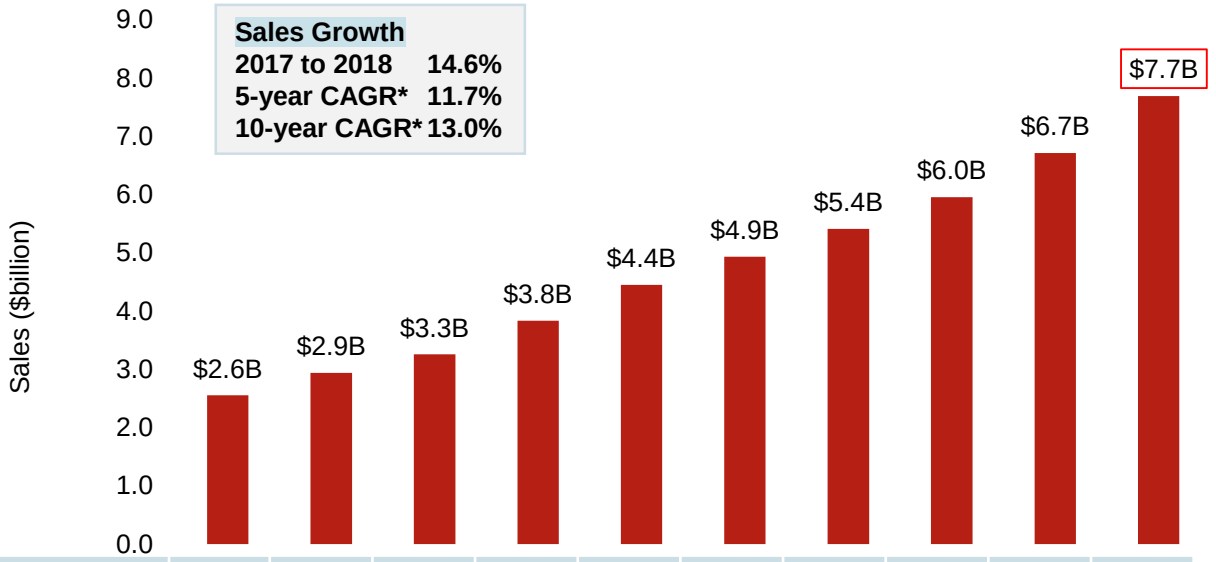
The first biosimilar was introduced in Canada in 2009. By 2018, a total of nine biologic medicines had one or more biosimilars approved for sale in Canada, offering the promise of lower prices and market competition. However, biosimilar sales only amounted to $146 million in 2018 or 1.9% of the $7.7 billion biologic market.

This is a complex market space, and while there has been a successful uptake of biosimilars in many other countries, Canada has lagged behind. One clear example of this is the billion dollar Canadian market for infliximab. In 2018, the originator biologic, Remicade, still accounted for the vast majority of infliximab sales although biosimilars had been available for a number of years.

Biologics are a class of medicines formed from living organisms or from their cells using advanced biotechnology processes. They are typically larger and more complex than chemically produced pharmaceutical drugs. In Canada, biologic drugs are listed in Schedule D of the *Food and Drugs Act*.

Health Canada defines a **biosimilar** as a biologic drug that is highly similar to a biologic drug that was already authorized for sale. There are no expected clinically meaningful differences in efficacy and safety between a biosimilar and the **originator or reference** biologic.

Sales of biologic medicines in Canada, 2009 to 2018



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Biologic share of pharmaceutical sales	13.5%	15.1%	17.2%	19.9%	22.7%	24.0%	24.7%	25.9%	27.4%	30.1%
Biologic sales per capita	$76	$86	$95	$110	$127	$139	$151	$164	$183	$208
Biosimilar sales ($million)	**<$0.1**	**$0.1**	**$0.9**	**$2.0 (0.1%)**	**$3.3 (0.1%)**	**$4.3 (0.1%)**	**$5.7 (0.1%)**	**$12.5 (0.2%)**	**$60.8 (0.9%)**	**$146.3 (1.9%)**

Note: Includes all prescription biologics and insulin biologics sold in Canada as of 2018.
* CAGR, compound annual growth rate.
Data source: IQVIA MIDAS® Database, prescription retail and hospital markets, 2018.

Methods and Limitations

This analysis focuses on biologic medicines with sales in the Canadian market as of 2018.

(1) List of Medicines

Biologic medicines were selected for analysis based on the following criteria:

- **Biologic (Schedule D)** as per Health Canada's Drug Product Database (DPD)

AND

- **Prescription biologic (Schedule-Prescription)** as per Health Canada's DPD

All insulin biologics were included in the analysis, regardless of whether they required a prescription in Canada.

Exclusions: To improve consistency in the analysis of international comparisons, certain therapeutic classes, such as sera and immunoglobulins and diagnostic agents were excluded from the sample analyzed.

(2) International Analysis

Biologics containing the same medicinal ingredients as those identified in the **List of Medicines** were included in the international analysis.

The international markets examined include the Organisation for Economic Co-operation and Development (OECD) members, with a focus on the seven countries the PMPRB currently considers in reviewing the prices of patented medicines (PMPRB7): France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States.

(3) Canadian Market Analysis

The results reported for the private and public drug plans in Canada reflect the biologics selected for this study. This selection may vary from other PMPRB reports.

Drug costs reported are the amounts accepted toward reimbursement and do not reflect off-invoice price rebates or price reductions resulting from confidential product listing agreements.

1. International Sales and Price Comparison

Biologic medicines account for a significant share of global pharmaceutical sales.

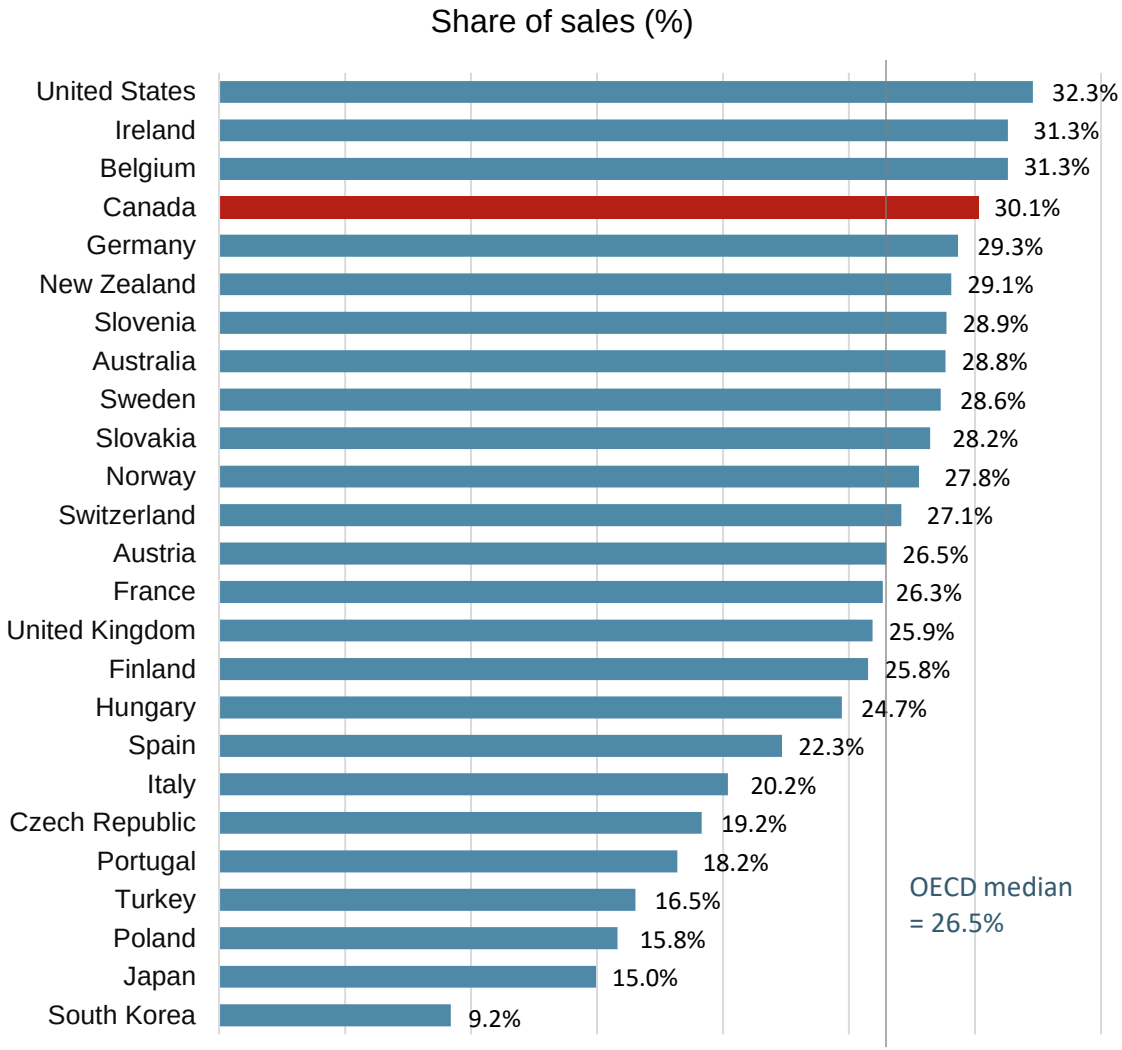
This section reports on the market dynamics of biologics approved in Canada, exploring domestic and international trends for these medicines.

