Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

MEDS

ENTRY WATCH 2018

National Prescription Drug Utilization Information System

NPDUIS

Canada

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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 health care 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. The Advisory Committee is composed of representatives from public drug plans in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, the Non-Insured Health Benefits Program (NIHB), and Health Canada. It also includes observers from CIHI, the Canadian Agency for Drugs and Technologies in Health (CADTH), the Ministère de la Santé et des Services sociaux du Québec (MSSS), and the pan-Canadian Pharmaceutical Alliance (pCPA) Office.

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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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EXECUTIVE SUMMARY

This is the fourth edition of the PMPRB's *Meds Entry Watch* report, which explores the market entry of new medicines in Canada and other countries. Building on the retrospective analysis of trends since 2009, this report focuses on medicines that received first-time market approval through the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada in 2017 and 2018, and analyzes their uptake, pricing, sales, and availability as of the last quarter of 2018 (Q4-2018). This edition includes a new Canadian section with information on medicines that received their first Health Canada approval in 2017, as well as those that were approved for new indications.

The IQVIA MIDAS® Database was the primary source for the sales and list prices of new medicines in Canadian and international markets, as well as for the quantity sold.

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 (UK), and the United States (US).

This publication informs decision makers, researchers, and patients of the evolving market dynamics of emerging therapies in Canadian and international pharmaceutical markets.

Key Findings

(A) Trends in New Medicine Approvals, 2009 to 2017

Although the market impact of new medicine approvals has varied from year to year since 2009, the landscape has been characterized by a continued rise in the number of specialized treatments.

- Medicines approved since 2009 accounted for over one third of brand-name medicine sales in Canada and the PMPRB7 by Q4-2018.
- From 2009 to 2017, slightly less than half (48%) of all new medicines had sales in Canada, ahead of the OECD median (40%) but behind most PMPRB7 countries, many of which have lower average patented medicine prices.
- New medicines with Canadian sales from 2009 to 2017 accounted for 94% of all new medicine sales in the OECD by Q4-2018, indicating that the higher-selling medicines were among those approved and sold in Canada.
- Orphan medicines are now dominating the market, accounting for 46% of new approvals in 2017 and 59% in 2018, a significant increase from the 33% average share between 2009 and 2014.
- Approximately 30% of the new medicine approvals in 2017 and 2018 were for the treatment of cancer, over half of which were orphan oncology medicines with treatments costs exceeding $7,500 per 28-day cycle.
- The majority of non-oncology medicines approved in 2017 and 2018 were high-cost, with 36 of the 60 with available treatment costs exceeding $10,000 annually. These results represent a continued trend toward high-cost medicines, with lower-cost medicines accounting for a smaller share of new approvals in recent years.

(B) 2017 New Medicine Approvals

More new medicines were approved in 2017 than in previous years, with a significant increase in the number of high-cost orphan and oncology medicines entering the market.

- 52 new medicines received market approval through the FDA, the EMA, and/or Health Canada in 2017, significantly more than in 2016 and far above the average annual rate of 35 medicines approved from 2009 to 2014.
- 46% of the 2017 new medicines received an orphan designation from the FDA and/or the EMA and 35% were biologic therapies.
- Many new medicines came with a high cost: 14 were oncology medicines with costs exceeding $5,000 per 28-day treatment and 20 were non-oncology medicines with annual costs exceeding $10,000.

Fewer medicines were approved in Canada than in the US and Europe in 2017, although Canada compared favourably to the OECD in terms of the corresponding share of sales.

- 27 of the 52 new medicines first approved in 2017 had market authorization in Canada by Q4-2018, compared to 49 approved by the FDA and 34 by the EMA.
- 18 of the 27 approved medicines recorded sales in Canada by the end of 2018, placing Canada sixth in the OECD and in line with the PMPRB7 countries for the number of new medicines with sales.
- Although these 18 medicines represent a relatively small portion of the total number of approvals in 2017, they accounted for 88% of total sales for new medicines in the OECD.

Antivirals and central nervous system medicines accounted for the majority of 2017 new medicine sales in the last quarter of 2018.

- Overall, sales for new medicines were highly concentrated, with antivirals to treat hepatitis C making up almost 30% of new medicine sales in Canada and the PMPRB7 in 2018. Central nervous system therapies and antineoplastics followed, with 20% and 15% of the market, respectively.
- Glecaprevir/pibrentasvir, an antiviral for hepatitis C, was the top-selling new medicine in Q4-2018, accounting for over 25% of international new medicine sales.

(C) 2018 New Medicine Approvals

The relatively high rate of new medicine approvals in 2017 was sustained through 2018, as the number of new high-cost specialty therapies continued to rise.

- 51 new medicines received market approval through the FDA, the EMA, and/or Health Canada in 2018, of which 19 had approval in Canada by the third quarter of 2019.
- Nearly 60% (30) of the new medicines received an orphan designation from the FDA and/or the EMA.
- Oncology treatments continued to account for around one third of new approvals, and over a quarter of new medicines were biologic therapies.
- Based on preliminary results, 12 of the 14 oncology medicines with available treatment costs exceeded $5,000 per 28-day cycle.

(D) Spotlight on Canada

A number of medicines received their first Canadian approval in 2017, though new indications approved for existing medicines had a greater impact on sales.

- 36 new-to-Canada medicines were approved for market in 2017, of which 25 had reported sales by Q4-2018, accounting for 1.6% of the total pharmaceutical market.
- The top-selling Canadian approvals from 2017 received their first international market authorization in the same year.
- New and extended indications for previously marketed medicines contributed $594 million to the $1.07 billion growth in pharmaceutical sales in Canada between 2017 and 2018.

The next edition of *Meds Entry Watch* will build on this analysis to provide further insight into the medicines introduced in 2018 and a preliminary look at those approved in 2019, as well as a retrospective review of trends in new medicines over the past five years.

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INTRODUCTION

Meds Entry Watch is an annual PMPRB publication that explores the dynamics of new medicines entering Canadian and international markets, providing information on their availability, sales, and prices.

This report builds on the three previous editions to provide a broader retrospective analysis of medicines that have entered the market since 2009, and offers a detailed analysis of the new medicines approved in 2017 along with a preliminary examination of those approved in 2018. New medicines are identified for each year based on the date of their first market authorization through the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada.

This edition also features a new section focused on medicines that received their first Canadian approval in 2017. In addition to reporting the prices of new medicines approved in Canada in comparison with international markets, this analysis monitors the sales of existing medicines that received approvals for new indications in the same year.

The report consists of four main parts: Part A provides an overview of longer-term trends from 2009 to 2017; Part B focuses on new medicines that received market approval in 2017; Part C presents a preliminary analysis of the new medicines approved in 2018; and Part D spotlights Health Canada approvals in 2017.

This publication informs decision makers, researchers, and patients of emerging therapies in Canadian and international pharmaceutical markets.

METHODS

This report analyzes new medicines that received initial market approval through the FDA, the EMA, and/or Health Canada in 2017 and 2018. For the purpose of this study, new medicines were identified at the medicinal ingredient level. A new medicine was selected for analysis if it received first-time market authorization from any of these regulatory bodies during the calendar year, even if it was not yet listed for reimbursement or if there were no recorded sales in the available data. Using these criteria, 52 new medicines were identified for the 2017 analysis in Section B and 51 were identified for the preliminary analysis of 2018 medicines in Section C. The approval of these medicines in Canadian and international markets was assessed as of the end of 2018.

The selection of medicines featured in the analysis of the Canadian market in Section D differs from the previous sections. Medicines analyzed in Section D include new and previously marketed medicinal ingredients that received their first Canadian market authorization through Health Canada in 2017. This includes a number of the medicines in the 2017 analysis in Section B, but also encompasses additional medicines that may have received initial approval through the FDA or EMA in previous years and were approved for the Canadian market in 2017. Section D also reports on the sales of medicines previously marketed in Canada that received authorization for additional or extended indications in 2017.

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 (UK), and the United States (US).

The IQVIA MIDAS® Database (all rights reserved) was the main data source for the sales and list prices of new medicines in Canadian and international markets, as well as the number of units sold. MIDAS data reflects the national retail and hospital sectors of each country, including payers in all market segments (public, private, and out-of-pocket).

Sales and volume data encompass all versions of a medicine available in a particular country, produced by any manufacturer in any strength and form. For more information on the MIDAS Database and other NPDUIS source materials, see the Reference Documents section of the Analytical Studies page on the PMPRB website.

Canadian prices were based on MIDAS data, if available; otherwise, they were taken from publicly available results of the Common Drug Review (CDR) or pan-Canadian Oncology Drug Review (pCODR) processes published by the Canadian Agency for Drugs and Technologies in Health (CADTH). Treatment costs were calculated using Canadian list prices where possible; if not, the foreign median price was used. Information on dosing regimens was taken from the product monographs published by Health Canada, or if not available, from the FDA or EMA. All medicines were reviewed as of Q3-2019, unless otherwise specified.

Prices and foreign-to-Canadian price ratios were reported for the highest-selling form and strength of each medicine in Canada, or in the PMPRB7 if no Canadian sales were available at the time of the analysis. The foreign-to-Canadian price ratios presented in this report are expressed as an index with the Canadian price set to a value of one and the international median reported relative to this value. For more details on how foreign-to-Canadian price ratios are calculated, see the Reference Documents section of the Analytical Studies page on the PMPRB website.

Prices and sales in foreign currencies were converted into Canadian dollars using the 12-month or 3-month average exchange rate for the year or quarter, respectively.

Historical results for the period from 2009 to 2014 were based on the methodology employed in the first issue of *Meds Entry Watch*, which identified new medicines based on the date of first recorded sales in the MIDAS Database. This change in methodology is not expected to have a meaningful impact on the overall results.

LIMITATIONS

New medicines reported in Sections B and C were selected for analysis based on their date of market approval by the FDA, the EMA, and/or Health Canada; however, some may have an earlier approval date in other international markets. Likewise, the medicines included in this analysis do not necessarily represent all of those introduced in 2017 and 2018, as other national regulatory bodies not examined in this report may have approved additional medicines. Nevertheless, this should have a very limited effect on the results, as the FDA and EMA are major regulatory bodies representing large international markets and have regulatory approaches similar to those in Canada.

This report reflects the initial market penetration of these new medicines, and their availability and uptake are expected to increase in subsequent years. The availability of a new medicine in a given country at any point in time is influenced by a variety of factors including the manufacturer's decision to launch, as well as the timing of that decision; the regulatory approval process in place; and the existing market dynamics.

Market approval through the EMA does not necessarily mean that the medicine is available in any given European country. Likewise, medicines approved through the FDA or Health Canada may not necessarily be reimbursed and/or have any recorded sales.

Some medicines with sales may not be reported in the IQVIA MIDAS® Database, and thus, the sales of new medicines in any given country may be slightly under-reported. However, as the effect is expected to be relatively consistent across all markets, this should have only a minimal impact on the overall findings.

Canadian and international sales and prices are based on manufacturer list prices as reported in the MIDAS Database, and do not capture price rebates, managed entry agreements (also known as product listing agreements), or patient access schemes. The methodology used by MIDAS for estimating medicine prices varies by country, depending on data availability, and may include assumed regulated margins and/or markups.

Publicly available prices from the Canadian Agency for Drugs and Technologies in Health (CADTH) are based on the manufacturers' submitted prices, which may differ upon market entry.

