



Patented
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Review Board

Conseil d'examen
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brevetés



CHARTBOOK


National Prescription Drug Utilization Information System

NPDUIS

Biologics in Canada

Part 2: Biosimilar Savings, 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.

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Introduction

Biologics are a high-growth market segment. In Canada, sales of biologic medicines have tripled over the last decade, reaching \$7.7 billion in 2018 and accounting for almost one third of all pharmaceutical sales.

While biosimilars of infliximab, etanercept, insulin glargine, and filgrastim saved Canadians an estimated \$93.9 million in drug costs in 2018, the savings could have been many times greater if domestic uptake and pricing had been more closely aligned with median OECD levels.

Drawing on current trends in domestic and international biosimilar pricing and uptake, this analysis estimates the additional savings that could be achieved by increasing the uptake and/or lowering the prices of biosimilars in Canada.

This is the second publication in a two-part chartbook series. The first part in the series, *Biosimilars in Canada. Part 1: Market Trends, 2018*, examines the market dynamics of biologics in Canada and compares Canadian and international trends in biologic sales and pricing, as well as biosimilar uptake.

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.

Background

Biosimilars are launched later in Canada than in Europe, and when they do arrive, biosimilar uptake tends to be lower. Even though the biosimilar discounts in Canada are greater than in other countries, Canadians still end up paying more, as the discounts do not offset the higher reference price of the more expensive originator biologics.

Why biosimilar savings matter

Historically, the savings from generic substitution and generic price reductions have helped to offset the cost pressures from new drugs and increased utilization for Canadian drug plans. However, in recent years, the impact from these savings has been gradually declining.

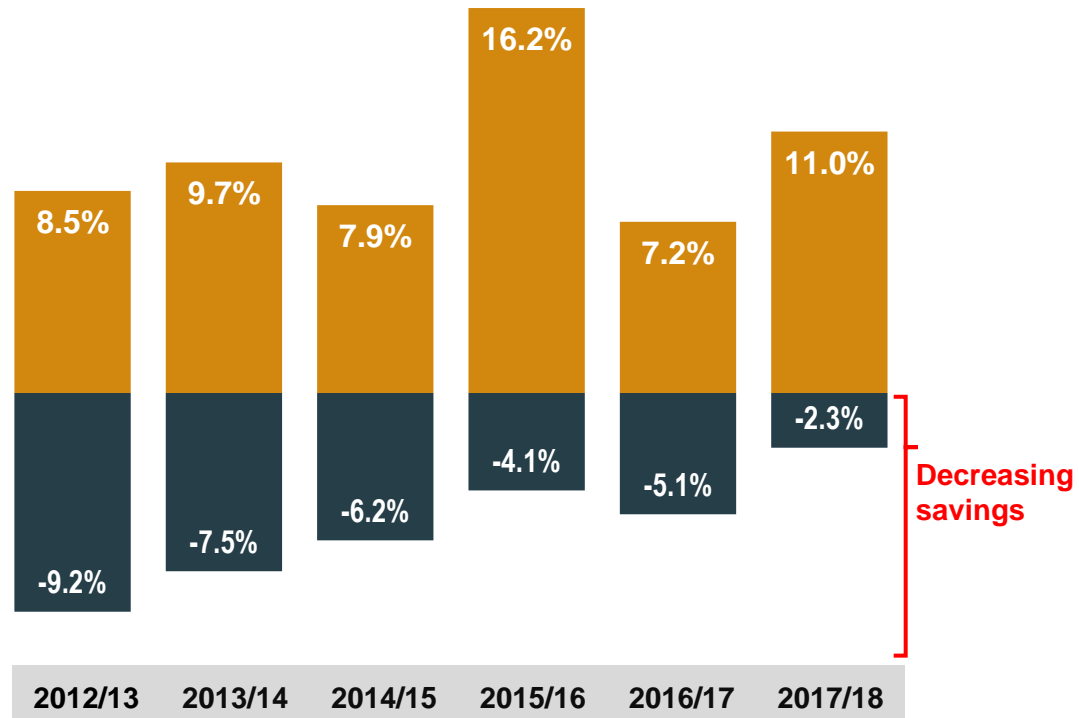
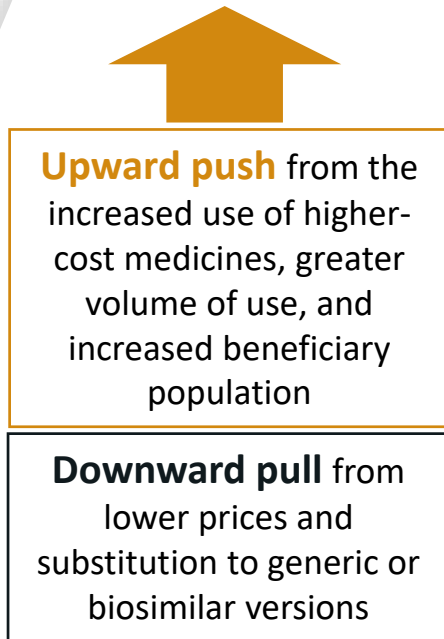
Given the high-growth market for biologics in Canada, biosimilars offer an excellent opportunity for significant cost savings; but this is a complex market space, and these potential savings have yet to be fully realized. Unlike small molecule medicines, which experience a relatively quick market adjustment after generic entry, most originator biologics in Canada continue to dominate the market long after the introduction of a biosimilar. This, in turn, limits the savings for Canadian payers and their potential ability to fund new therapies that are increasingly coming at high prices.