The results primarily reflect the sales and use of originator biologics, as they make up almost the entire Canadian market.

Biologic medicines account for almost one third of the total pharmaceutical sales in Canada

The biologic medicines approved in Canada also made up a large share of pharmaceutical sales in international markets. The median OECD sales share of these medicines was 26.5% in 2018, slightly lower than in Canada, which ranked fourth among the OECD countries.

FIGURE 1.1 Biologic medicine share of total pharmaceutical sales, OECD, 2018



Note: The analysis includes all prescription biologics and insulin biologics sold in Canada as of 2018.

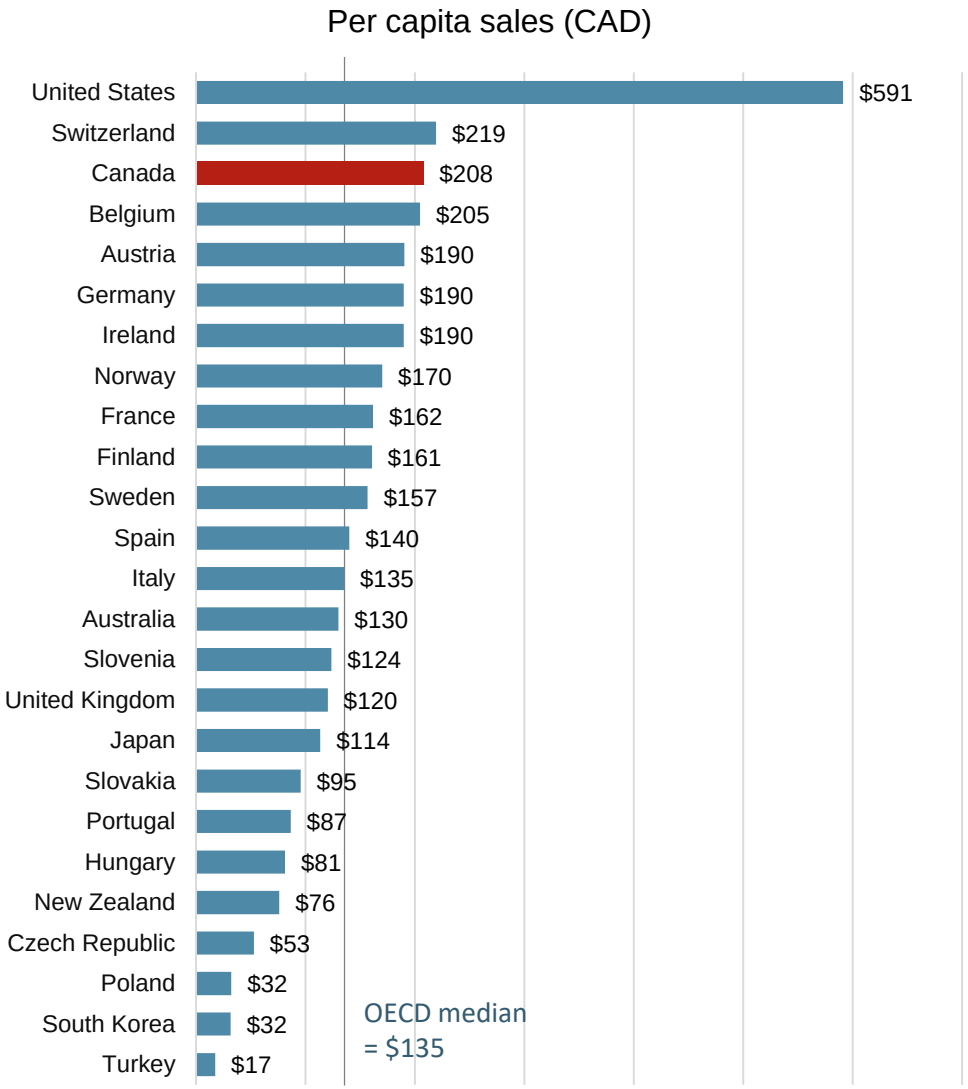
Countries with limited sales data were excluded from this analysis.

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

Canada spends more on biologics per capita than almost all other industrialized countries

Canadians spent an average of $208 per person on biologic medicines in 2018. This represented the third highest per capita sales among the OECD countries, well above the international median of $135.

FIGURE 1.2 Per capita sales of biologic medicines, OECD, 2018



Note: The analysis includes all prescription biologics and insulin biologics sold in Canada as of 2018.