Aggregated international sales and pricing data are heavily skewed towards the United States due to its relatively large population, and as a result, the ranking of medicines by international sales generally reflects the order of sales in the US.

The assessment of medicine availability in Canada does not consider non-marketed medicines available through programs that authorize the sale of medicines in exceptional circumstances, such as the Special Access Programme in Canada (SAP).

A TRENDS IN NEW MEDICINE APPROVALS, 2009–2017

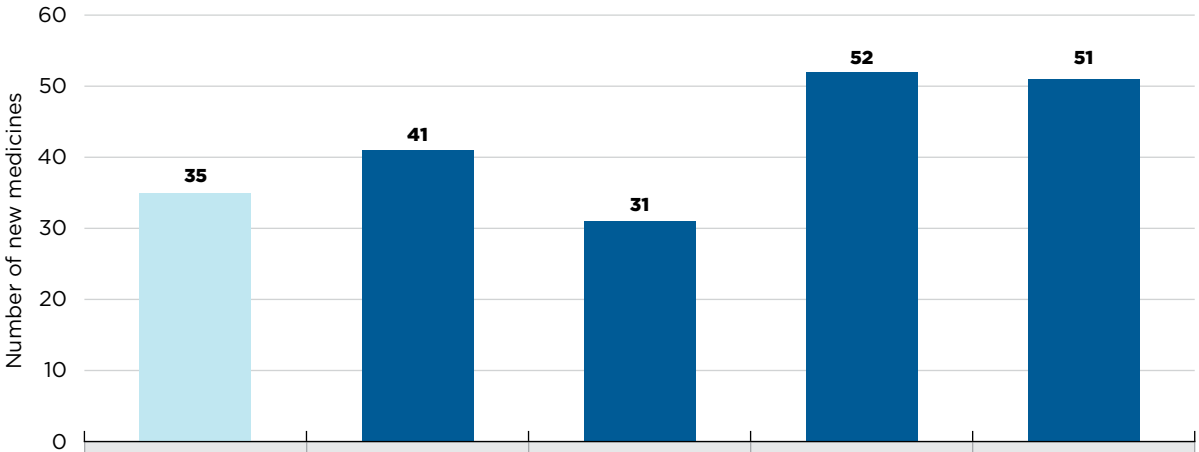
A greater number of new medicines have been approved in recent years, including a rising share of new specialty treatments. Medicines first approved between 2009 and 2017 accounted for over one third of all brand-name sales by the end of 2018. Nearly half of these had recorded Canadian sales by Q4-2018, placing Canada 10th in the OECD and behind most PMPRB7 countries. Despite this, Canada ranked fourth in terms of the share of total new medicine sales, which suggests that the top-selling medicines were among those approved.

In 2017, 52 new medicines received first-time market approval through the FDA, the EMA, and/or Health Canada, a considerable increase from the 31 approved the year before and the annual average of 35 reported from 2009 to 2014 (Figure A1). Almost half (24) of these medicines received an orphan designation from the FDA and/or EMA, representing a sustained rise over the 33% average share from 2009 to 2014.

An additional 51 new medicines were approved in 2018, of which nearly 60% (30) received an orphan designation and close to one third (15) were approved to treat cancer.

New medicines continued to be concentrated in a few therapeutic areas, mostly notably among antineoplastic agents and antivirals. The number of approvals increased in 2017 for central nervous system medicines, ophthalmologicals, and non-steroidal products for inflammatory skin disorders. Additionally, a number of new migraine treatments were approved in 2018.

FIGURE A1 New medicines approved in Canada and the PMPRB7*, 2009 to 2018



	Average 2009–2014	2015	2016	2017	2018
Share of orphan medicines	33%	54%	42%	46%	59%
Share of oncology medicines	20%	34%	16%	33%	29%

Note: New medicines reported between 2009 and 2014 were identified based on the date of first recorded sales, while those reported for 2015 onward were determined based on the date of first-time market approval by the US Food and Drug Administration, the European Medicines Agency, and/or Health Canada.

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

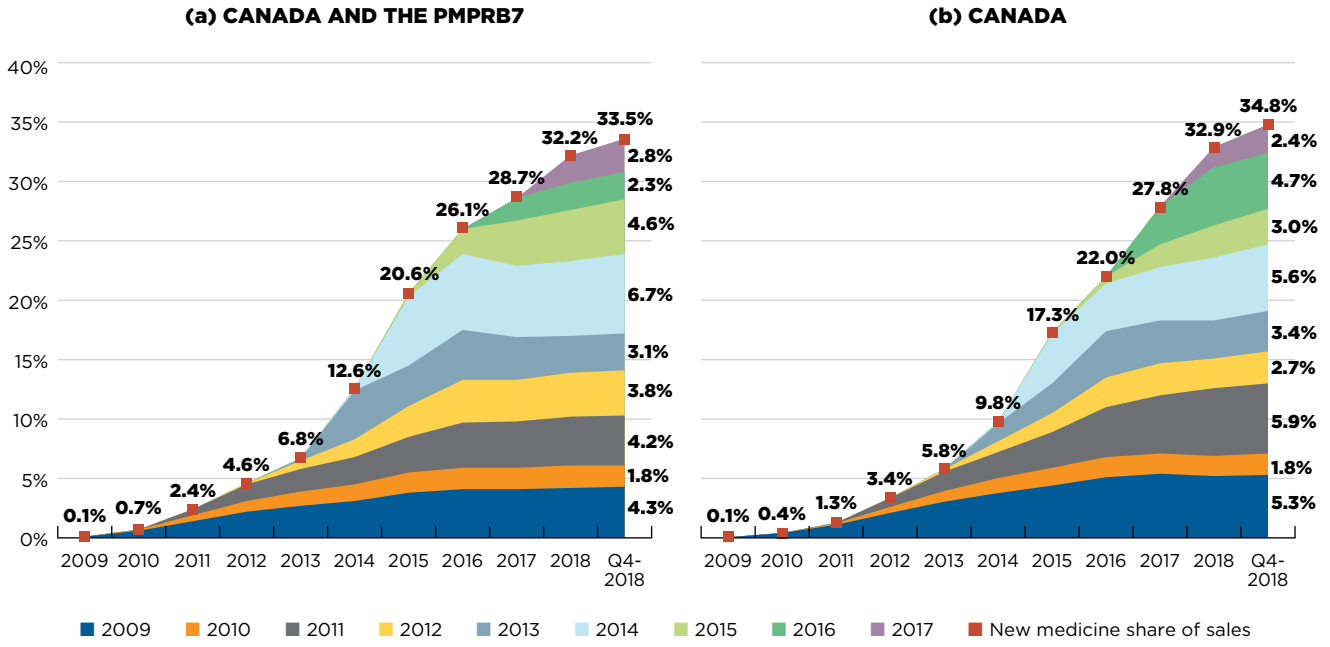
Data source: IQVIA MIDAS® Database, 2009 to 2014 (all rights reserved); US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

Following a period of steep year-over-year uptake in the sales of new medicines, recent entrants have held a relatively modest share of the market. Despite a significant number of approvals in 2017, these new medicines accounted for 2.8% of all brand-name pharmaceutical sales by Q4-2018. New medicines approved between 2009 and 2017 collectively made up one third of the total market in Canada and comparator countries (Figure A2).

Notably, new medicines accounted for a slightly larger share of the Canadian market than their corresponding share of the market in Canada and the PMPRB7. Driving this difference was a marked difference between the influence of the 2016 new medicines in Canada and internationally; whereas the 2016 medicines held only a 2.3% share across the PMPRB7 by Q4-2018, they represented 4.7% of all sales in Canada. This may be due, in part, to a greater impact from the hepatitis C treatment Epclusa (sofosbuvir/velpatasvir), which accounted for 0.6% of total pharmaceutical sales in the PMPRB7 and 2.2% of Canadian sales in Q4-2018.

In any given year, the impact of new medicines on pharmaceutical sales depends on their number, therapeutic relevance, and treatment costs. For example, the entry of new direct-acting antivirals (DAAs) for hepatitis C in 2014 continues to have a high impact on sales, accounting for one fifth of the new medicine share of the brand-name pharmaceutical market by Q4-2018.

FIGURE A2 **New medicine cumulative share of all brand-name medicine sales by year of approval* (2009 to 2017), Canada and the PMPRB7†**



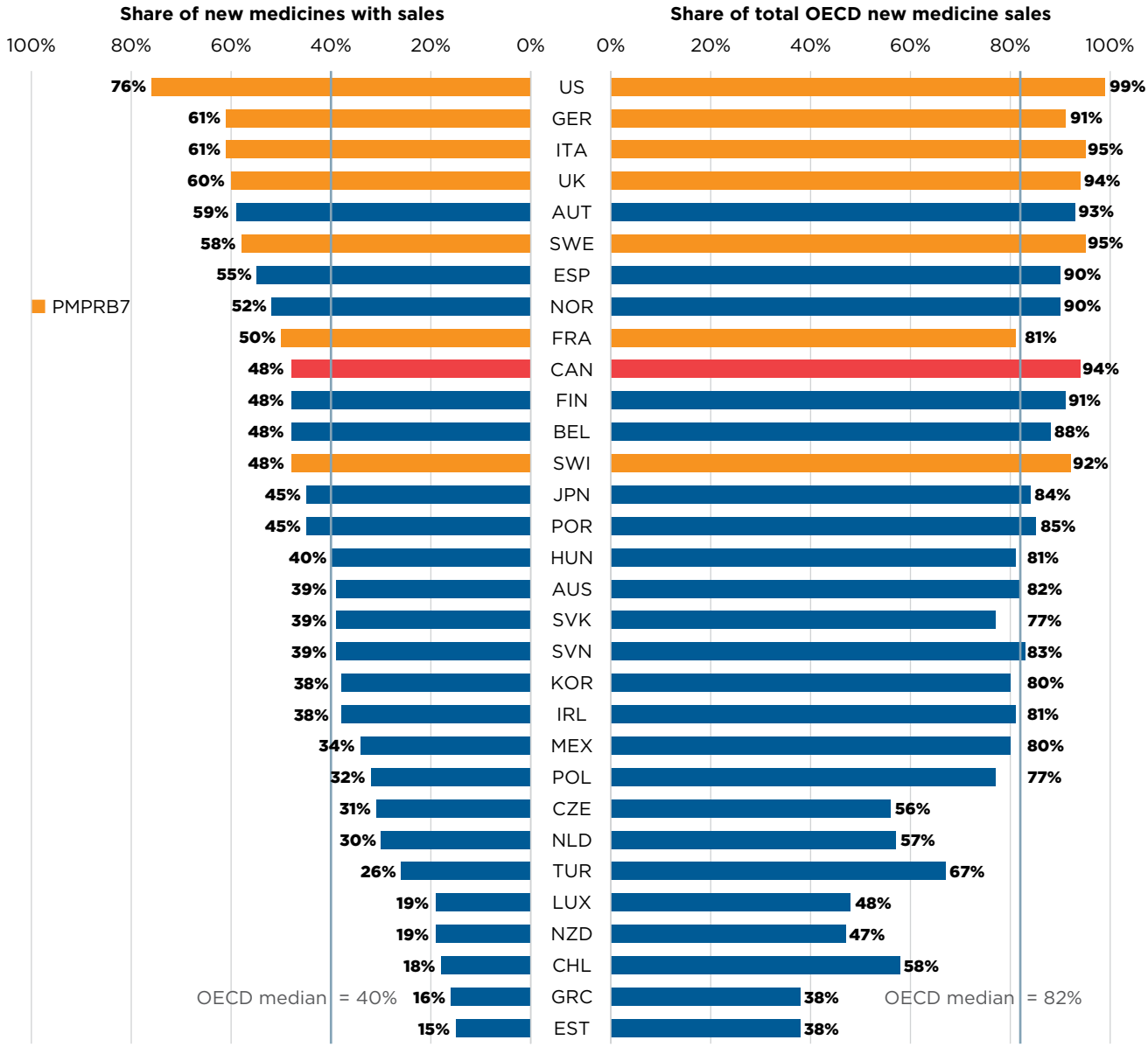
* New medicines introduced between 2009 and 2014 were identified based on the date of first reported sales, while those reported for 2015 onward were determined based on the date of first-time market approval by the US Food and Drug Administration, the European Medicines Agency, and/or Health Canada.