Despite the availability of a biosimilar alternative, the originator biologic Remicade still accounted for the vast majority of infliximab sales in 2018, a market worth over \$1 billion in Canada. Since then, policy initiatives by public plans in British Columbia and Alberta, as well as by Green Shield Canada, have been introduced to promote switching to available biosimilars. Future analyses will measure the impact of these policy changes on the market in Canada.

Why biosimilar savings matter

▶ Drug cost growth, Canadian public drug plans, 2012/13 to 2017/18

Net change: -0.8% 2.0% 2.5% 12.0% 2.0% 8.3%



Total growth rate **24.8%**
Compound annual growth rate **7.7%**

Note: The upward push in 2015/16 and the downward pull in 2016/17 were heavily influenced by the introduction of direct-acting antiviral drugs for hepatitis C.

Values may not add to totals due to rounding and the cross effect.

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

Methods and Limitations

This analysis explores the potential savings from a select number of biosimilars that have been launched in the Canadian market or are expected to be available by the end of 2020.

Estimated savings are based on various scenarios of market entry, uptake, and price discounts, as observed in Canadian and foreign markets. Estimates are based on an aggregate of the potential savings of select biosimilars in the third year following market entry.

Pricing and uptake information were calculated by converting the physical quantities of drugs into a standard unit of measure. This allowed for the aggregation of units across groups of drugs, which would not otherwise be possible.

International availability, uptake, and pricing information were determined based on data from the IQVIA MIDAS® Database for member countries in the Organisation for Economic Co-operation and Development (OECD).

Combination products were excluded from the analysis and reported Canadian sales. Somatropin (omnitrope) was also excluded from the analysis due to low sales and data limitations in estimating overall savings.

The anticipated launch dates reported in this chartbook were based on reviews of various publicly available sources. These dates are estimates and may change at any time.

Methods: Selection of Medicines

Ten biologic medicines met the selection criteria for analysis.

Biologic medicine*	2018 Canadian sales	Biosimilar(s) availability [†] in EU and US	First biosimilar availability in Canada		
			Approval	First sales [‡]	Anticipated launch
Infliximab	\$1,123M	EU, US	Jan-14	Q1-2015	–
Ranibizumab	\$317M	–	–	–	2020
Etanercept	\$309M	EU,	Aug-16	Q4-2016	–
Insulin glargine	\$285M	EU, US	Sept-15	Q1-2016	–
Rituximab ^c	\$266M	EU, US	Apr-19	Q4-2019	–
Trastuzumab ^c	\$186M	EU, US	May-19	Q2-2019	–
Filgrastim	\$133M	EU, US	Dec-15	Q2-2016	–
Bevacizumab ^c	\$118M	EU, US	Apr-18	Q3-2019	–
Insulin lispro	\$77M	EU, US	Nov-17	Q4-2019	–
Pegfilgrastim	\$47M	EU, US	Apr-18	Q1-2019	–

Established biosimilars available in Canada for at least two years

Biosimilars recently launched in Canada or that are expected to be available by Q4-2020

* Oncology medicines are marked with a superscript “C”.

† Approval and/or sales.

‡ Sales for 2019 were based on data captured by Health Canada’s Drug Product Database (DPD).