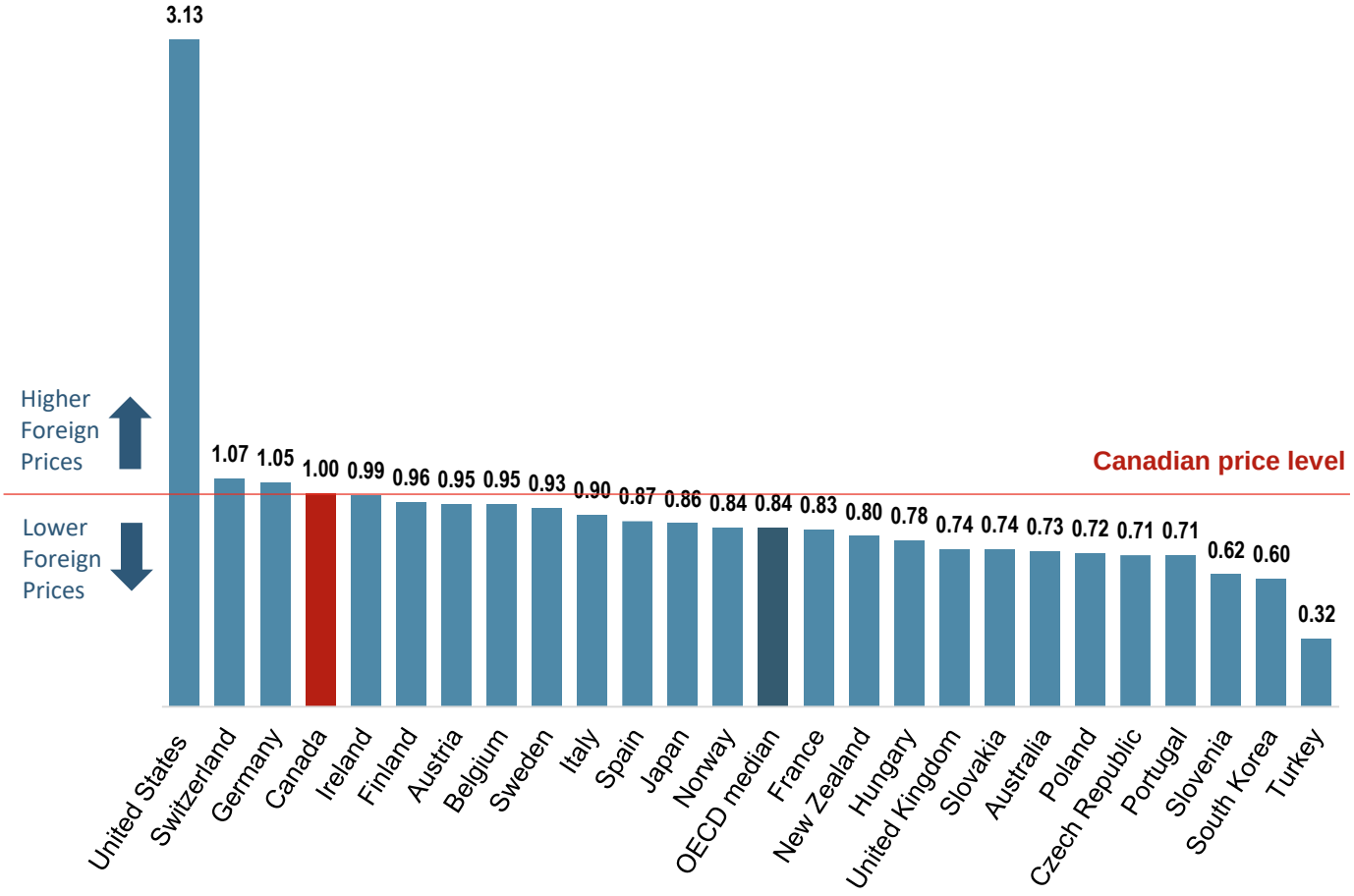
Countries with limited sales data were excluded from this analysis.

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

Canadian prices for originator biologics are among the highest in the OECD

The average price of originator biologics in Canada was the fourth highest in the OECD in 2018. While average US prices were considerably higher than those of any other country, the international median price was 16% lower than the Canadian level.

FIGURE 1.3 Average bilateral foreign-to-Canadian price ratios for originator biologics, OECD, 2018



Note: The analysis includes all originator prescription biologics and insulin biologics sold in Canada as of 2018.

Countries with limited sales data were excluded from this analysis.

For details on how foreign-to-Canadian price ratios are calculated, see the reference documents section of the Analytical Studies page on the PMPRB website.

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

2. Biologic Market in Canada

Biologics are specialty medicines that generally have high treatment costs. This section explores the cost of these medicines to public and private payers in Canada.

The analysis of public payers focuses on the jurisdictions participating in the NPDUIS initiative: all of the provincial public plans (with the exception of Quebec), Yukon, and the Non-Insured Health Benefits (NIHB) Program. These plans together account for approximately one third of the total annual spending on prescription drugs in Canada.

Note that plan designs, reimbursement policies, and reporting practices, as well as variations in the demographic and disease profiles of the beneficiary populations, vary widely across jurisdictions and limit comparability of the results.

The 10 top-selling originator biologics account for over half of all biologic sales in Canada

In Canada, the sales of originator biologics are highly concentrated, with the 10 top-selling medicines accounting for 55% of biologic sales or 17% of the total pharmaceutical market in 2018.

TABLE 2.1 Market share for the 10 top-selling originator biologics in Canada, 2018

Originator biologic (medicine)	**Sales ($million)**	**Share of biologic sales**	**Share of pharmaceutical sales**
Remicade (infliximab)	$1,081	14.1%	**4.2%**
Humira (adalimumab)	$800	10.4%	3.1%
Eylea (aflibercept)	$493	6.4%	1.9%
Stelara (ustekinumab)	$338	4.4%	1.3%
Lucentis (ranibizumab)	$317	4.1%	1.2%
Enbrel (etanercept)	$291	3.8%	1.1%
Lantus (insulin glargine)	$273	3.5%	1.1%
Rituxan (rituximab)	$266	3.5%	1.0%
Keytruda (pembrolizumab)	$202	2.6%	0.8%
Herceptin (trastuzumab)	$186	2.4%	0.7%
Total	**$5,534**	**55.2%**	**16.6%**

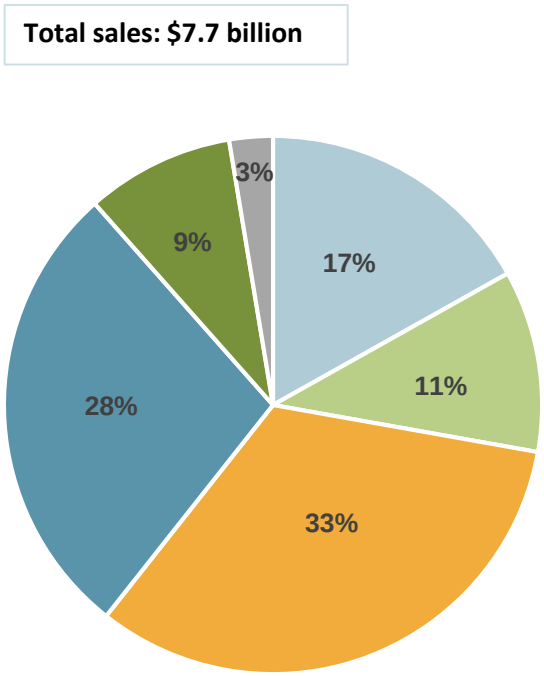
Note: Sales are reported at the trade name level and include all indications.

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

High-cost medicines account for 70% of biologic spending in Canada

Biologic medicines with average annual costs exceeding $10,000 made up $5.4 billion of the $7.7 billion in biologic sales in 2018.

FIGURE 2.1 Biologic medicine sales distribution by treatment cost, Canada, 2018



Treatment cost	Sales	Oncology	Other
<$5K	**$1.3B**	–	$1.3B
$5K to $10K	**$0.8B**	–	$0.8B
$10K to $20K	**$2.5B**	$0.3B	$2.3B
>$20K	**$2.2B**	$0.4B	$1.8B
EDRD*	**$0.7B**	$0.5B	$0.2B
NA	**$0.2B**	–	$0.2B
Total†	**$7.7B**	$1.2B	$6.5B

Note: Annual treatment costs are based on average annual per beneficiary costs for public and private plans.

* Expensive drugs for rare diseases (EDRDs) are defined as medicines having an FDA or EMA orphan designation and an annual treatment cost greater than $100,000 for non-oncology medicines or $7,500 per 28-day course of treatment for oncology medicines.

† Values may not add to total due to rounding.