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

Data source: IQVIA MIDAS® Database, 2009 to 2018. All rights reserved.

Of the 336 medicines approved in Canada and the PMPRB7 from 2009 to 2017, 48% had recorded sales in Canada by Q4-2018 (Figure A3). While this represents a greater share than the OECD median of 40%, it ranks below most PMPRB7 countries, many of which have lower average list prices for patented medicines (PMPRB). The new medicines sold in Canada accounted for 94% of the OECD sales for all new medicines analyzed, representing the fourth highest share in the OECD, well above the median of 82%. This suggests that although fewer new medicines were approved in Canada, the higher-selling new medicines were among those sold, which may have been partially influenced by Canada's proximity to the US market.

FIGURE A3 **Share of new medicines approved* in Canada and the PMPRB7† from 2009 to 2017 with available sales, and their respective share of OECD sales, by country, Q4-2018**



Note: Sales are based on manufacturer list prices and include sales for all OECD countries.

* New medicines introduced between 2009 and 2014 were identified based on the date of first reported sales, while those reported for 2015 onward were determined based on the date of first-time market approval by the US Food and Drug Administration, the European Medicines Agency, and/or Health Canada.

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

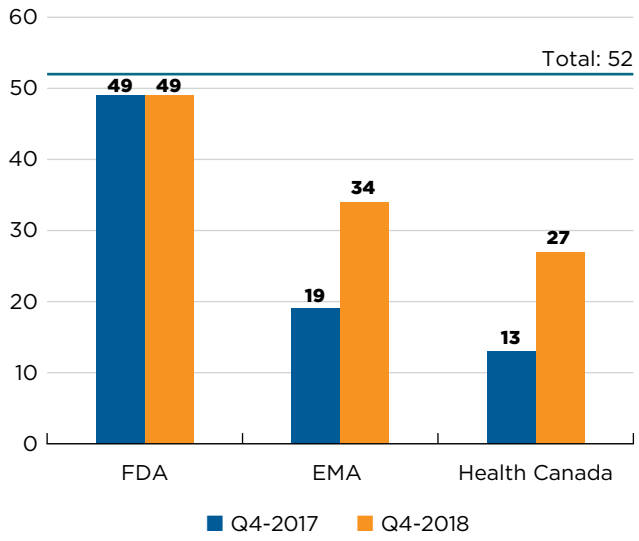
B NEW MEDICINE APPROVALS, 2017

A greater than average number of new medicines were approved in Canada, Europe, and the US in 2017, nearly half of which had an orphan designation. While relatively few of these medicines had sales in Canada by the end of 2018, those sold accounted for the majority of all new medicine sales.

Fifty-two new medicines were approved internationally in 2017, representing a considerable increase from the 31 medicines approved the year before. Nearly two thirds of these new medicines were high-cost, coming with treatment costs over $10,000 per year, or $5,000 per 28-day cycle for oncology medicines. Five new non-oncology medicines were identified as expensive drugs for rare diseases (EDRDs)—orphan-designated therapies exceeding $100,000 in annual treatment costs—while ten new oncology medicines qualified as EDRDs at over $7,500 per 28-day cycle.

By the end of 2018, just over half (27) of the 2017 new medicines had been approved in Canada. Both the FDA and the EMA, which represent two of the largest international markets, approved more new medicines than Canada at 49 and 34, respectively (Figure B1).

FIGURE B1 **Number of 2017 new medicines with market approval as of Q4-2017 and Q4-2018**

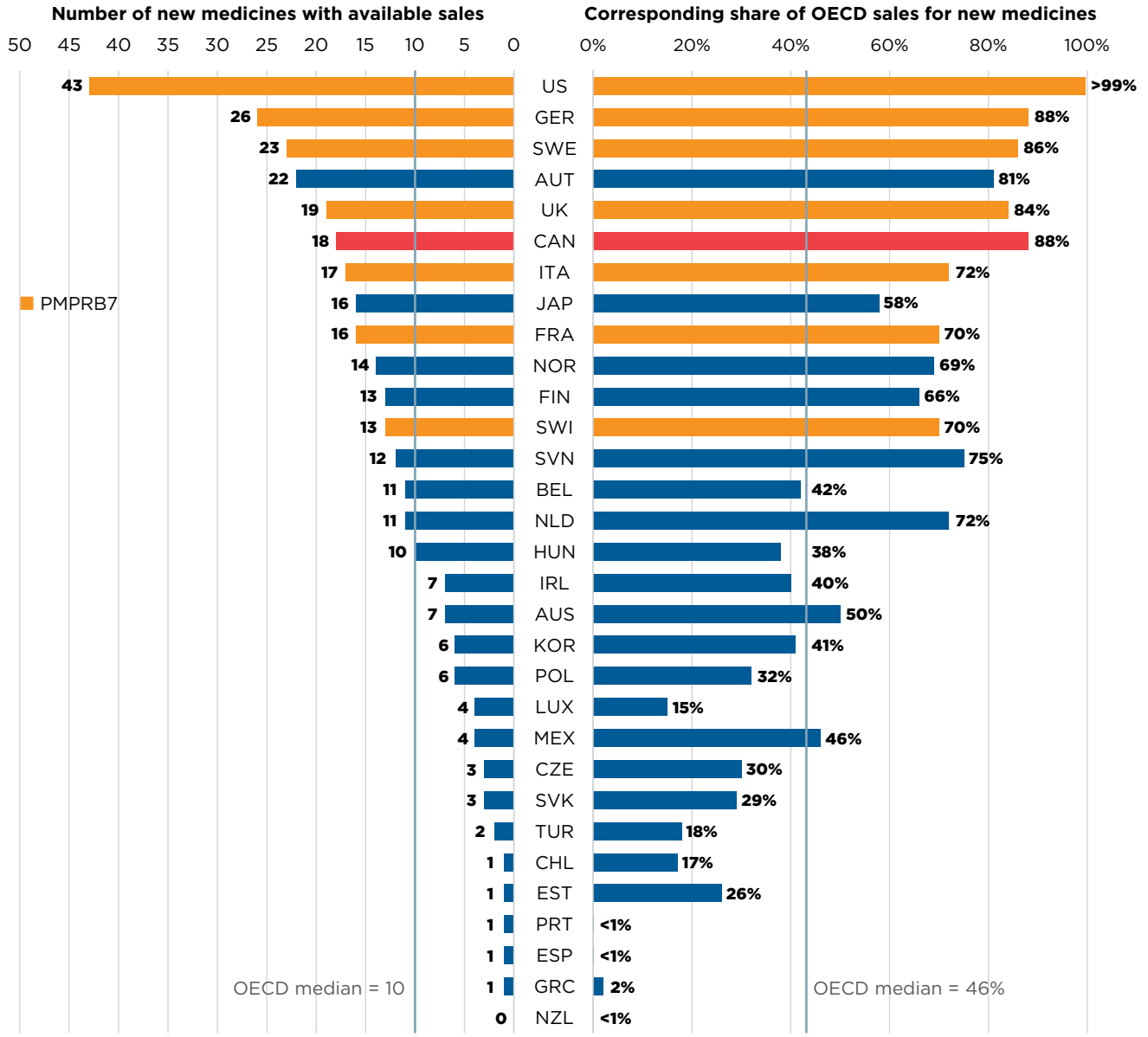


Data source: US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Health Canada databases.

Of the 27 medicines approved in Canada, 18 had sales data available in MIDAS by Q4-2018. This placed Canada sixth in the OECD in terms of the number of new medicines sold and third in terms of the corresponding OECD sales of these new medicines at 88%, marking an increase over 2016 results. The US market, which ranked first among all OECD countries, recorded sales for 43 of the medicines approved in 2017, representing over 99% of OECD sales.

These results reflect the initial market penetration, and the availability and uptake in sales for these new medicines are expected to increase in subsequent years.

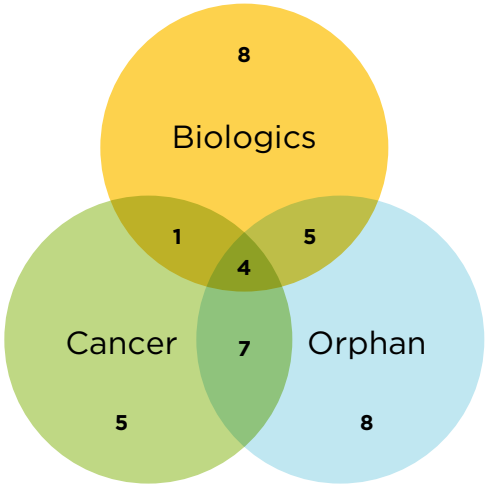
FIGURE B2 Number of 2017 new medicines with market approval and their share of OECD sales as of Q4-2018



Note: Based on medicines that received market approval through the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada in 2017 with recorded sales data as of Q4-2018.
Sales are based on manufacturer list prices and include sales for the selected new medicines in all OECD countries.
Data source: IQVIA MIDAS® Database, 2018 (all rights reserved); US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

Although new medicines approved in Canada and the PMPRB7 in 2017 covered a wide range of therapeutic classes, their sales were highly concentrated. The top four ATC classes by sales represented half of the 2017 new medicines and over 80% of all new medicine sales in Canada and the PMPRB7 by Q4-2018. Two medicines, glecaprevir/pibrentasvir and ocrelizumab, together accounted for 45% of sales and represented the top two therapeutic classes, antivirals and central nervous system drugs, respectively. Antineoplastics ranked as the third top-selling ATC class, with oncology treatments accounting for 12 of the 52 new medicines and 15% of sales.

As illustrated, a significant number of new medicines fell into multiple specialty categories. Most notably, 11 of the new oncology medicines and nine of the new biologic therapies were also orphan-designated, four of which belonged to all three groups. In total, 46% (24) of the 2017 new medicines received an orphan designation from the FDA and/or the EMA. The share of oncology medicines rose to 33%, and 35% of new medicines were biologics.



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

Table B1 lists the new medicines approved in 2017. For each medicine, the country with the first reported sales is given, along with the availability in Canada, the share of sales in Q4-2018, and the prices and corresponding treatment costs.[1] Prices are reported for the highest-selling form and strength of each medicine at the time of the analysis.

1. For more detailed supplementary information regarding the indication and manufacturer of each of the 2017 new medicines, see the *Meds Entry Watch* publication section of the Analytical Studies page on the PMPRB website.