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



1. Potential Savings from Established Biosimilars

The use of biosimilars of infliximab, etanercept, insulin glargine, and filgrastim, which have been available in Canada for at least two years, saved Canadians an estimated \$93.9 million in 2018. Assuming that the trend in uptake follows the status quo, in 2021, these savings will total \$294 million.

Using two different scenarios based on international experience, this section demonstrates the additional savings that Canadians could realize by increasing biosimilar uptake and/or lowering prices. Results are given for the unrealized savings potential in 2018, as well as the forecast savings for 2021.



Biosimilars savings model: Established biosimilars

Two scenarios based on OECD biosimilar uptake and pricing are used to determine the additional potential savings for 2018 and the forecasted savings for 2021.

OECD moderate estimate: Assumes that the uptake of biosimilars in Canada matches the OECD median (indexed to launch) and biosimilar prices remain at the Canadian level.

Under this scenario, the savings potential in 2018 would have increased from an estimated \$94 million to \$346 million.

OECD high estimate: Assumes that the uptake of biosimilars in Canada matches the median uptake in the **top four** OECD countries and the Canadian price matches the OECD median price.

Under this scenario, the savings potential in 2018 would have increased from an estimated \$94 million to \$808 million.

Canadians are only realizing a fraction of the potential savings from biosimilars

Increasing the uptake and/or lowering the prices of the four biosimilars analyzed would have a significant potential impact on the savings realized by Canadians.

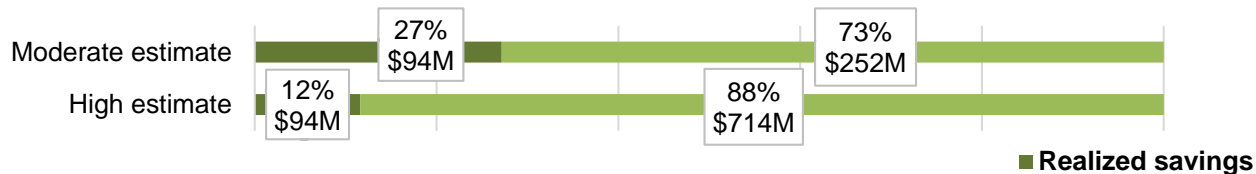
Projecting to 2021, if moderate OECD uptake rates are applied, the estimated savings from these biosimilars could be increased by \$401 million over the status quo estimate. If the high OECD estimate is applied, estimated future savings of \$1,136 million could be attained, \$842 million more than the Canadian estimate of \$294 million.

* Assuming that the total use of each medicine remained the same and that the price of the originator biologic did not drop after the launch of the biosimilar.

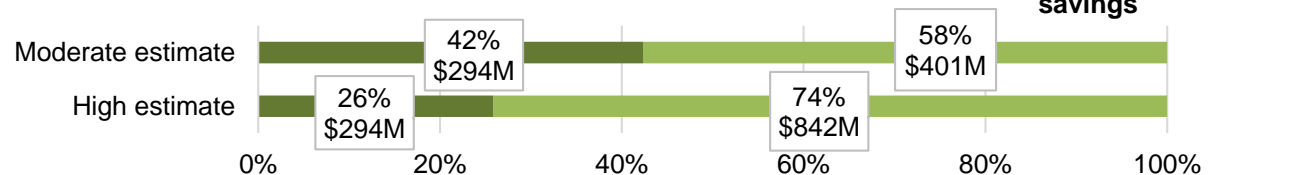
Data source: IQVIA MIDAS® Database, prescription retail and hospital markets. All rights reserved.

FIGURE 1.1 Estimated savings from biosimilars in Canada, realized and potential for 2018, and projected savings for 2021

Canadian savings versus potential savings, 2018



Canadian savings versus potential savings, forecast for 2021



Biologic medicine	Estimated* actual savings in 2018	Potential savings in 2018		Forecasted savings in 2021		
		OECD moderate estimate	OECD high estimate	Canadian status quo	OECD moderate estimate	OECD high estimate
Infliximab	\$55.2M	\$287.8M	\$588.0M	\$212.7M	\$568.6M	\$834.8M
Etanercept	\$11.4M	\$31.0M	\$86.2M	\$31.5M	\$78.8M	\$131.1M
Insulin glargine	\$5.5M	\$7.4M	\$35.4M	\$18.7M	\$17.1M	\$56.9M
Filgrastim	\$21.8M	\$19.4M	\$98.1M	\$31.2M	\$30.2M	\$112.9M
Savings	\$93.9M	\$345.6M	\$807.7M	\$293.9M	\$694.7M	\$1,135.7M



2. Infiximab case study

Infiximab is over a one billion dollar market in Canada.