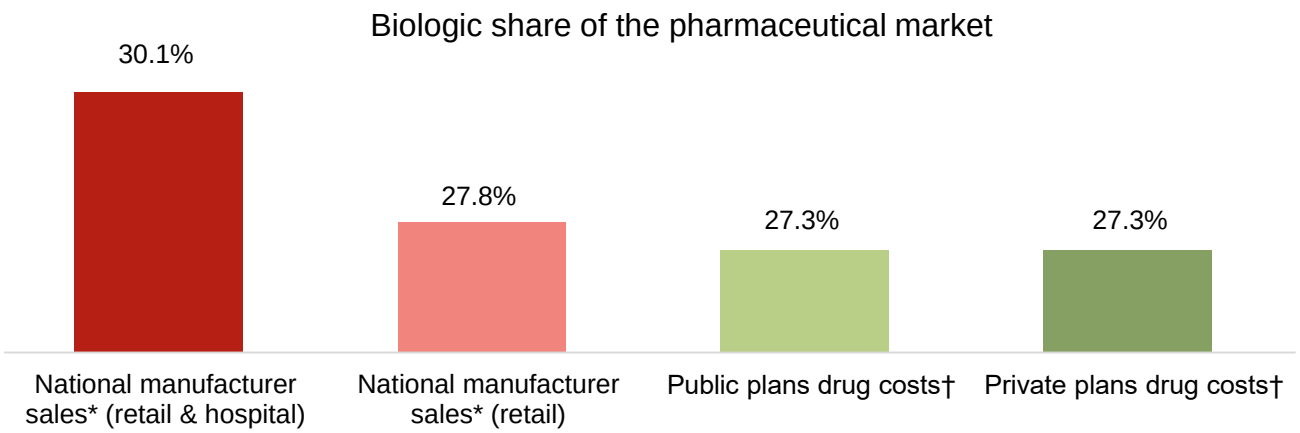
Data source: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information; IQVIA Private Pay Direct Drug Plan Database, 2018; IQVIA MIDAS® Database, prescription retail and hospital markets, 2018 (all rights reserved).

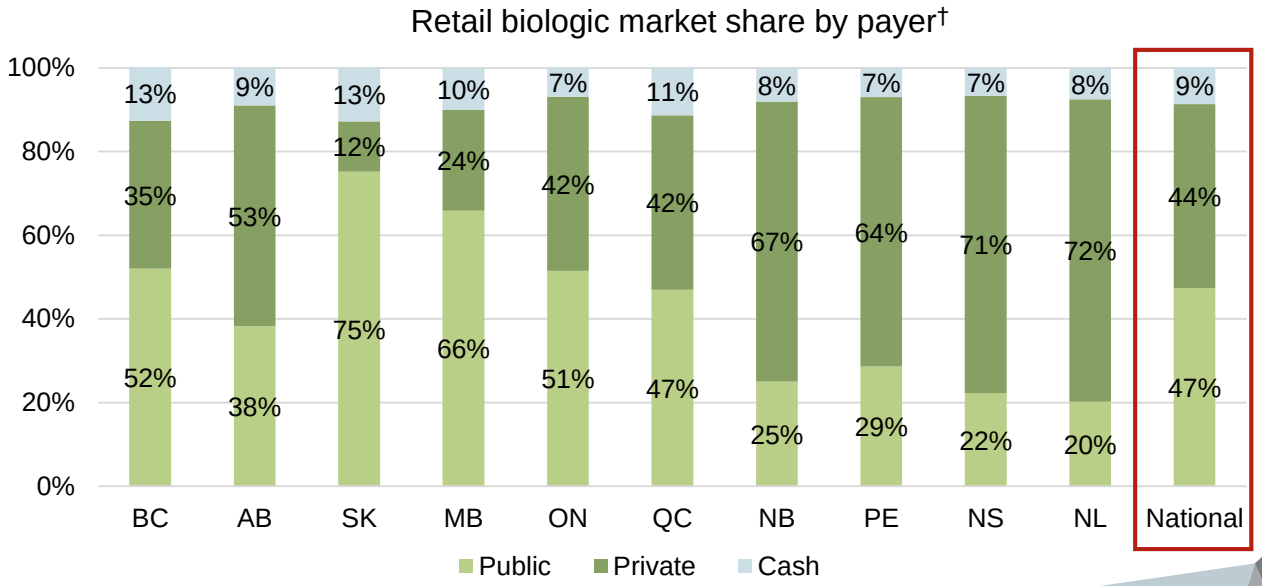
Biologics make up an important market segment for both public and private payers in Canada

Spending on biologic medicines made up 27.3% of the drug costs for both public and private plans with data reported in 2018.

The retail market for biologics in Canada is almost equally split between public and private payers. The variation across jurisdictions is influenced by individual plan designs.

FIGURE 2.2 Biologic medicine market shares by payer, Canada, 2018





* At manufacturer price levels.

† Drug costs include markups but exclude dispensing costs.

Data source:

National: IQVIA MIDAS® Database, prescription retail and hospital markets, 2018. All rights reserved.

Public plans: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

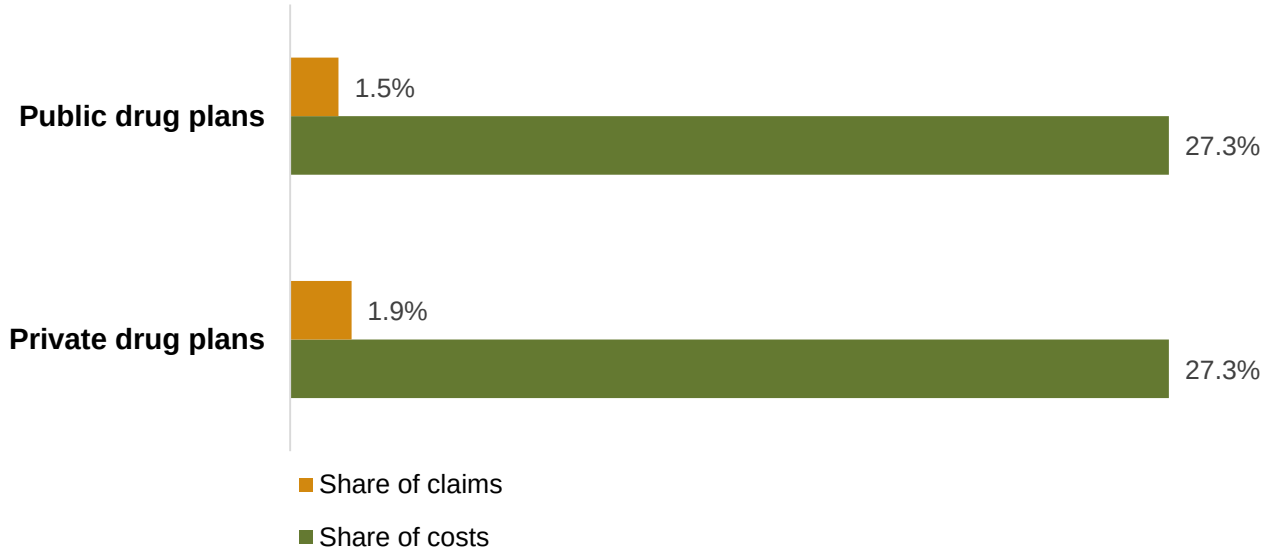
Private plans: IQVIA Private Pay Direct Drug Plan Database, 2018.

Market share by payer: IQVIA Payer Insights Database, 2018.

Biologics account for a disproportionately high share of drug plan costs compared to their share of claims

Although biologic medicines represented 27% of the total drug costs for Canadian public and private plans in 2018, their share of claims was much lower, at 1.5% and 1.9%, respectively. This is due, in part, to the high cost of biologics relative to other types of medicines. Also, because they are delivered by infusion or injection, many biologics may not be dispensed as frequently as other medicines.

FIGURE 2.3 Biologic medicine share of total claims and drug costs, Canadian public and private drug plans, 2018



Note: Drug costs include markups but exclude dispensing costs.