TABLE B1 **New medicines approved in 2017, availability, share of sales, prices, and treatment costs, ranked by therapeutic class share of sales, Q4-2018**

Rank	Therapeutic class*	Medicine (trade name, form, strength, volume)†	Availability			Share of new medicine sales (%)		No. of countries with sales	Canadian price§ (CAD)	PMPRB7‡ price (CAD)			Treatment cost**	
			First sale in Canada or PMPRB7		First sale in Canada	Medicine	Therapeutic class			Min	Median	Max	Treatment cost (CAD)	Annual/ Course
1	J5-Antivirals	Glecaprevir, pibrentasvir (Maviret, film-ctd tab, 100 mg + 40 mg)	US	Aug-17	Sept-17	25.7%	29.0%	8	236	187	230	251	79,240	16-week treatment
2		Voxilaprevir (Vosevi, film-ctd tab, 400 mg + 100 mg + 100 mg)	US	Jul-17	Sept-17	2.6%		7	699	684	854	1,020	58,752	12-week treatment
3		Letermovir (Prevymis, film-ctd tab, 480 mg)[O]	US/CAN	Dec-17	Dec-17	0.7%		4	245	452	477	501	24,450	100-day treatment
4	N7-Other central nervous system drugs	Ocrelizumab (Ocrevus, infus. vial/bottle, 30 mg/ml, 10 ml)[B]	US	Sept-17	Sept-17	17.0%	20.1%	8	8,446	7,124	8,955	18,885	33,786	Annual
5		Deutetrabenazine (Austedo, ctd tab, 12 mg)[O]	US	Jun-17	–	1.7%		1	–	108	108	108	19,760/ 158,100	Annual (6 mg/ 48 mg)
6		Edaravone (Radicava, infus. bag, 300 mcg/ml, 100 ml)[O]	US	Aug-17	–	1.2%		1	712	661	661	661	190,880/ 185,182	First year/ subsequent years
7		Cerliponase alfa (Brineura, infus. vial/ bottle, 30 mg/ml, 5 ml)[B,O]	SWE	May-17	–	0.2%		4	16,190[i]	15,569	30,478	346,556	841,900	Annual
8		Valbenazine (Ingrezza, capsule, 80 mg)[O]	US	Mar-17	–	0.1%		1	–	265	265	265	96,900	Annual
9	L1-Antineoplastics	Durvalumab (Imfinzi, infus. vial/bottle, 50 mg/ml, 10 ml)[B,C]	US	May-17	Nov-17	6.1%	14.5%	7	4,028	3,180	3,698	4,093	11,280	28-day cycle
10		Ribociclib (Kisqali, film-ctd tab, 200 mg)[C]	US	Mar-17	Apr-18	1.9%		7	101	68	92	236	6,340	28-day cycle
11		Abemaciclib (Verzenio, tab or film-ctd tab, 150 mg)[C]	US	Oct-17	–	1.8%		3	95[ii]	72	75	239	5,300	28-day cycle
12		Niraparib (Zejula, capsule, 100 mg)[C,O]	US	Apr-17	–	1.1%		7	–	119	158	247	13,300	28-day cycle
13		Midostaurin (Rydapt, capsule, 25 mg)[C,O]	FRA	Oct-16	Sept-17	0.9%		8	166	150	167	193	9,270	28-day cycle
14		Inotuzumab ozogamicin (Besponsa, infus. dry bottle, 0.9 mg-1 mg)[B,C,O]	FRA	Apr-17	May-18	0.8%		8	14,256	15,759	15,775	21,645	48,490/ 40,375	21-day cycle/ subsequent 28-day cycle
15		Avelumab (Bavencio, infus. vial/bottle, 20 mg/ml, 10 ml)[B,C,O]	US	Mar-17	Dec-17	0.6%		8	1,391	1,143	1,350	1,850	9,738	28-day cycle
16		Acalabrutinib (Calquence, capsule, 100 mg)[C,O]	US	Nov-17	–	0.6%		1	–	283	283	283	15,840	28-day cycle

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Rank	Therapeutic class*	Medicine (trade name, form, strength, volume)†	Availability			Share of new medicine sales (%)		No. of countries with sales	Canadian price§ (CAD)	PMPRB7‡ price (CAD)			Treatment cost**	
			First sale in Canada or PMPRB7		First sale in Canada	Medicine	Therapeutic class			Min	Median	Max	Treatment cost (CAD)	Annual/ Course
17		Enasidenib (Idhifa, film-ctd tab, 100 mg)[C,O]	US	Jul-17	–	0.3%		1	–	972	972	972	27,227	28-day cycle
18		Brigatinib (Alunbrig, film-ctd tab, 180 mg)[C,O]	US	May-17	–	0.1%		3	337[ii]	236	416	596	9,435	28-day cycle
19		Tisagenlecleucel (Kymriah, infus. bag)[B,C,O,G]	GER	Aug-17	–	0.1%		1	–	482,549	482,549	482,549	482,549	One-time treatment
20		Neratinib (Nerlynx, film-ctd tab, 40 mg)[C]	US	Jul-17	–	0.1%		1	–	74	74	74	12,538	28-day cycle
21		Copanlisib (Aliqopa, inf. dry bottle, 60 mg)[C,O]	US	Sept-17	–	0.1%		1	–	5,393	5,393	5,393	16,200	28-day cycle
22		Tivozanib (Fotivda, capsule, 1.34 mg)[C]	GER	Nov-17	–	0.1%		2	–	145	194	242	4,070	28-day cycle
23	D5-Nonsteroidal products for inflammatory skin disorders	Dupilumab (Dupixent, prefill syrng sc, 150 mg/ml, 2 ml)[B]	US	Mar-17	Feb-18	8.1%	12.7%	7	1,068	780	1,013	1,801	29,386/ 27,800	First year/ subsequent years
24		Guselkumab (Tremfya, prefill syrng sc, 100 mg/ml, 1 ml)[B]	US	Aug-17	Nov-17	4.1%		7	3,139	2,984	3,543	12,430	22,100/ 20,500	First year/ subsequent years
25		Brodalumab (Siliq/ Kyntheum, prefill syrng sc, 140 mg/ml, 1.5 ml)[B]	SWE	Jul-17	Jul-18	0.6%		6	627	670	896	2,164	17,230/ 16,300	First year/ subsequent years
26	J7-Vaccines	Herpes zoster vaccine [recombinant, adjuvanted] (Shingrix Vaccine, vial im, 100 mcg/ml, 0.5 ml)[B]	US	Dec-17	Jan-18	6.8%	6.8%	3	119	122	148	174	240	Treatment (2 doses)
27	A10-Diabetes	Semaglutide (Ozempic, prefill pen, 1.34 mg/ml, 1.5 ml)	US	Jan-18	Feb-18	5.2%	5.7%	5	132	113	378	643	1,720 to 3,440	Annual
28		Ertugliflozin (Steglaro, film-ctd tab, 5 mg)	US	Jan-18	May-17	0.5%		3	2[i]	2	7	11	894	Annual
29	R3-Anti-asthma and COPD products	Benralizumab (Fasenra, prefill syrng sc, 30 mg/ml, 1 ml)[B]	US	Dec-17	Mar-18	3.0%	3.0%	7	3,770	2,908	3,299	5,880	30,160/ 24,500	First year/ subsequent years
30	M1-Anti-inflammatory and anti-rheumatic products	Baricitinib (Olumiant, film-ctd tab, 2 mg)[O]	UK	Apr-17	Sept-18	1.8%	2.8%	8	50	34	43	85	18,270	Annual
31		Sarilumab (Kevzara, prefill syrng/autoinj, 175 mg/ml, 1.14 ml)[B]	CAN	Feb-17	Feb-17	1.0%		8	718	564	769	1,941	50,500	Annual
32	B2-Blood coagulation system, other products	Emicizumab (Hemlibra, vial sc, 150 mg/ml, 1 ml)[B,O]	US	Nov-17	–	2.5%	2.5%	6	–	15,980	17,446	18,537	683,900/ 635,000	First year/ subsequent years
33		Coagulation Factor IX [recombinant], glycoPEGylated (Rebinyn, vial dry, 2000 IU)[B]	SWE	Jun-17	–	0.1%		2	–	4	4	4	8 to 13	Dose

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Rank	Therapeutic class*	Medicine (trade name, form, strength, volume)†	Availability			Share of new medicine sales (%)		No. of countries with sales	Canadian price§ (CAD)	PMPRB7‡ price (CAD)			Treatment cost**	
			First sale in Canada or PMPRB7		First sale in Canada	Medicine	Therapeutic class			Min	Median	Max	Treatment cost (CAD)	Annual/ Course
34	H4-Other hormones	Abaloparatide (Tymlos, prefill pen, 2 mg/ml, 1.56 ml)	US	Jun-17	–	0.9%	1.0%	1	–	2,131	2,131	2,131	25,500	Annual
35		Angiotensin II (Giapreza, infus. vial/bottle, 2.5 mg/ml, 1 ml)	US	Feb-18	–	<0.1%		1	–	1,915	1,915	1,915	550/320	Max titration/ maintenance per hour
36	S1-Ophthalmologicals	Netarsudil (Rhopressa, eye drops, 0.02%, 2.5 ml)	US	Apr-18	–	0.5%	0.7%	1	–	6	6	6	2,175	Annual (per eye)
37		Latanoprostene bunod (Vyzulta, eye drops, 0.02%, 2.5 ml)	US	Dec-17	–	0.2%		1	–	4	4	4	1,626	Annual (per eye)
38		Cenegermin (Oxervate, eye drops, 20 mcg/ml, 1 ml)[B,O]	GER	Nov-17	–	<0.1%		2	–	23	23	23	7,690	8-week treatment (per eye)
39		Voretigene neparvovec (Luxturna)[B,O,G]	US	Feb-18	–	<0.1%		1	–	23,567	23,567	23,567	561,595	One-time treatment (per eye)
40	A3-Functional gastro-intestinal disorder drugs	Plecanatide (Trulance, tab, 3 mg)	US	Mar-17	–	0.6%	0.6%	1	–	16	16	16	5,900	Annual
41	A6-Drugs for constipation and bowel cleansers	Naldemedine (Symproic, film-ctd tab, 200 mcg)	US	Oct-17	–	0.2%	0.2%	1	–	13	13	13	4,800	Annual
42	A7-Intestinal disorder products	Telotristat ethyl (Xermelo, film-ctd tab, 250 mg)[O]	US	Mar-17	–	0.2%	0.2%	5	85[i]	16	19	81	92,199	Annual
43	J1-Systemic antibacterials	Delafloxacin (Baxdela, tab, 450 mg)	US	Jan-18	–	0.1%	0.1%	1	–	87	87	87	870/2,450	5-day/ 14-day treatment
44		Vaborbactam (Vabomere, inf. dry bottle, 1 g + 1 g)	US	Aug-17	–	0.1%		1	–	197	197	197	16,590	14-day treatment
45	D10-Anti-acne prepararations	Ozenoxacin (Ozanex, cream, 1%, 10 g)	CAN	Jan-18	Jan-18	0.1%	0.1%	1	2	NA	NA	NA	NA	Topical use
46	A16-Other alimentary tract and metabolism products	Vestronidase alfa (Mepsevii, infus. vial/ bottle, 2 mg/ml, 5 ml)[B,O]	US	Dec-17	–	<0.1%	<0.1%	1	–	2,630	2,630	2,630	683,900	Annual (25kg)