The infiximab biosimilar Inflectra first entered the Canadian market in 2015. From that time until the end of 2018, Canadians spent a total of \$62 million on the biosimilar, resulting in estimated savings of \$108 million. Following this same trend, the anticipated savings from 2019 until the end of 2021 would be an estimated \$447 million.

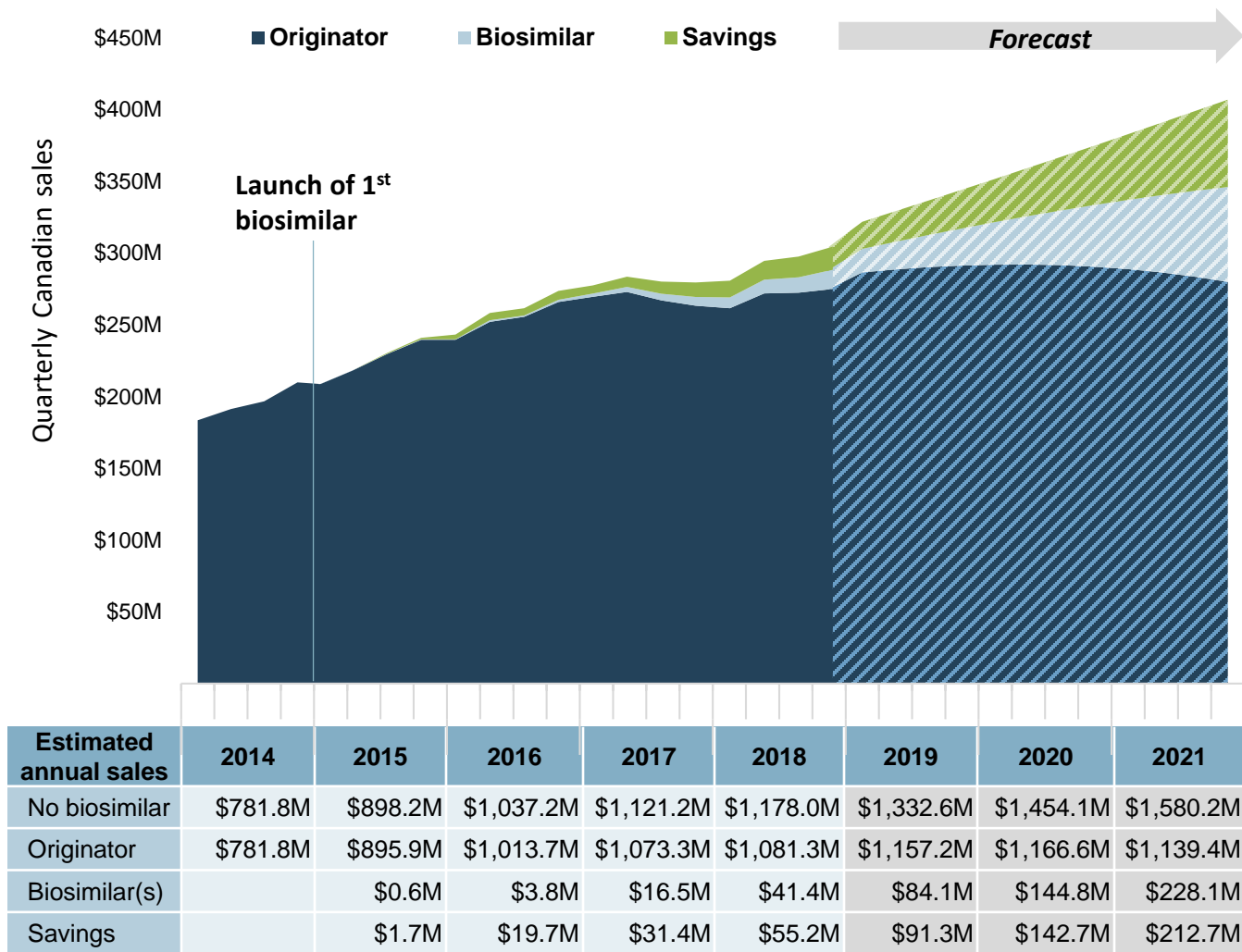
However, if the biosimilar uptake was increased to the median OECD level for the 2019 to 2021 period, these forecasted savings could more than triple. Using higher uptake values and median OECD prices would increase the estimated savings even further to well over \$2 billion, more than five-fold the anticipated level using the current Canadian trends.