Data source:

Public plans: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

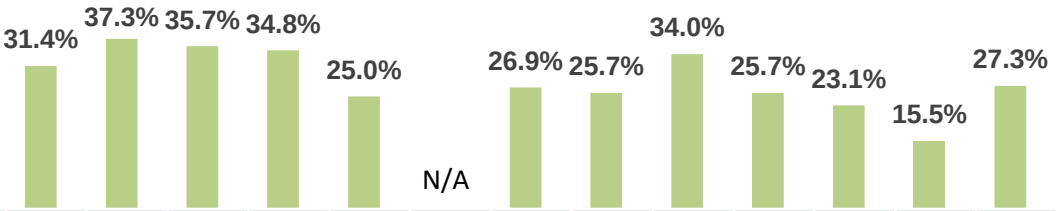
Private plans: IQVIA Private Pay Direct Drug Plan Database, 2018.

There is a marked variation in the biologic share of costs and claims across Canadian public and private drug plans

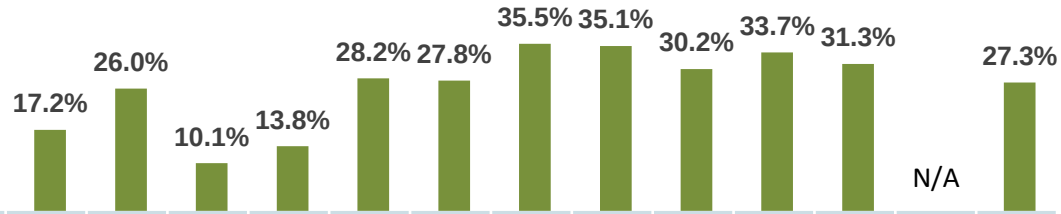
The variation among provinces is influenced, in part, by the types of public drug program offered in each jurisdiction and the medicines that they cover.

The biologic share of drug costs in the private market in each province is likely impacted by their coverage in the public drug programs.

FIGURE 2.4 Biologic medicine share of total drug costs and claims, Canadian public and private drug plans by jurisdiction, 2018



Biologic share of costs	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NIHB	Total
Biologic share of claims	1.5%	2.2%	3.1%	1.7%	1.3%	—	1.6%	2.3%	4.0%	2.1%	2.7%	1.5%	**1.5%**



Biologic share of costs	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NIHB	Total
Biologic share of claims	2.0%	2.5%	1.3%	1.5%	2.2%	1.5%	2.4%	2.9%	3.4%	2.6%	3.0%	—	**1.9%**

Data source:

Public plans: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

Private plans: IQVIA Private Pay Direct Drug Plan Database, 2018.

3. Biosimilar Uptake and Pricing

An increasing number of biosimilars have entered the market in recent years. While European countries have experienced some success in terms of early market entry, price discounts, and uptake, Canada has lagged behind.

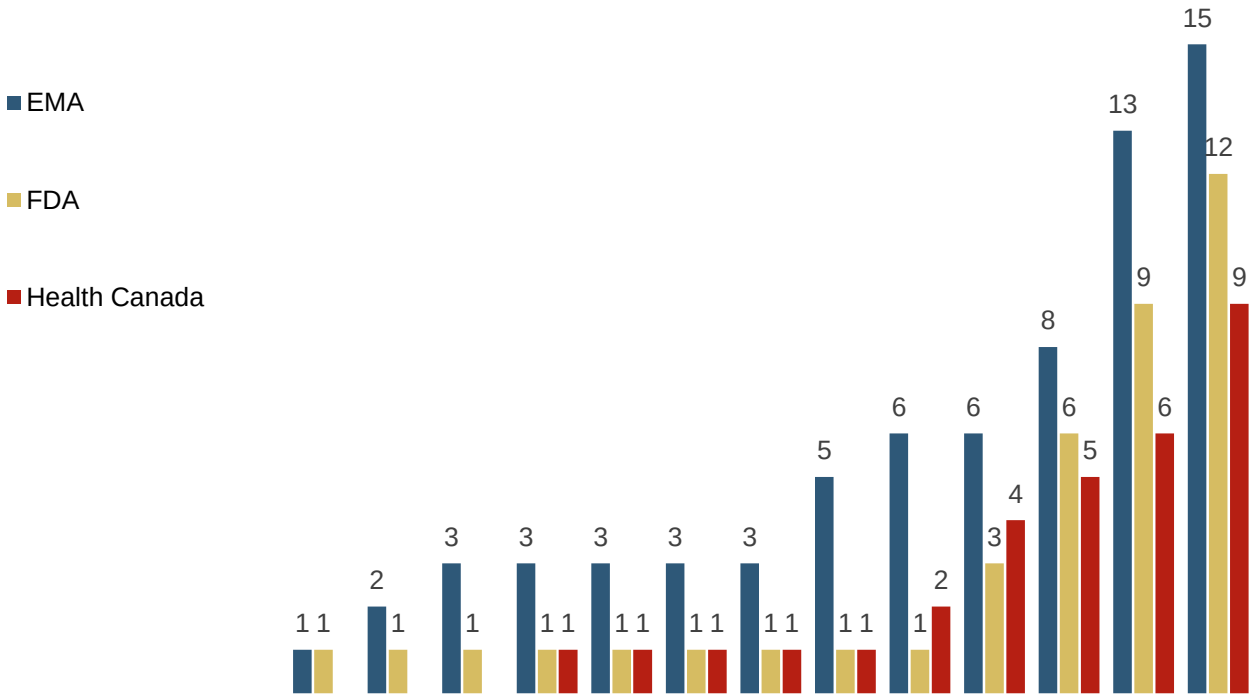
This section explores some of the differences between Canadian and international markets in terms of the number of biosimilar approvals, as well as uptake and pricing, based on publicly available information. It also looks more closely at the uptake of individual biosimilar medicines available in Canada.

The time between the approval and first sales of biosimilars medicines in a market is influenced by a variety of factors including the length of the remaining patent protection for the originator biologic and any relevant patent litigation, as well as the manufacturer's decision to launch a biosimilar and the timing of that decision.

An increasing number of biosimilars have received market approval in recent years

As of the end of 2018, biosimilars for 15 distinct biologic medicines were approved by the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), or Health Canada, with the majority introduced to the market within the last four years.

FIGURE 3.1 Cumulative number of medicines* with biosimilars approved in Europe, the US, or Canada, 2006 to 2018



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Cumulative no. of medicines with approved biosimilars*	**1**	**2**	**3**	**3**	**3**	**3**	**3**	**5**	**6**	**6**	**9**	**14**	**15**

* All available trade names are counted as one biosimilar medicine (e.g., multiple biosimilar trade names referencing the same originator biologic).

Data source: US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

Canada lags behind Europe in the number of biosimilars approved and marketed

By the end of 2018, Health Canada had approved biosimilars for 9 of the 15 biologic medicines, and 5 of these had recorded sales in Canada. By comparison, biosimilars for all 15 medicines were approved in Europe, and there were recorded sales for all but 2.

In 2019, biosimilars for trastuzumab and rituximab were approved by Health Canada and recorded first sales. In addition, first sales were recorded for three other biosimilar medicines: bevacizumab, insulin lispro, and pegfilgrastim.