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Rank	Therapeutic class*	Medicine (trade name, form, strength, volume)†	Availability			Share of new medicine sales (%)		No. of countries with sales	Canadian price§ (CAD)	PMPRB7‡ price (CAD)			Treatment cost**	
			First sale in Canada or PMPRB7		First sale in Canada	Medicine	Therapeutic class			Min	Median	Max	Treatment cost (CAD)	Annual/ Course
47	V3-All other therapeutic products	Lutetium Lu 177 dotatate (Lutathera, infus. vial/bottle, 370 mg/ml, 30 ml)[C,O]	FRA	Apr-15††	–	<0.1%	<0.1%	1	–	23,567	23,567	23,567	140,000	32-week treatment
48	T2-Diagnostic tests	Macimorelin (Macrilen, oral u-d powdr, 0.05%, 120 ml)[O]	US	Jul-18	–	<0.1%	<0.1%	1	–	5,605	5,605	5,605	NA	Topical use
49	B1-Antithrombotic agents	Betrixaban (Bevyxxa, capsule, 80 mg)	US	Jan-18	–	<0.1%	<0.1%	1	–	15	15	15	540 to 640	35- to 42-day treatment
50	L03-Immunostimulants	Axicabtagene ciloleucel (Yescarta)[B,C,O,G]	FDA	Oct-17	Feb-19‡‡									
51	P01-Antiprotozoals	Benznidazole (Benznidazole)[O]	FDA	Aug-17	–									
52	L01-Antineoplastic agents	Padeliporfin (Tookad)[C]	EMA	Nov-17	–									

■ No sales data in MIDAS® as of Q4-2018 – date of approval by FDA, EMA, and/or Health Canada.

Note: A medicine was considered to be new in 2017 if it received initial market authorization through the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada during the calendar year.
Availability and sales information refer to all forms and strengths of the medicine, while pricing and treatment costs are based on the highest-selling form and strength indicated.
Sales are based on manufacturer list prices.

* Level 2 of the Anatomical Classification of Pharmaceutical Products, as reported in MIDAS, except for the new medicines without sales data in MIDAS, for which the reporting is based on the Anatomic Therapeutic Chemical (ATC) Classification System maintained by the World Health Organization (WHO).

† B: biologic; C: cancer; O: orphan medicines; G: gene therapies.

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

§ Canadian unit prices were retrieved from IQVIA MIDAS® Database, where available; otherwise, they were taken from:
i CADTH's Canadian Drug Expert Committee Recommendation report.
ii pCODR Expert Review Committee (pERC) Recommendation report.

** Treatment costs were calculated using Canadian list prices if available; otherwise, the foreign median price or available foreign price was used. Information on dosing regimens was taken from the product monograph provided by Health Canada, or the FDA or EMA if unavailable though Health Canada.

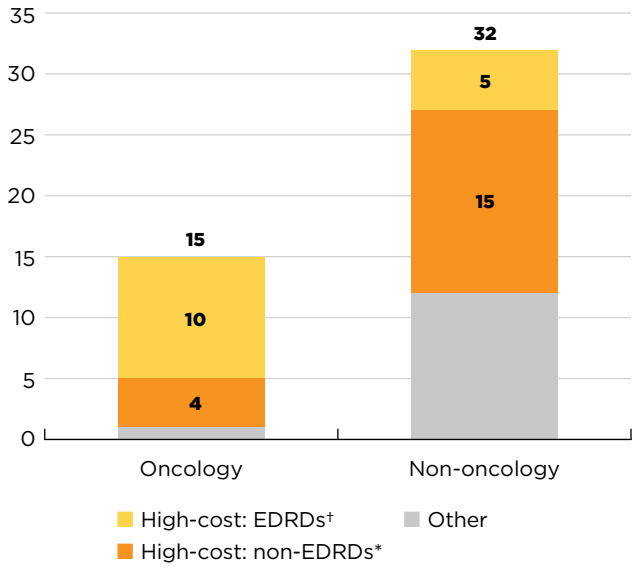
†† Lutetium Lu 177 dotatate has been added to the list of 2017 new medicines reported in the previous edition of *Meds Entry Watch*. Despite being approved individually in France in 2015, it received its first market authorization from the EMA in 2017.

‡‡ Notice of Compliance issued as of Q3-2019.

Data source: IQVIA MIDAS® Database, 2018 (all rights reserved); US Food and Drug Administration Novel Drugs 2017; European Medicines Agency Human Medicines Highlights 2017; Health Canada databases.

Many of the 2017 new medicines came with a high treatment cost: 14 oncology medicines had costs exceeding $5,000 for a 28-day regimen; and 20 non-oncology medicines had annual costs exceeding $10,000. Ten oncology and five non-oncology orphan medicines qualified as expensive drugs for rare diseases with treatments costs over $7,500 per 28-day cycle or $100,000 annually, respectively.

FIGURE B3 Number of high-cost new medicines approved in 2017, Q4-2018



Note: This analysis considers the 47 new medicines approved in 2017 with treatment costs available as of Q4-2018.

* High-cost medicines have treatment costs exceeding $5,000 per 28-day cycle for oncology or $10,000 annually for non-oncology.

† Expensive drugs for rare diseases (EDRDs) have an orphan designation through the FDA or EMA and treatment costs exceeding $7,500 per 28-day cycle for oncology medicines or $100,000 annually for non-oncology.

Twenty-seven of the medicines first approved in 2017 were authorized for market in Canada by the end of 2018. Of these, 24 had been reviewed by the PMPRB's Human Drug Advisory Panel (HDAP) as of the third quarter of 2019. The HDAP scientific review found that 75% of the new medicines assessed demonstrated slight or no improvement over their therapeutic comparators.[2]

Table B2 provides an overview of the recommendations and negotiation status for the 27 approved medicines, while Table B3 provides further details on the pharmacoeconomic assessments conducted by CADTH through the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR).

By the third quarter of 2019, 24 new medicines had been reviewed by CADTH for public reimbursement, of which 11 had completed pan-Canadian Pharmaceutical Alliance (pCPA) negotiations and five others had negotiations underway. Thirteen non-oncology medicines reviewed by the CDR received a recommendation to reimburse with clinical criteria and/or conditions while four received a recommendation not to reimburse. Of the oncology medicines reviewed by pCODR, five were recommended for funding on the condition that their cost effectiveness be improved to an acceptable level and one was recommended not to reimburse. One orphan oncology medicine, midostaurin (Rydapt), received a recommendation to reimburse without conditions.

A review of private drug plan data found that over two thirds (19) of the 27 new medicines were reimbursed by at least one private drug plan by the end of 2018. However, these are preliminary results, and their interpretation is limited. For example, if the approval date in Canada was near the end of the 2018 calendar year, the uptake in private plans may only have occurred in 2019 and would not be reflected in these results.

2 Results of the HDAP reviews are published in the PMPRB's *Annual Report*. The upcoming 2018 edition will include updated information on assessments for this list of medicines.

Table B3 reports information related to the results of the health technology assessments for the new medicines, including the indications assessed; the recommended condition for reimbursement; the primary evaluation; the range of reported incremental cost-effectiveness ratios (ICER) reported; and the price reduction required for the medicine to achieve an ICER of $50,000 per quality-adjusted life year (QALY). The results suggest that most new medicines sold in Canada were not cost-effective at the submitted price, and the vast majority of these medicines were approved on the condition that their price be reduced. At the high end of the reported range, the price of some medicines would need to be decreased by more than 99% in order to achieve an ICER of $50,000 per QALY. Brodalumab, midostaurin, and voxilaprevir were the only medicines to fall within the $50,000/QALY threshold.

TABLE B2 **Recommendations, negotiation status, and reimbursement decisions for 2017 new medicines approved in Canada by Q4-2018**

		Health Canada approval	CADTH recommendation‡			pCPA negotiation status§			Private plans
ATC*	Medicine (trade name)†	Notice of Compliance	Reimburse	Reimburse with clinical criteria and/or conditions	Do not reimburse	Active	Completed and closed	No negotiations	Reimbursed
L1	Avelumab (Bavencio)[B,C,O]	Dec-17							
M1	Baricitinib (Olumiant)[O]	Aug-18							
R3	Benralizumab (Fasenra)[B]	Feb-18							
L1	Brigatinib (Alunbrig) [C,O]	Jul-18							
D5	Brodalumab (Siliq/Kyntheum)[B]	Mar-18							
N7	Cerliponase alfa (Brineura)[B,O]	Dec-18							
B2	Coagulation Factor IX [recombinant], glycoPEGylated (Rebinyn)[B]	Nov-17							
D5	Dupilumab (Dupixent)[B]	Nov-17							
L1	Durvalumab (Imfinzi)[B,C]	May-18							
N7	Edaravone (Radicava)[O]	Oct-18							
B2	Emicizumab (Hemlibra)[B,O]	Aug-18							
A10	Ertugliflozin (Steglatro)	May-18							
J5	Glecaprevir, pibrentasvir (Maviret)	Aug-17							
D5	Guselkumab (Tremfya)[B]	Nov-17							
J7	Herpes zoster vaccine [recombinant, adjuvanted] (Shingrix Vaccine)[B]	Oct-17							
L1	Inotuzumab ozogamicin (Besponsa)[B,C,O]	Mar-18							

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ATC*	Medicine (trade name)†	Health Canada approval	CADTH recommendation‡			pCPA negotiation status§			Private plans
		Notice of Compliance	Reimburse	Reimburse with clinical criteria and/or conditions	Do not reimburse	Active	Completed and closed	No negotiations	Reimbursed
S1	Latanoprostene bunod (Vyzulta)	Dec-18		■		■			
J5	Letermovir (Prevymis)[O]	Nov-17		■		■			■
L1	Midostaurin (Rydapt)[C,O]	Jul-17	■				■		■
N7	Ocrelizumab (Ocrevus)[B]	Feb-18		■			■		■
D10	Ozenoxacin (Ozanex)	Jan-17			■			■	■
L1	Ribociclib (Kisqali)[C]	Mar-18		■			■		■
M1	Sarilumab (Kevzara)[B]	Jan-17		■			■		■
A10	Semaglutide (Ozempic)	Jan-18		■			■		■
A7	Telotristat ethyl (Xermelo)[O]	Oct-18			■				
L1	Tisagenlecleucel (Kymriah)[B,C,O,G]	Sep-18		■					
J5	Voxilaprevir (Vosevi)	Aug-17		■			■		■

Note: Non-oncology medicines were assessed through CADTH's Common Drug Review process, while oncology medicines were assessed through the pan-Canadian Oncology Drug Review (pCODR) process.

* Level 2 of the Anatomical Classification of Pharmaceutical Products, as reported in MIDAS®.

† B: biologic; C: cancer; O: orphan medicines; G: gene therapies.

‡ Initial or final recommendation issued as of Q3-2019.

§ As of Q3-2019.

Data source: IQVIA Private Drug Plan database, 2018; Health Canada Notice of Compliance Database; Canadian Agency for Drugs and Technologies in Health (CADTH) reports; pan-Canadian Pharmaceutical Alliance (pCPA) reports.