This section illustrates the potential savings from the use of infiximab biosimilars from 2015 to 2021 under three different scenarios: current Canadian trends; the OECD moderate estimate; and the OECD high estimate.

Future savings will be limited based on the current uptake and pricing of infliximab

If the current trend in biosimilar uptake continues, biosimilar sales are forecast to reach \$457 million from 2019 to 2021. This would result in an estimated \$447 million in savings over that period.

FIGURE 2.1 Estimated cost savings of infliximab biosimilars, based on quarterly Canadian sales from 2015 to 2018 and forecast to 2021



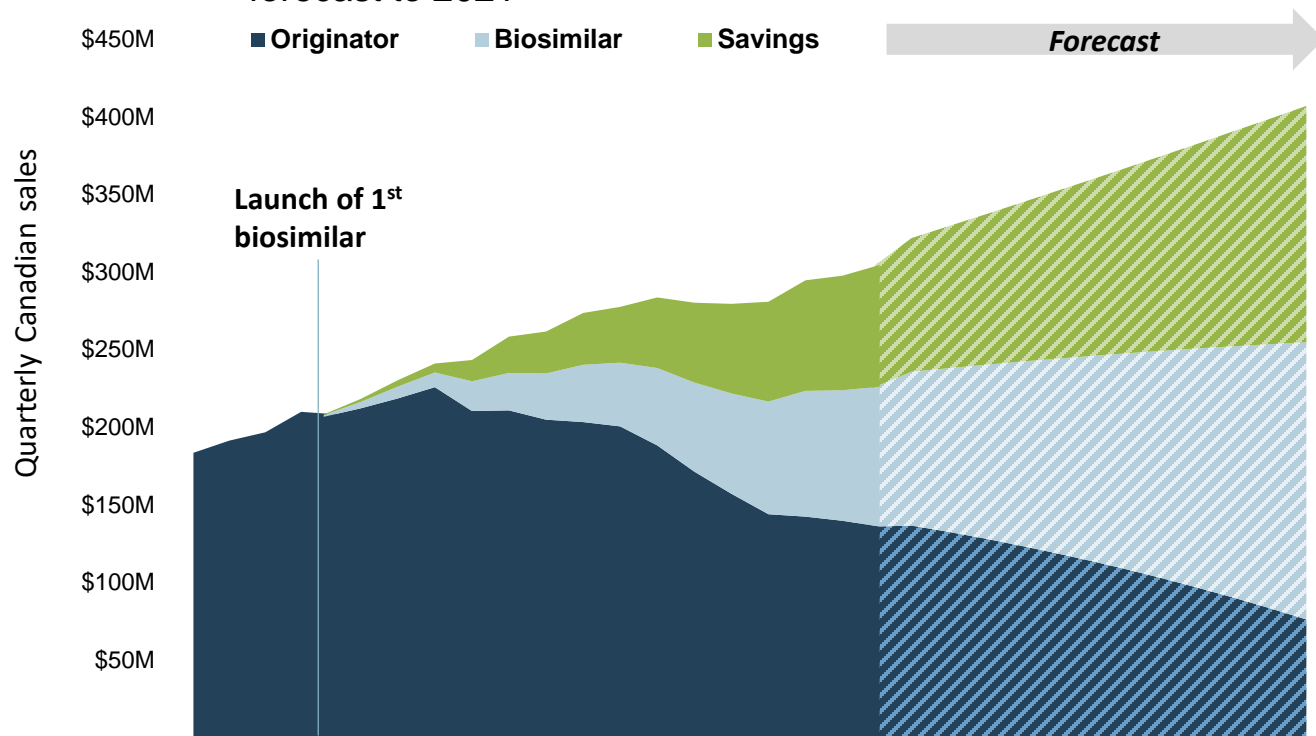
Note: Due to rounding, the originator, biosimilar, and savings values may not add to the total biosimilar value in any given year.

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

If the uptake in infliximab biosimilars in Canada matched the median OECD level, savings could potentially increase by almost \$1 billion over 3 years

For the 2019 to 2021 period, increased biosimilar uptake would result in forecasted biosimilar sales of \$1,644 million. This would give rise to an estimated \$1,412 million in savings, \$965 million more than in the Canadian uptake scenario.