TABLE 3.1 Initial biosimilar approvals and market availability in Europe, the US, and Canada as of Q4-2018

Medicine (originator biologic)						
	Approval	**First sales**	**Approval**	**First sales**	**Approval**	**First sales**
Infliximab (Remicade)	Sept-13	Q4-2013	Apr-16	Q4-2016	Jan-14	**Q1-2015**
Adalimumab (Humira)	Mar-17	Q4-2018	Sept-16		May-18	
Etanercept (Enbrel)	Jan-16	Q1-2016	Aug-16		Aug-16	**Q4-2016**
Trastuzumab (Herceptin)	Nov-17	Q2-2018	Dec-17			
Insulin glargine (Lantus)	Sept-14	Q2-2015	Dec-15*	Q4-2016	Sept-15	**Q1-2016**
Rituximab (MabThera/Rituxan)	Feb-17	Q2-2017	Nov-18			
Filgrastim (Neupogen)	Sept-08	Q4-2008	Mar-15	Q3-2015	Dec-15	**Q2-2016**
Bevacizumab (Avastin)	Jan-18		Sept-17		Apr-18	
Epoetin alfa (Eprex/Erypo)	Aug-07	Q4-2007	May-18	Q3-2018		
Insulin lispro (Humalog)	Jul-17	Q4-2017	Dec-17*	Q1-2018	Nov-17	
Enoxaparin† (Clexane/Lovenox)	Sept-16	Q1-2017	N/A	N/A		
Pegfilgrastim (Neulasta)	Sept-18	Q4-2018	Jun-18	Q3-2018	Apr-18	
Somatropin (Genotropin)	Apr-06	Q2-2006	May-06*	Q1-2007	Apr-09	**Q3-2009**
Teriparatide (Forsteo/Forteo)	Jan-17		*			
Follitropin alfa (GONAL-f)	Sept-13	Q2-2014				
Total	**15**	**13**	**12**	**7**	**9**	**5**

* Approved or will be approved via 505(b)(2) pathway in the United States.

† Lovenox was not approved under a Biologic License Application in the US. While generic versions of the originator medicine have been approved under the FDA's Abbreviated New Drug Application, they are not reflected in this analysis.

Data source: US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Health Canada databases. IQVIA MIDAS® Database, prescription retail and hospital markets, 2018. All rights reserved.

The prices of some biosimilars are markedly higher in Canada

Despite offering comparable discounts, prices of four of the five biosimilars sold in Canada were higher than in international markets in 2018. This was likely due to the variation in the prevailing originator prices.

For example, although Canada had a greater biosimilar discount for insulin glargine, the average price level in the OECD was 23% lower than the price in Canada in the last quarter of 2018.

TABLE 3.2 Prices and discount rates of biosimilars with sales as of Q4-2018

Medicine	Biosimilar price in Canada (CAD)	Foreign-to-Canadian price ratios		Biosimilar discount relative to price† of originator biologic		
		PMPRB7*	OECD	Canada	Median PMPRB7*	Median 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	–	–	–	–	25.9%	29.5%
Filgrastim	$166.41	0.61	0.37	21.0%	36.4%	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	–	–	–	–	16.9%	20.5%
Sales-weighted average		**0.85**	**0.61**	**30.0%**	**26.0%**	**30.7%**

Note: Prices and discounts are reported as sales-weighted averages of all available forms and strengths.

* France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States.

† The median discounts were calculated based on the price of the biosimilar as of Q4-2018 and the originator in the quarter before biosimilar introduction.

‡ Could not be calculated due to data limitations.

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

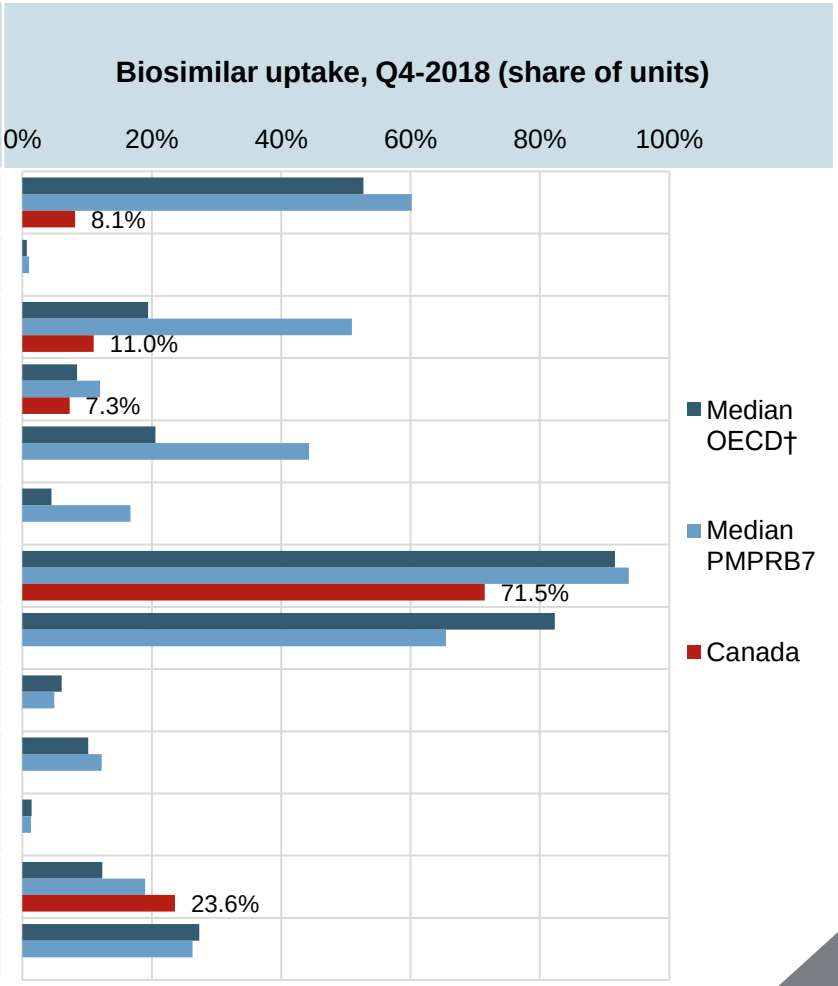
Biosimilar uptake in Canada is relatively modest compared to other OECD markets

At the end of 2018, only the somatropin biosimilar had outpaced international uptake. Even after considering the time of launch, the uptake of infliximab, etanercept, and insulin glargine biosimilars in Canada lagged behind other countries.

Filgrastim, with a biosimilar uptake of 71.5%, was much closer to the international norms. This medicine, which is prescribed for acute indications, is predominantly prescribed to treatment-naïve patients, which may account for its higher uptake.

FIGURE 3.2 Biosimilar share of units, by medicine, in Canada, OECD, and PMPRB7 as of Q4-2018

Biologic medicine	Sales in Canada, 2018 ($million)
Infliximab	$1,123
Adalimumab	$800
Etanercept	$309
Insulin glargine	$285
Rituximab	$266
Trastuzumab	$186
Filgrastim*	$133
Epoetin alfa*	$103
Insulin lispro	$77
Enoxaparin sodium*	$58
Pegfilgrastim*	$47
Somatropin	$43
Follitropin alfa*	$18



* Generally used to treat acute conditions.

† Canada is excluded from the median OECD value.

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

Factors that may influence biosimilar uptake in Canada

Factor	Description
Interchangeability	**In Canada, as in most countries, biosimilars are not interchangeable with the reference biologic** ▪ The decision to prescribe a biosimilar or switch an existing patient to the biosimilar version rests primarily with the prescribing physician ▪ Not all biosimilars are approved for the same indication(s) as the originator biologic ▪ Payers can play a significant role by encouraging the use of biosimilars through preferential reimbursement policies
Payer policies	**Most Canadian public payers have implemented policies of reimbursing the biosimilar for naïve patients – with limited impact,** as nothing prevents the physician from prescribing a different brand-name medicine
Switching	**Switching from an ongoing biological treatment to an approved biosimilar has not been encouraged in Canada until recently** ▪ New initiatives include biosimilar switching policies in British Columbia and Alberta, and the biosimilar transition program offered by Green Shield
Maintaining market share	**Strategies/initiatives undertaken by the manufacturer of the originator biologic that may limit the uptake of biosimilars:** ▪ Free reference biologics reportedly offered to hospitals, where treatment is often initiated ▪ Exclusivity agreements with third-party infusion clinic networks ▪ Fees to specialists for administering the medicine ▪ Patient Support Programs: offer services like access to clinics and reimbursement navigation

4. Infliximab Case Study

Infliximab was one of the first biologic medicines with biosimilar sales in Canada.