TABLE B3 Summary of Common Drug Review and pan-Canadian Oncology Drug Review assessments for 2017 new medicines approved in Canada, Q2-2019

Medicine (trade name)*	Date of recommendation†	Indication(s)	Conditional on price‡	Type of evaluation (primary)§	Incremental cost-effectiveness ratio (ICER) ($ per QALY)	Price reduction range ($50,000 per QALY)
Avelumab (Bavencio)[B,C,O]	Mar-18	Metastatic Merkel cell carcinoma	Yes	CUA	84,000 to 126,000	–
Benralizumab (Fasenra)[B]	Aug-18	Severe eosinophilic asthma	Yes	CUA	62,000 to 1,534,803	15% to 95%
Brigatinib (Alunbrig)[C,O]	Aug-19	Non-small cell lung cancer	Do not reimburse	CUA/CEA	117,763 to 163,603	–
Brodalumab (Siliq/Kyntheum)[B]	Jun-18	Psoriasis, moderate to severe plaque	Yes	CUA	43,000	–
Cerliponase alfa (Brineura)[B,O]	May-19	Neuronal ceroid lipofuscinosis type 2	Yes	CUA	1,718,976	>99%
Dupilumab (Dupixent)[B]	Jun-18	Atopic dermatitis	Do not reimburse	CUA	579,672	84%
Durvalumab (Imfinzi)[B,C]	May-19	Non-small cell lung cancer	Yes	CUA/CEA	162,670	–
Edaravone (Radicava)[O]	Mar-19	Amyotrophic lateral sclerosis	Yes	CUA	1,441,000 to 3,152,000	>99%
Ertugliflozin (Steglatro/Segluromet)	Jan-19	Diabetes mellitus, type 2	Do not reimburse	CCA	–	–
Glecaprevir, pibrentasvir (Maviret)	Jan-18	Hepatitis C, chronic	Yes	CUA	69,000 to Dominated**	3% to 12%
Guselkumab (Tremfya)[B]	Feb-18	Psoriasis, moderate to severe plaque	Yes	CUA	1,606,003 to Dominated**	–
Inotuzumab ozogamicin (Besponsa)[B,C,O]	Jul-18	Acute lymphoblastic leukemia	Yes	CUA/CEA/CCA	Dominant** to 200,597	–
Letermovir (Prevymis)[O]	Jun-18	Cytomegalovirus infection, prophylaxis	Yes	CUA	51,052	0.1%
Midostaurin (Rydapt)[C,O]	Dec-17	Acute myeloid leukemia	No	CUA/CEA	22,579	–
Ocrelizumab (Ocrevus)[B]	Nov-17	Multiple sclerosis, relapsing	Yes	CUA	214,504 to Dominated**	50%
	Apr-18	Primary progressive multiple sclerosis			588,143	82%
Ozenoxacin (Ozanex)	Oct-18	Impetigo	Do not reimburse	CUA	171,907 to 244,184	28% to 51%
Ribociclib (Kisqali)[C]	Apr-18	Advanced or metastatic breast cancer	Yes	CUA/CEA	175,827 to 204,805	–
Sarilumab (Kevzara)[B]	Apr-17	Arthritis, rheumatoid	Yes	CCA	–	–
Semaglutide (Ozempic)	May-19	Diabetes mellitus, type 2	Yes	CUA	–	–
Tisagenlecleucel (Kymriah)[B,C,O,G]	Jan-19	Relapsed or refractory B-cell acute lymphoblastic leukemia	No	CUA	211,870	65%
Voxilaprevir (Vosevi)	Jan-18	Hepatitis C, chronic	Yes	CUA	923 to 16,864	–

Note: The type of evaluation and the incremental cost-effectiveness ratio (ICER) are based on the CDR estimate (base case) and the pCODR Economic Guidance Panel (EGP) evaluations. The table reports the low-bound and high-bound range estimated for all comparators and conditions analyzed. Cost-utility analysis (CUA) and cost-effectiveness analysis (CEA) evaluations are provided as a range per quality-adjusted life year (QALY). Additional information can be accessed at https://www.cadth.ca.

* B: biologic; C: cancer; O: orphan medicines; G: gene therapies.

† Initial or final recommendation issued as of Q2-2019.

‡ Price was explicitly defined as a condition for reimbursement.

§ CUA: cost-utility analysis; CEA: cost-effectiveness analysis; CCA: cost comparison analysis.

** Dominated indicates that a high-bound ICER value cannot be calculated as the product is more costly and less effective than comparator products. Dominant refers to a negative low-bound ICER value, which indicates that the product is less costly and more effective than comparators.

Data source: Canadian Agency for Drugs and Technologies in Health (CADTH) reports.

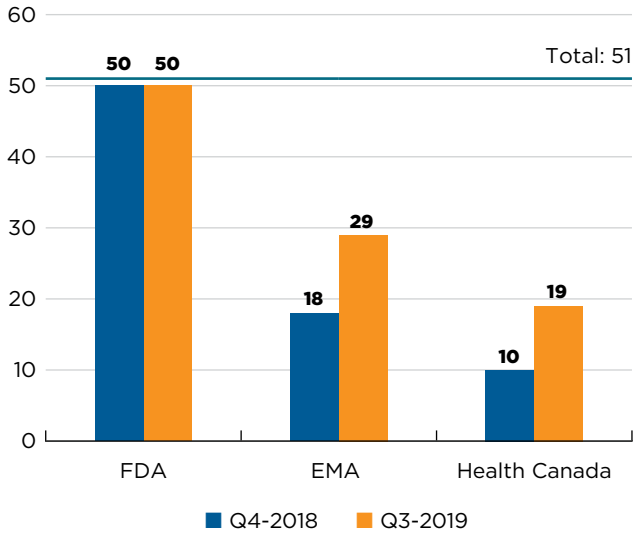
C NEW MEDICINE APPROVALS, 2018

The notable rate of approvals in 2017 was sustained through 2018, with a comparable number of new medicines authorized for market. More than half of the new medicines approved received an orphan designation, including many new oncology medicines, while a quarter were biologic therapies. Almost all new cancer treatments were high-cost, and one non-oncology orphan medicine was introduced at over $3.5 million per year.

In 2018, 51 new medicines received first-time market approval through the FDA, the EMA, and/or Health Canada. As of the third quarter of 2019, Canada had approved 19 of these new medicines, trailing behind the EMA (29) and the FDA (50) (Figure C1).

By Q4-2018, 40 new medicines had available sales in Canada, the US, and/or Europe. Over two thirds (28) of these came with treatment costs exceeding $10,000 per year or $5,000 per 28-day course. Table C1 provides a full list of the 51 new medicines approved in 2018 along with the country with first reported sales, the availability in Canada, and the prices and treatment costs where available.[3] Note that this information reflects the early availability and uptake of these medicines in the markets analyzed. Prices are reported for the highest-selling form and strength of each medicine.

FIGURE C1 Number of 2018 medicines with market approval as of Q4-2018 and Q3-2019



Note: Based on medicines that received market approval through the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and/or Health Canada in 2018.
Data source: US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

3 For more detailed supplementary information regarding the indication and manufacturer of each of the 2018 new medicines, see the *Meds Entry Watch* publication section of the Analytical Studies page on the PMPRB website.

TABLE C1 New medicines approved in 2018, availability, prices, and treatment costs, Q4-2018

Medicine (trade name, form, strength, volume)*	Therapeutic class†	Availability		No. of countries with sales	Canadian price§ (CAD)	PMPRB7‡ price (CAD)			Treatment cost**	
		First sale in Canada or PMPRB7	First sale in Canada			Min	Median	Max	Treatment cost (CAD)	Annual/ Course
Andexanet alfa (Andexxa, vial dry, 100 mg)	B2-Blood coagulation system, other products	US Sept-18	–	1	–	3,594	3,594	3,594	31,629	Dose
Apalutamide (Erleada, film-ctd tab, 60 mg)[C]	L2-Cytostatic hormone therapy	US Feb-18	Jul-18	3	29	111	111	111	3,259	28-day cycle
Avatrombopag (Doptelet, film-ctd tab, 20 mg)[O]	B2-Blood coagulation system, other products	US Jun-18	–	1	–	1,124	1,124	1,124	11,244/ 16,867	5-day treatment
Bictegravir (Biktarvy, film-ctd tab, 50 mg + 200 mg + 25 mg)	J5-Antivirals	US Feb-18	Aug-18	6	38	32	39	115	13,840	Annual
Baloxavir marboxil (Xofluza, film-ctd tab, 20 mg)	J5-Antivirals	US Nov-18	–	1	–	95	95	95	191	Dose
Binimetinib (Mektovi, film-ctd tab, 15 mg)[C,O]	L1-Antineoplastics	US Jun-18	–	3	–	37	51	71	8,573	28-day cycle
Burosumab (Crysvita, vial sc, 30 mg/ml, 1 ml)[B,O]	M5-Other drugs for disorders of the musculoskeletal system	GER Apr-18	–	2	–	6,041	10,654	15,267	183,232	Annual
Caplacizumab (Cablivi, vial dry, 10 mg)[O]	B6-All other hematological agents	FRA Sept-18	–	2	–	2,057	4,475	6,894	143,206	Treatment††
Cemiplimab (Libtayo, infus. vial dry, 50 mg/ml, 7 ml)[B,C]	L1-Antineoplastics	US Oct-18	–	1	–	10,775	10,775	10,775	10,775	28-day cycle
Dacomitinib (Vizimpro, film-ctd tab, 15 mg)[C,O]	L1-Antineoplastics	US Oct-18	–	1	117[ii]	505	505	505	3,267	28-day cycle
Damoctocog alfa pegol (Jivi, vial dry ret., 2000 IU)[B]	B2-Blood coagulation system, other products	US Sept-18	–	1	–	4	4	4	422 to 592	Annual
Doravirine (Pifeltro, film-ctd tab, 100 mg)	J5-Antivirals	US Sept-18	Nov-18	2	16	54	54	54	5,747	Annual
Duvelisib (Copiktra, capsule, 25 mg)[C,O]	L1-Antineoplastics	US Oct-18	–	1	–	246	246	246	13,750	28-day cycle
Elagolix (Orilissa, film-ctd tab, 150 mg)	H1-Pituitary and hypothalamic hormones	US Aug-18	Oct-18	2	6	38	38	38	1,131	Annual
Elapegademase (Revcovi, vial im, 1.6 mg/ml, 1.5 ml)[B,O]	A16-Other alimentary tract and metabolism products	US Nov-18	–	1	–	11,795	11,795	11,795	3,577,947	Annual
Encorafenib (Bravtovi, capsule, 75 mg)[C,O]	L1-Antineoplastics	US Jun-18	–	3	–	47	51	71	8,627	28-day cycle
Eravacycline (Xerava, inf. dry bottle, 50 mg)	J1-Systemic antibacterials	US Oct-18	–	1	–	56	56	56	623 to 2,179	4- to 14-day treatment
Erenumab (Aimovig, prefill autoinj, 70 mg/ml, 1 ml)	N2-Analgesics	US May-18	Dec-18	7	554	527	622	808	6,646	Annual
Fostamatinib (Tavalisse, film-ctd tab, 100 mg)[O]	B6-All other hematological agents	US May-18	–	1	–	194	194	194	191,036/ 212,802	Fist year/ subsequent years

(continued on the next page)