FIGURE 2.2 Estimated cost savings of infliximab biosimilars, based on quarterly sales under the OECD moderate scenario from 2015 to 2018 and forecast to 2021



Estimated annual sales	2014	2015	2016	2017	2018	2019	2020	2021
No biosimilar	\$781.8M	\$898.2M	\$1,037.2M	\$1,121.2M	\$1,178.0M	\$1,332.6M	\$1,454.1M	\$1,580.2M
Originator	\$781.8M	\$863.5M	\$829.6M	\$717.5M	\$562.2M	\$521.8M	\$443.9M	\$345.9M
Biosimilar(s)		\$22.4M	\$110.1M	\$213.0M	\$328.0M	\$434.5M	\$543.3M	\$665.7M
Savings		\$12.4M	\$97.6M	\$190.7M	\$287.8M	\$376.3M	\$466.9M	\$568.6M
Foregone savings		\$10.7M	\$77.8M	\$159.3M	\$232.6M	\$285.0M	\$324.2M	\$355.9M

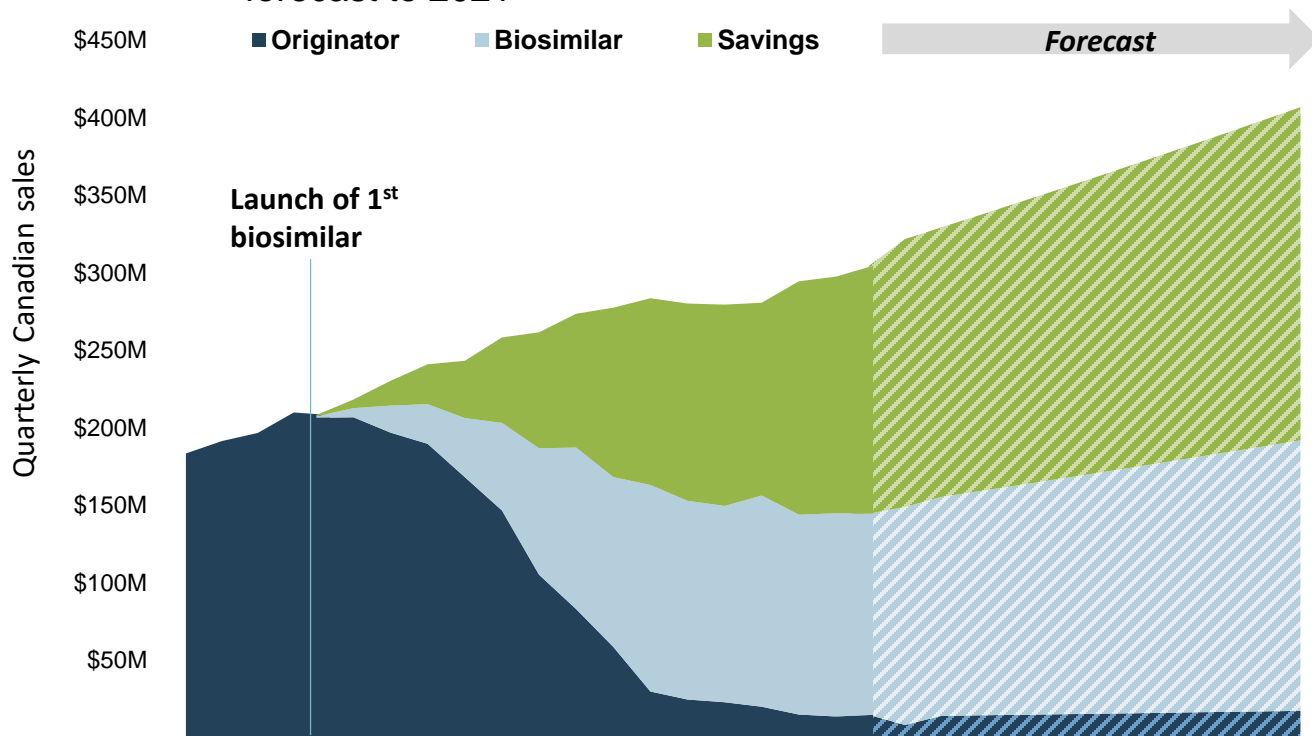
Note: Due to rounding, the originator, biosimilar, and savings values may not add to the total biosimilar value in any given year.