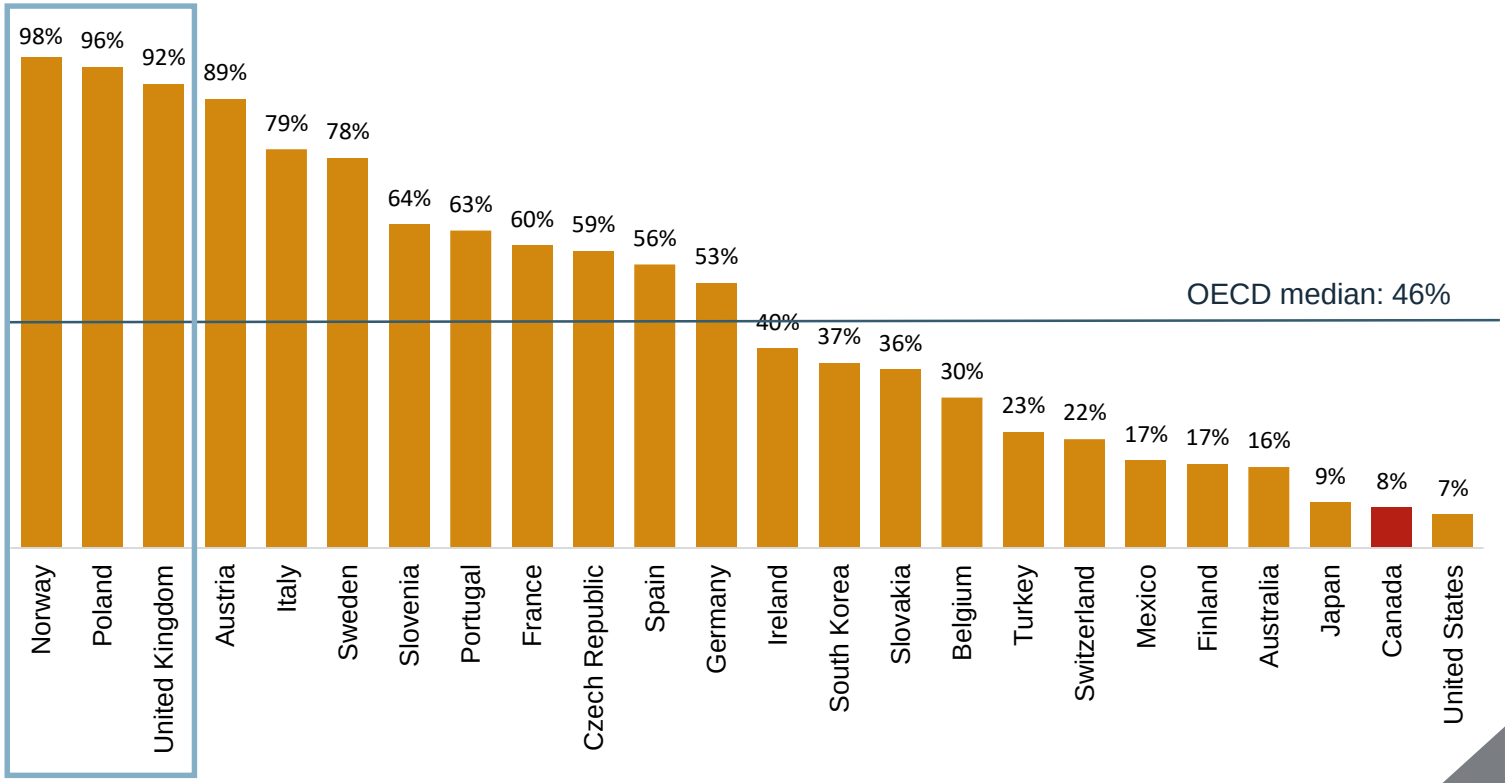
Although the biosimilar Inflectra was first sold in Canada in 2015, its uptake has been limited, and by the end of 2018 the originator biologic Remicade still maintained a significant market share. This analysis examines the relative use and costs of Remicade and Inflectra in Canadian public drug plans within the context of their therapeutic class of disease-modifying antirheumatic drugs (DMARDs).

This section also compares the overall Canadian experience with the policy-driven uptake of infliximab biosimilars in international markets. These policies include switching, which is a physician-driven decision to exchange one medicine for another during the course of treatment, and substitution, which is the practice of dispensing an alternate medicine at the pharmacy level without consulting the prescriber.

Canada lags well behind other OECD countries in terms of infliximab biosimilar uptake

The uptake of Inflectra in Canada was only 8% in 2018, well below the OECD median of 46% for infliximab biosimilars.

FIGURE 4.1 Uptake of infliximab biosimilars (share of units), OECD, Q4-2018

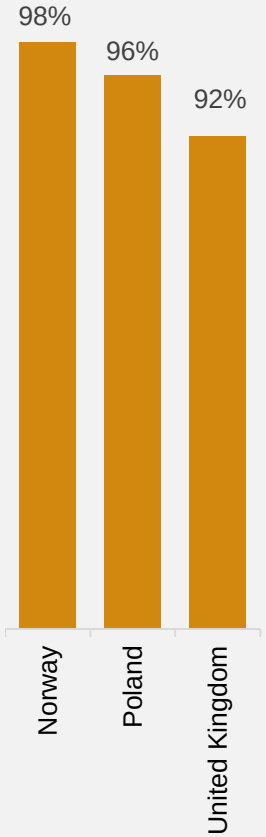


Note: Countries with limited data were excluded from the analysis.

Data source: IQVIA MIDAS® Database, prescription retail and hospital markets, Q4-2018. All rights reserved.

International success in biosimilar uptake is driven by high-impact policies and initiatives

The uptake of infliximab biosimilars in Norway, Poland, and the United Kingdom exceeded 90% in 2018, well above the OECD median.



Data source: IQVIA MIDAS® Database, prescription retail and hospital markets, Q4-2018. All rights reserved.

FIGURE 4.2 Select European biosimilar policies and initiatives for infliximab, Norway, Poland, and the United Kingdom, 2018

Norway	**National single-winner tender –** Physicians are required to prescribe the cheapest medicine (hospital use and some outpatient use products). **Switching –** This is allowed and common in practice. **Physician education –** The **NOR-SWITCH** study demonstrated that the infliximab biosimilar Remsima was not inferior to Remicade.
Poland	**Substitution** – Biosimilar substitution is allowed. **Tendering** – Patients are required to use the tender winning medicine. **Initiation –** Therapy-naïve patients with IBD should be initiated on the biosimilar. **Switching –** The Ministry of Health "takes the view that any exchange within the scope of drugs containing infliximab at any level of therapy is permissible."*
United Kingdom	**Initiation** – The treatment should be initiated with the cheapest available biologic medicine. **Switching** – Pilot switching programmes from Remicade to biosimilars of infliximab were found to be highly acceptable to patients and clinicians. **Guidance –** The National Health Service in England recommended that 9 out of 10 new patients should be initiated on the best value medicine within 3 months of a biosimilar launch, and at least 80% of existing patients should be switched to the best value biologic within 12 months.

* Medicines for Europe, Biosimilar Medicines Sector Group. 2019. *Positioning statements on physician-led switching for biosimilar medicines*. Brussels, Belgium.

Data source: International Policies on the Appropriate Use of Biosimilar Drugs, CADTH. Additional references were consulted for polices in Poland and the UK, see the Endnotes.

Only a small number of patients using Remicade switch to the biosimilar

Patients already established on treatments make up most of the biologic DMARD market.

While infliximab continued to account for 30% of the biologic DMARD patients and 45% of the drug costs for Canadian public plans in 2017/18, Inflectra only represented 1% of patients and 0.6% of costs.