Medicine (trade name, form, strength, volume)*	Therapeutic class†	Availability			No. of countries with sales	Canadian price§ (CAD)	PMPRB7‡ price (CAD)			Treatment cost**	
		First sale in Canada or PMPRB7		First sale in Canada			Min	Median	Max	Treatment cost (CAD)	Annual/ Course
Fremanezumab (Ajovy, prefill syrng sc, 150 mg/ml, 1.5 ml)[B]	N2-Analgesics	US	Sept-18	–	1	–	724	724	724	8,685	Annual
Galcanezumab (Emgality, prefill autoinj, 120 mg/ml, 1 ml)[B]	N2-Analgesics	US	Oct-18	–	1	–	723	723	723	9,400/ 10,120	First year/ Subsequent years
Gilteritinib (Xospata, film-ctd tab, 40 mg)[C,O]	L1-Antineoplastics	US	Dec-18	–	1	–	315	315	315	8,832	28-day cycle
Glasdegib (Daurismo, film-ctd tab, 100 mg)[C,O]	L1-Antineoplastics	US	Dec-18	–	1	–	753	753	753	21,091	28-day cycle
Ibalizumab (Trogarzo, infus. vial/ bottle, 150 mg/ml, 1.33 ml)[B,O]	J5-Antivirals	US	Apr-18	–	1	–	1,362	1,362	1,362	149,766/ 141,597	First year/ Subsequent years
Inotersen (Tegsedi, prefill syrng sc, 189 mg/ml, 1.5 ml)[O]	N7-Other central nervous system drugs	GER	Oct-18	–	1	–	14,063	14,063	14,063	731,300	Annual
Ivosidenib (Tibsovo, film-ctd tab, 250 mg)[C,O]	L1-Antineoplastics	US	Aug-18	–	1	–	531	531	531	29,747	28-day cycle
Lanadelumab (Takhzyro, vial sc, 150 mg/ml, 2 ml)[O]	B6-All other hematological agents	US	Sept-18	–	2	–	19,422	22,934	26,446	596,288	Annual
Larotrectinib (Vitrakvi, capsule, 100 mg)[C,O]	L1-Antineoplastics	US	Dec-18	–	1	320[ii]	712	712	712	39,860	28-day cycle
Lorlatinib (Lorbrena, film-ctd tab, 100 mg)[C,O]	L1-Antineoplastics	US	Nov-18	–	1	–	675	675	675	18,888	28-day cycle
Lusutrombopag (Mulpleta, film-ctd tab, 3 mg)	B2-Blood coagulation system, other products	US	Sept-18	–	1	–	1,441	1,441	1,441	10,089	7-day treatment
Mogamulizumab (Poteligeo, infus. vial/bottle, 4 mg/ml, 1 ml)[B,C,O]	L1-Antineoplastics	US	Oct-18	–	1	–	4,321	4,321	4,321	120,993/ 60,496	28-day cycle
Moxetumomab pasudotox (Lumoxiti, inf. dry bottle, 1 mg)[B,C,O]	L1-Antineoplastics	US	Nov-18	–	1	–	2,543	2,543	2,543	21,363	28-day cycle
Patisiran (Onpattro, infus. vial/ bottle, 2 mg/ml, 5 ml)[O]	N7-Other central nervous system drugs	US	Aug-18	–	2	–	12,032	12,418	12,804	452,025	Annual
Plazomicin (Zemdri, infus. vial/ bottle, 50 mg/ml, 10 ml)	G4-Urologicals	US	Jul-18	–	1	–	400	400	400	3,357 to 5,875	4- to 7-day treatment
Revefenacin (Yulperi, lung u-d liq, 175 mcg/dose, 3 ml)	R3-Anti-asthma and COPD products	US	Dec-18	–	1	–	43	43	43	15,805	Annual
Talazoparib (Talzenna, capsule, 1 mg)[C]	L1-Antineoplastics	US	Oct-18	–	2	–	611	611	611	17,096	28-day cycle
Tezacaftor (Symdeko, film-ctd tab, 150 mg + 100 mg)[O]	R7–Other respiratory system products	US	Feb-18	–	2	–	294	364	435	132,944	Annual
Tildrakizumab (Ilumya, prefill syrng sc, 100 mg/ml, 1 ml)[B]	D5-Nonsteroidal products for inflammatory skin disorders	US	Oct-18	–	2	–	6,218	11,458	16,698	68,748/ 49,652	First year/ Subsequent years

(continued on the next page)

Medicine (trade name, form, strength, volume)*	Therapeutic class†	Availability		No. of countries with sales	Canadian price§ (CAD)	PMPRB7‡ price (CAD)			Treatment cost**	
		First sale in Canada or PMPRB7	First sale in Canada			Min	Median	Max	Treatment cost (CAD)	Annual/ Course
Velmanase alfa (Lamzede, inf. dry bottle, 10 mg)O	A16-Other alimentary tract and metabolism products	GER	Mar-18	–	–	–	1,379	1,830	2,282	666,297	Annual
Zirconium cyclosilicate (Lokelma, oral u-d powder, 10 g/dose)	V3-All other therapeutic products	SWE	Mar-18	–	–	–	23	26	28	9,457/ 9,354	First year/ Subsequent years
Calaspargase pegol (Asparlas)B,C,O	Not assigned as of Q3-2019	FDA	Dec-18	–							
Emapalumab (Gamifant)B,O	L04-Immunosuppressants	FDA	Nov-18	–							
Moxidectin (Moxidectin)O	P02-Anthelmintics	FDA	Jun-18	–							
Omadacycline (Nuzyra)	J01-Antibacterials for systemic use	FDA	Oct-18	–							
Pegvaliase (Palynziq)B,O	A16 – Other alimentary tract and metabolism products	FDA	May-18	–							
Ravulizumab (Ultomiris)O	L04-Immunosuppressants	FDA	Dec-18	Aug-19‡‡							
Sarecycline (Seysara)	J01- Antibacterials for systemic use	FDA	Oct-18	–							
Segesterone acetate (Annovera)	Not assigned as of Q3-2019	FDA	Aug-18	–							
Tafenoquine (Krintafel)O	P01-Antiprotozoals	FDA	Jul-18	–							
Tagraxofusp (Elzonris)O	L01-Antineoplastic agents	FDA	Dec-18	–							
Tecovirimat (Tpoxx)O	J05-Antivirals for systemic use	FDA	Jul-18	–							

No sales data in MIDAS® as of Q4-2018 – date of approval by FDA, EMA, and/or Health Canada

Note: A medicine was considered to be new in 2018 if it received market approval through the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada during the calendar year.
Availability and sales information refers to all forms and strengths of the medicine while pricing and treatment costs are based on the highest-selling form and strength indicated.
Sales are based on manufacturer list prices.

* B: biologic; C: cancer; O: orphan medicines.

† Level 2 of the Anatomical Classification of Pharmaceutical Products, as reported in MIDAS, except for the new medicines without sales data in MIDAS, for which the reporting is based on the Anatomic Therapeutic Chemical (ATC) Classification System maintained by the World Health Organization (WHO).

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

§ Canadian unit prices were retrieved from IQVIA MIDAS® Database, where available; otherwise, they were taken from:
i CADTH's Canadian Drug Expert Committee Recommendation report.
ii pCODR Expert Review Committee (pERC) Recommendation report.

** Treatment costs were calculated using Canadian list prices if available; otherwise, the foreign median price or available foreign price was used. Information on dosing regimens was taken from the product monograph provided by Health Canada, or the FDA or EMA if unavailable though Health Canada.

†† Based on assumption of one-day plasma exchange.

‡‡ Notice of Compliance issued as of Q3-2019.

Data source: IQVIA MIDAS® Database, 2018 (all rights reserved); US Food and Drug Administration Novel Drugs 2018; European Medicines Agency Human Medicines Highlights 2018; Health Canada Notice of Compliance Database.

D SPOTLIGHT ON CANADA

This new section reports on sales and prices of medicines that received their first Canadian approval in 2017, and analyzes the market impact of existing medicines that received approval for additional or extended indications in the same year.

Health Canada granted initial market authorization to 36 medicines in 2017, of which 25 had sales by the end of 2018, accounting for 1.6% of the Canadian pharmaceutical market. Table D1 reports on the availability, sales, and pricing of these 36 new-to-Canada medicines as of Q4-2018. Notably, the five highest-selling medicines were also reported in the list of 2017 new medicines in Section B, indicating that they received their first international approval in the same year.

This table also provides foreign-to-Canadian price ratios for each medicine. These ratios compare the median prices in the PMPRB7 countries with those in Canada to reflect how much more or less Canadians would have paid for a new medicine if they had paid the median international price. The average price of the medicine in Canada is set to a value of one and the corresponding foreign median prices are reported relative to this value.

The average ratio reported across all new medicines was 1.58, indicating that foreign prices at Q4-2018 were 58% higher than those in Canada. However, this result is heavily skewed toward prices in the US market. For medicines with prices available in only one foreign country, typically the US, the average foreign-to-Canadian price ratio was 7.91. When medicines with fewer than two comparator countries were excluded, the average ratio dropped to 1.01, indicating that Canadian prices were on par with those internationally for medicines with established international markets. Given the differences in Canadian and international policies for price increases, this ratio is expected to decrease over time.

TABLE D1 Medicines first approved in Canada in 2017, availability, sales, and prices, ranked by share of sales, Q4-2018