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

With a higher uptake in infliximab biosimilars and Canadian prices matching the OECD median level, anticipated savings could potentially increase by more than \$1.8 billion over 3 years

If the Canadian uptake of infliximab biosimilars matched the median of the top four OECD countries and the biosimilar price matched the OECD median price, the forecasted biosimilar sales from 2019 to 2021 would be \$1,876 million. This would give rise to an estimated \$2,310 million in savings, \$1,863 million more than in the Canadian uptake scenario.

FIGURE 2.3 Estimated cost savings of infliximab biosimilars, based on quarterly sales under the OECD high scenario from 2015 to 2018 and forecast to 2021



Estimated annual sales	2014	2015	2016	2017	2018	2019	2020	2021
No biosimilar	\$781.8M	\$898.2M	\$1,037.2M	\$1,121.2M	\$1,178.0M	\$1,332.6M	\$1,454.1M	\$1,580.2M
Originator	\$781.8M	\$800.2M	\$503.2M	\$135.9M	\$63.2M	\$51.2M	\$61.9M	\$67.3M
Biosimilar(s)		\$49.7M	\$280.6M	\$498.2M	\$526.7M	\$574.4M	\$624.0M	\$678.1M
Savings		\$48.2M	\$253.4M	\$487.1M	\$588M	\$707M	\$768.2M	\$834.8M
Foregone savings		\$46.6M	\$233.7M	\$455.7M	\$532.8M	\$615.7M	\$625.5M	\$622.1M

Note: Due to rounding, the originator, biosimilar, and savings values may not add to the total biosimilar value in any given year.

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



3. Forecasted Savings for New Biosimilars

With many new biosimilars entering the market, there is a potential for significant future savings.

This section forecasts the potential savings for six biologic medicines with biosimilars that recently entered the Canadian market or that are expected to be available in Canada by the end of 2020: ranibizumab, rituximab, trastuzumab, bevacizumab, insulin lispro, and pegfilgrastim.

Their potential uptake, price, and resulting savings are estimated based on the experience of similar biosimilars in Canadian and international markets.

Biosimilars savings model: New biosimilars

Three scenarios are used to calculate the potential savings from these biosimilars in 2023.

Canadian estimate: Assumes that the Canadian price of the originator biologic is discounted by the average Canadian biosimilar discount (30.05%), unless it has a publicly available price.

OECD moderate estimate: Assumes that the OECD median uptake is combined with the Canadian prices used in the first scenario.

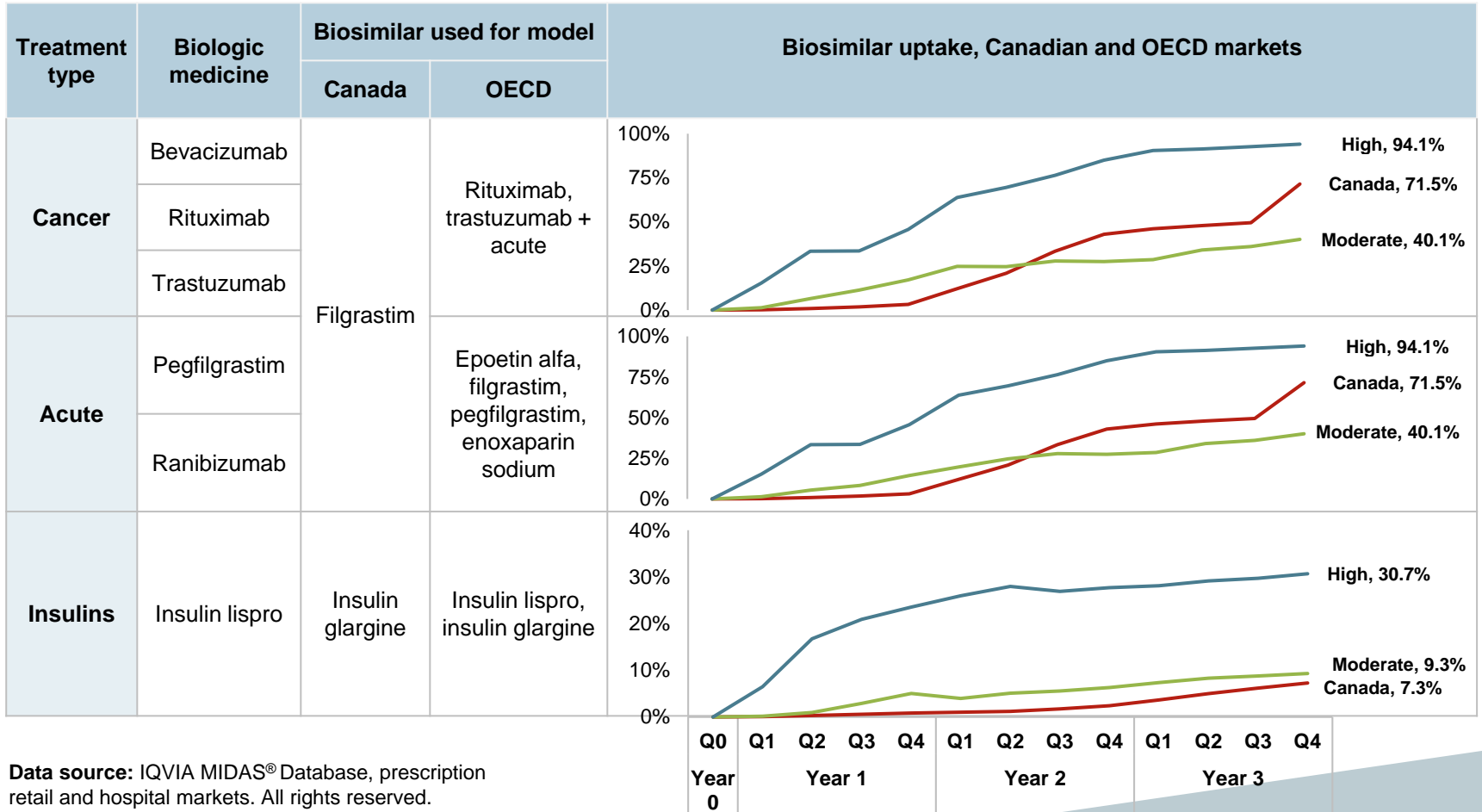
OECD high estimate: Assumes that the median uptake in the top four OECD countries is combined with the OECD median price. If no OECD biosimilar price is available, the OECD median prices are discounted by the OECD average biosimilar discount of 29.51%.