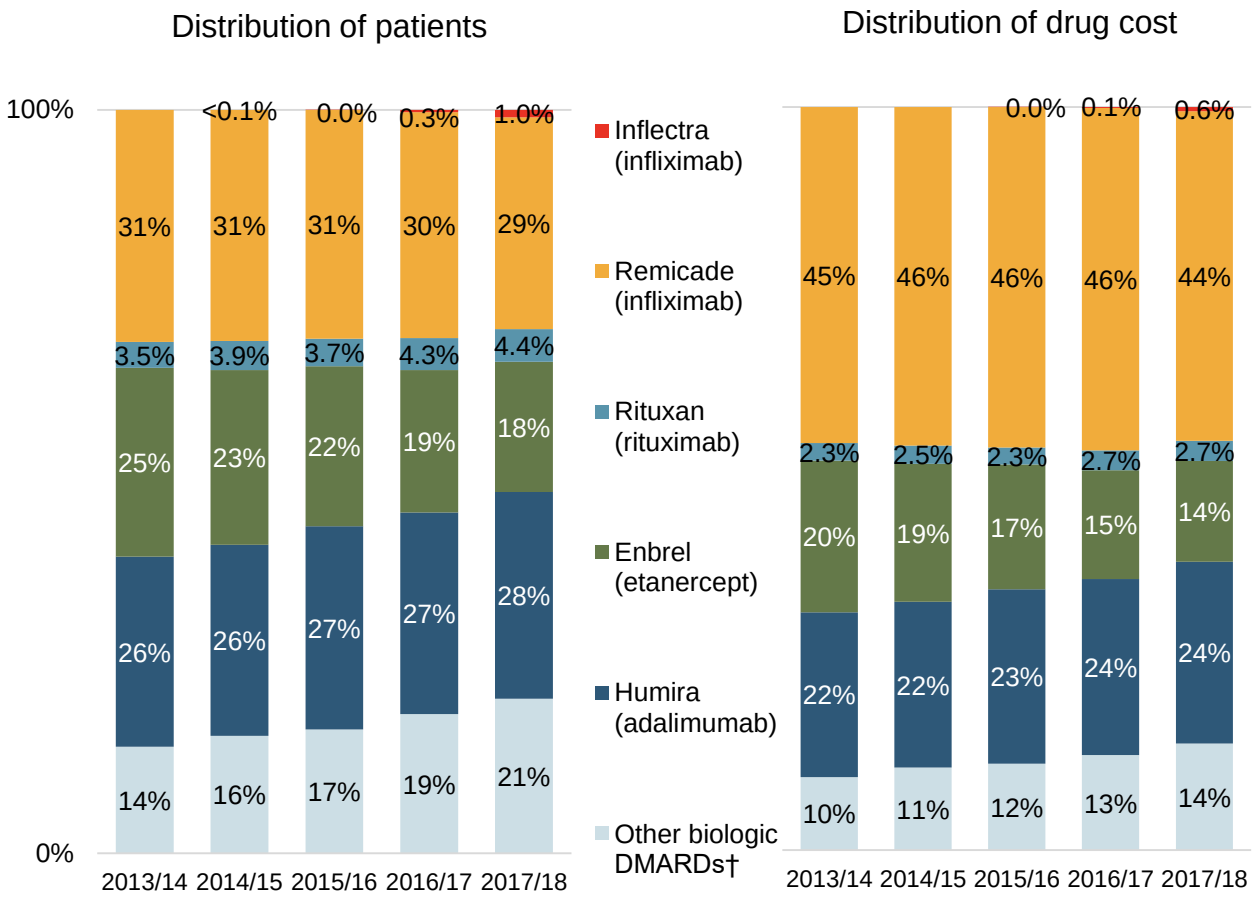
Note: Results apply to Canadian public drug plans participating in the NPDUIS initiative**.**

***** Disease-modifying antirheumatic drugs are commonly used in the treatment of rheumatoid arthritis as well as other inflammatory conditions such as plaque psoriasis and inflammatory bowel disease.

† Includes Simponi, Orencia, Actemra, and Cimzia.

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

FIGURE 4.3 Distribution of established patients on biologic DMARDs* before and after the introduction of Inflectra, Canadian public drug plans, 2013/14 to 2017/18

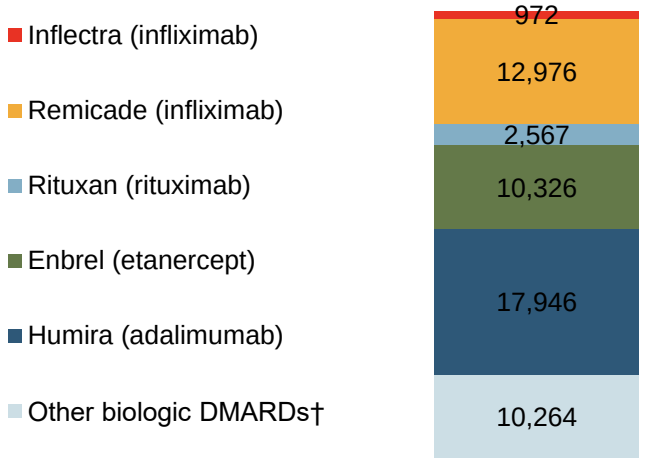


Switching patients to biosimilars could result in significant savings

Patients using biologic DMARDs made up less than 1% of the eligible beneficiaries in public plans in fiscal year 2017/18, but accounted for over 10% of all drug costs.

FIGURE 4.4 Distribution of patients on biologic DMARDs*, public drug plans, 2017/18

Number of beneficiaries using biologic DMARDs	55,051



All public plans	
Total no. of active beneficiaries (thousands)	**6,912.4**
Share of active beneficiaries using biologic DMARDs	**0.8%**
Drug cost for biologic DMARDs (millions)	**$1,019.6**
Share of total drug costs	**11.2%**

Note: Results apply to Canadian public drug plans participating in the NPDUIS initiative**.**

***** Disease-modifying antirheumatic drugs (DMARDs) are commonly used in the treatment of rheumatoid arthritis as well as other inflammatory conditions such as plaque psoriasis and inflammatory bowel disease.

† Includes Simponi, Orencia, Actemra, and Cimzia.

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

Biosimilar Initiatives in Canada

Given the high cost of biologics in Canada, biosimilars offer the potential for important savings. Recently, Canadian payers have undertaken a number of initiatives to increase biosimilar uptake, which are outlined in the table below.

The second part in the *Biologics in Canada* chartbook series will explore the potential for increased biosimilar savings in more detail.

Payer		Initiative
Public payers	Quebec	Quebec only reimburses the lowest priced version of infliximab.
	Manitoba	New patients are required to try two Tier 1 medicines before being reimbursed for a Tier 2 medicine; Tier 1 biologic medicines have been determined to be the most cost-effective.
	British Columbia	In 2019, British Columbia became the first Canadian province to initiate a switch to biosimilar medicines for patients covered under the PharmaCare program. Under the policy, patients using Enbrel, Remicade, and Lantus for specific indications are required to switch to the biosimilar.
	Alberta	Alberta announced that all patients taking Enbrel, Remicade, Lantus, Neupogen, Neulasta, and Copaxone for indications ranging from rheumatoid arthritis to diabetes and multiple sclerosis will be required to switch to the biosimilar.
Private payers		Green Shield Canada (GSC) initiated a pilot program in 2018. The program targeted patients taking Remicade and Enbrel for three rheumatic conditions and reduced reimbursement to the biosimilar price. Under the program, the patient could switch to the biosimilar or remain on the biologic and pay the cost difference. Since then, GSC has opened its biosimilar transition program to any sponsor who wishes to take part.

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Endnotes

Additional references consulted for biosimilar policies and initiatives in Poland and the United Kingdom:

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