Medicine (trade name, form, strength, volume)*	Therapeutic class†	Availability		Share of 2017 Canadian new medicine sales	No. of PMPRB7 countries with sales	Price (CAD)		
		First sale in the PMPRB7	First sale in Canada			Canada	PMPRB7‡ median	Foreign-to-Canadian price ratio
Dupilumab (Dupixent, prefill syrng sc, 150 mg/ml, 2 ml)[B]	D5X0-Other nonsteroidal products for inflammatory skin disorders	Mar-17	Feb-18	21.1%	6	1,069	1,013	0.95
Herpes zoster vaccine [recombinant, adjuvanted] (Shingrix Vaccine, vial im, 100 mcg/ml, 0.5 ml)[B]	J7E2-Varicella vaccines	Dec-17	Jan-18	18.1%	2	119	148	1.25
Durvalumab (Imfinzi, infus. vial/bottle, 50 mg/ml, 10 ml)[B,C]	L1G0-Monoclonal antibody antineoplastics	May-17	Nov-17	13.9%	5	4,028	3,698	0.92
Guselkumab (Tremfya, prefill syrng sc, 100 mg/ml, 1 ml)[B]	D5B0-Systemic antipsoriasis products	Jul-17	Nov-17	9.9%	6	3,139	3,450	1.10
Insulin degludec (Tresiba, prefill pen ret., 200 IU/ml 3 ml)	A10C5-Human insulins and analogues, long-acting	Dec-12	Sept-17	8.4%	6	44	31	0.70
Glecaprevir, pibrentasvir (Maviret, film-ctd tab, 100 mg + 40 mg)	J5D3-Hepatitis C antivirals	Jul-17	Sept-17	6.4%	7	236	230	0.97
Ocrelizumab (Ocrevus, infus. vial/bottle, 30 mg/ml, 10 ml)[B]	N7A0-Multiple sclerosis products	Apr-17	Sept-17	6.2%	7	8,446	8,506	1.01
Voxilaprevir (Vosevi, film-ctd tab, 400 mg + 100 mg + 100 mg)	J5D3-Hepatitis C antivirals	Jul-17	Sept-17	5.7%	6	699	854	1.22
Lifitegrast (Xiidra, oph u-d liq, 5%, 0.2 ml)	S1K9-Dry eye products, other	Jul-16	Feb-18	2.6%	1	4	11	2.99
Nusinersen (Spinraza, vial, 2.4 mg/ml, 5 ml)[O]	N7X0-All other CNS drugs	Feb-17	Aug-17	2.4%	7	120,597	113,453	0.94
Brexpiprazole (Rexulti, film-ctd tab, 1 mg)	N5A1-Atypical antipsychotics	Jul-15	Apr-17	1.3%	1	4	46	12.83
Sarilumab (Kevzara, prefill syrng/autoinj, 175 mg/ml, 1.14 ml)[B]	M1C0-Specific anti-rheumatic agents	May-17	Feb-17	1.0%	7	718	711	0.99
Midostaurin (Rydapt, capsule, 25 mg)[C,O]	L1H0-Protein kinase inhibitor antineoplastics	Oct-16	Sept-17	0.8%	7	166	166	1.00
Eliglustat (Cerdelga, capsule, 84 mg)[O]	A16A0-Other alimentary tract and metabolism products	Sept-14	Nov-17	0.7%	5	625	558	0.89
Eluxadoline (Viberzi, film-ctd tab, 100 mg + 40 mg)	A3G0-Gastro-intestinal sensorimotor modulators	Dec-15	Apr-17	0.4%	3	2	2	1.01
Letermovir (Prevymis, film-ctd tab, 480 mg)[O]	J5B3-Herpes antivirals	Dec-17	Dec-17	0.3%	2	246	249	1.01
Olaratumab (Lartruvo, infus. vial/bot., 16 mg/ml, 50 ml)[B,C,O]	L1G0-Monoclonal antibody antineoplastics	Nov-16	Dec-17	0.3%	5	2,027	1,915	0.94
Netupitant (Akynzeo, capsule, 300 mg + 500 mcg)	A4A2-NK1 antagonist antiemetics/ antinauseants	Oct-14	Nov-17	0.2%	7	138	103	0.75
Atezolizumab (Tecentriq, infus. vial/ bottle, 60 mg/ml, 20 ml)[B,C]	L1G0-Monoclonal antibody antineoplastics	May-16	May-17	0.2%	7	7,091	6,596	0.93
Avelumab (Bavencio, infus. vial/bottle, 20 mg/ml, 10 ml)[B,C,O]	L1G0-Monoclonal antibody antineoplastics	Mar-17	Dec-17	0.1%	7	1,391	1,350	0.97

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Medicine (trade name, form, strength, volume)*	Therapeutic class†	Availability		Share of 2017 Canadian new medicine sales	No. of PMPRB7 countries with sales	Price (CAD)		
		First sale in the PMPRB7	First sale in Canada			Canada	PMPRB7‡ median	Foreign-to-Canadian price ratio
Lixisenatide (Soliqua, prefill pen ret., 100 IU/ml + 33 mcg/ml, 3 ml)	A10C9-Other human insulins and analogues	Feb-13	Sept-17	0.1%	4	39	42	1.09
Obeticholic acid (Ocaliva, film-ctd tab, 5 mg)O	A5A9-Other bile therapy and cholagogues	Jun-16	Aug-17	0.1%	6	104	138	1.33
Propiverine (Mictoryl, capsule ret., 30 mg)	G4D4-Urinary incontinence products	Jan-81	Apr-17	0.1%	3	1	1	1.01
Ozenoxacin (Ozanex, cream, 1%, 10 g)	D10A0-Topical anti-acne preparations	–	Jan-18	<0.1%	0	2	–	–
Neisseria meningitidis B rLP2086 [subfamilies A,B] (Trumenba, prefill im, 120 mcg/ml, 0.5 ml)B	J7D2-Meningococcal vaccines	Nov-14	Feb-18	<0.1%	5	101	116	1.15
Anthrax immune globulin [human] (Anthrasil)B	J6BB19-Anthrax immunoglobulin	–	–	–	–	–	–	–
Coagulation Factor IX [recombinant], glycoPEGylated (Rebinyn, vial dry, 2000 IU)B	B2D2-Factors II, VII, IX and X	Jun-17	–	–	1	–	4	–
Cysteamine bitartrate (Procysbi, capsule, 75 mg)O	A16A0-Other alimentary tract and metabolism products	Mar-98	–	–	5	–	28	–
Defibrotide (Defitelio, infus. vial/bottle, 80 mg/ml, 2.5 ml)B,O	B1C4-Platelet cAMP enhancing platelet aggregation inhibitors	May-86	–	–	5	–	556	–
Florbetaben [18F]§ (Neuraceq)	T1G0-Radiodiagnostic agents	–	–	–	–	–	–	–
Ioflupane [123i] (Datscan, vial IV, 5 ml)	T1G0-Radiodiagnostic agents	May-05	–	–	2	–	1,168	–
Migalastat (Galafold, capsule, 123 mg)O	A16A0-Other alimentary tract and metabolism products	May-16	–	–	5	–	1,661	–
Necitumumab (Portrazza, infus. vial/bottle, 16 mg/ml 50 ml)B,C	L1G0- Monoclonal antibody antineoplastics	Dec-15	–	–	2	–	3,082	–
Peramivir (Rapivab, infus. bag, 5 mg/ml, 60 ml)	J5B4-Influenza antivirals	Dec-14	–	–	1	–	405	–
Sebelipase alfa (Kanuma, infus. vial/bottle, 2 mg/ml, 10 ml)B,O	A16A0-Other alimentary tract and metabolism products	Aug-15	–	–	4	–	9,142	–
Vernakalant (Brinavess, infus. vial/bottle, 20 mg/ml, 25 ml)	C1B0-Anti-arrhythmics	Sept-10	–	–	3	–	519	–

Note: Some medicines with sales may not be reported in IQVIA's MIDAS Database; for example, although there is no Canadian sales data available in MIDAS for cysteamine bitartrate (Procysbi), it was the subject of a Notice of Hearing issued by the PMPRB in January 2019 for allegations of excessive pricing.

* B: biologic; C: cancer; O: orphan medicines.

† Level 4 of the Anatomical Classification of Pharmaceutical Products, as reported in MIDAS; if unavailable in MIDAS, the reporting is based on the Anatomical Therapeutic Chemical (ATC) Classification System maintained by the World Health Organization (WHO).

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

§ Canadian and international sales are not reported due to limitations in the available data for this medicine.

Data source: IQVIA MIDAS® Database, 2018, all rights reserved; Health Canada Notice of Compliance Database.

Thirty-four previously marketed medicines were granted new or extended indications by Health Canada in 2017. As a group, these medicines grew by 17%, or nearly $600 million, from 2017 to 2018. By comparison, the Canadian pharmaceutical market grew by 4%, or slightly over $1 billion, over the same period. As a result, existing medications with new indications accounted for 55% of total Canadian pharmaceutical sales growth from 2017 to 2018. Of these medicines, velpatasvir, pembrolizumab, and adalimumab made the greatest positive contributions to the sales growth, while ledipasvir had the greatest negative impact. For the full list of medicines with new indications, as well as their change in sales from 2017 to 2018, see Appendix I.

TABLE D2 Change in sales of existing medicines with new or extended indications in Canada, 2017 to 2018

	2017 sales	2018 sales	Net change in sales (% change)
Existing medicines with new indications in 2017	$3.50B	$4.09B	$0.59B (17%)
Total Canadian market	$27.43B	$28.51B	$1.07B (4%)

Data source: IQVIA MIDAS® Database, 2017 to 2018.

REFERENCES

European Medicines Agency. 2018. *Human Medicines Highlights 2017.* Available: https://www.ema.europa.eu/en/news/human-medicines-highlights-2017

European Medicines Agency. 2019. *Human Medicines Highlights 2018.* Available: https://www.ema.europa.eu/en/news/human-medicines-highlights-2018

Food and Drug Administration. 2018. *Novel Drugs 2017.* Silver Spring, Maryland: US FDA, Center for Drug Evaluation and Research. Available: https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2017

Food and Drug Administration. 2017. *Novel Drugs 2018.* Silver Spring, Maryland: US FDA, Center for Drug Evaluation and Research. Available: https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2018

Health Canada. 2019. *Drug and medical device highlights 2018: Helping you maintain and improve your health.* Ottawa: Health Canada. Available: https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/drug-medical-device-highlights-2018.html

PMPRB. 2018. *Annual Report, 2017.* Ottawa: Patented Medicine Prices Review Board. Available: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1380&lang=en

APPENDIX I

Change in sales of existing medicines with new or extended indications approved by Health Canada in 2017, T4-2018

Medicine	Therapeutic area*	Net change in sales, 2017 to 2018 (CAD)
Velpatasvir	J05-Antivirals for systemic use	$165,364,017
Pembrolizumab	L01-Antineoplastic agents	$129,871,160
Adalimumab	L04-Immunosuppressants	$82,621,593
Palbociclib	L01-Antineoplastic agents	$62,768,398
Nivolumab	L01-Antineoplastic agents	$55,849,340
Ibrutinib	L04-Immunosuppressants	$55,121,910
Ipilimumab	L01-Antineoplastic agents	$20,124,772
Omalizumab	R03-Drugs for obstructive airway diseases	$18,836,248
Liraglutide	A10-Drugs used in diabetes	$17,976,801
Ranibizumab	S01-Ophthalmologicals	$15,493,537
Clostridium botulinum toxin type A	M03-Muscle relaxants	$15,460,818
Abacavir	J05-Antivirals for systemic use	$13,165,506
Dulaglutide	A10-Drugs used in diabetes	$12,204,709
Leuprorelin	L02-Endocrine therapy	$9,689,172
Trametinib	L01-Antineoplastic agents	$6,459,854
Everolimus	L01-Antineoplastic agents	$6,195,859
Tocilizumab	L04-Immunosuppressants	$5,425,992
Dabrafenib	L01-Antineoplastic agents	$5,407,516
Lurasidone	N05-Psycholeptics	$4,975,261
Glycopyrronium	R03-Drugs for obstructive airway diseases	$3,655,720
Canakinumab	L04-Immunosuppressants	$3,496,843
Eltrombopag	B02-Antihemorrhagics	$3,122,527
Mifepristone	G03-Sex hormones and modulators of the genital system	$3,049,514
Lenvatinib	L01-Antineoplastic agents	$3,007,169
Panitumumab	L01-Antineoplastic agents	$2,899,708
Lacosamide	N03-Antiepileptics	$2,856,104
Fulvestrant	L02-Endocrine therapy	$1,964,094
Eribulin	L01-Antineoplastic agents	$1,107,911
Anakinra	L04-Immunosuppressants	-$161,847
Aripiprazole	N05-Psycholeptics	-$2,254,351
Crizotinib	L01-Antineoplastic agents	-$4,756,882
Daratumumab	L01-Antineoplastic agents	-$7,148,422
Etanercept	L04-Immunosuppressants	-$7,417,108
Ledipasvir	J05-Antivirals for systemic use	-$112,198,908
TOTAL		**$594,234,535**

* Level 2 of the Anatomical Therapeutic Chemical (ATC) Classification System maintained by the World Health Organization (WHO).
Data source: IQVIA MIDAS® Database, 2017 to 2018.