Canadian and OECD uptake is modelled after the uptake of similar biologic medicines currently available in the related market. Biosimilar uptake is measured for the first three years after introduction indexed to the year of launch. Total medicine use was projected based on the Canadian use of the originator biologic.

Biosimilars savings model: Uptake modelling for new biosimilars

Five of the biosimilars analyzed have indications for acute diseases or cancer. Their potential rate of uptake in Canada is modelled after the indexed uptake of the filgrastim biosimilar, which has a higher Canadian market share than median OECD share in the third year after launch. The new insulin medicine is expected to follow a similar trend as insulin glargine.

► **FIGURE 3.1** Biosimilar uptake by treatment type, three years after launch, Canada and the OECD



New biosimilars entering the Canadian market present an opportunity for significant future savings

In 2023, the total savings from these new biosimilar medicines in Canada could vary from \$222 million to \$447 million depending on their rate of uptake and price discount.

► **TABLE 3.1** Estimated potential savings of new biosimilars in 2023, Canada

Biologic medicine*	2018 Canadian sales	First biosimilar availability			2023 forecast sales†	Potential savings in 2023		
		Approval	First sales	Anticipated launch		Canadian estimate	OECD	
							Moderate estimate	High estimate
Ranibizumab	\$317M	–	–	2020	\$372M	\$79M (21.3%)	\$54M (14.6%)	\$201M (54.2%)
Rituximab ^c	\$266M	Apr-19	Q4-2019	2020	\$283M	\$59M (20.8%)	\$40M (14.2%)	\$83M (29.3%)
Trastuzumab ^c	\$186M	May-19	Q2-2019	–	\$194M	\$46M (23.8%)	\$39M (20.2%)	\$83M (43.0%)
Bevacizumab ^c	\$118M	Apr-18	Q3-2019	–	\$130M	\$30M (23.4%)	\$26M (19.8%)	\$54M (41.4%)
Insulin lispro	\$77M	Nov-17	Q4-2019	–	\$96M	\$3M (3.1%)	\$3M (3.4%)	\$12M (12.8%)
Pegfilgrastim	\$47M	Apr-18	Q1- 2019	–	\$22M	\$5M (20.7%)	\$4M (17.9%)	\$13M (61.7%)
Total savings (2023)	\$1,011M	–	–	–	\$1,097M	\$222M (20.3%)	\$167M (15.2%)	\$447M (40.7%)

* Oncology medicines are marked with a superscript “C”.

† Assuming no biosimilar availability.

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

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