Patented Medicine Prices Review Board

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MEDS

ENTRY WATCH

5th Edition

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 fifth edition of the PMPRB's *Meds Entry Watch* report, which explores the market entry of new medicines in Canada and other countries. Building on a retrospective analysis of trends since 2015, 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 2018 and 2019, and analyzes their uptake, pricing, sales, and availability as of the last quarter of 2019 (Q4-2019).

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 Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom (UK), which will comprise the PMPRB11 comparator countries. Where appropriate, the United States (US) is included to provide additional context.

In addition to the international analysis, a Canadian-focused section provides information on medicines that received their first Health Canada approval in 2018, as well as a retrospective review of quarterly approvals over the past five years.

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, 2015 to 2019

Approximately 50 new medicines have been approved in each of the last three years, with orphan and oncology medicines making up a significant portion of new approvals.

- Across Canada, US, and Europe, just over fifty new medicines were approved in both 2017 and 2018, with 47 new approvals in 2019.
- Between 2015 and 2019, the shares of new approvals for orphan and oncology medicines averaged 27% and 48%, respectively, with variations from year to year.

A considerable portion of the new medicines approved internationally between 2015 and 2018 had Canadian sales by the end of 2019.

- New medicines approved between 2015 and 2018 accounted for approximately 12% of brand-name medicine sales in Canada and the PMPRB11 in Q4-2019.
- Just under 40% of these medicines had sales in Canada by Q4-2019, ahead of the OECD median (32%).
- New medicines approved from 2015 to 2018 with Canadian sales accounted for 87% of all new medicine sales in the OECD in Q4-2019, indicating that the higher-selling medicines continue to be among those approved and sold in Canada.

(B) 2018 New Medicine Approvals

Fifty-one new medicines were approved in 2018, with a pronounced increase in the number of orphan medicines authorized for market.

- 51 new medicines received market approval through the FDA, the EMA, and/or Health Canada in 2018.
- Over 60% of the 2018 new medicines received an orphan designation from the FDA and/or the EMA, while more than 30% were indicated for the treatment of cancer.
- Over two thirds of the new medicines had high treatment costs: 13 oncology medicines had costs exceeding $5,000 per 28-day cycle and 21 non-oncology medicines had annual costs exceeding $10,000.

Fewer medicines were approved in Canada than in the US and Europe in 2018, although Canada compared favourably to the OECD in terms of the corresponding share of sales.

- 20 of the 51 new medicines first approved in 2018 had market authorization in Canada by Q4-2019, compared to 50 approved by the FDA and 32 by the EMA.
- Of the 20 approved medicines, nine had recorded sales in Canada by the end of 2019, placing Canada ninth in the OECD and in line with the PMPRB11 countries for the number of new medicines with sales.
- Although these nine medicines represent a relatively small portion of the total number of approvals in 2018, they accounted for 75% of total sales for new medicines in the OECD.

Sales for 2018 new medicines were highly concentrated, with a single antiviral medicine accounting for the majority of new medicine revenue in the last quarter of 2019.

- The HIV treatment Biktarvy (bictegravir) was responsible for 52% of OECD new medicine sales in Q4-2019, making up the vast majority of the 53% total share held by the antivirals class.
- Analgesics were the second highest-selling class with three migraine medicines (erenumab, galcanezumab, and fremanezumab) accounting for 15% of 2018 new medicine sales.
- Respiratory disease treatments accounted for one tenth of international new medicine sales, attributable to the new medicine tezacaftor, which is used in cystic fibrosis treatments Symdeko and Trikafta.
- Oncology medicines, comprised of cytostatic hormone therapy and antineoplastics, made up 8% of new medicine sales.

(C) 2019 New Medicine Approvals

The rate of new medicine approvals in 2018 was sustained through 2019, bringing a number of new high-cost oncology treatments to the market.

- 47 new medicines received market approval through the FDA, the EMA, and/or Health Canada in 2019. Of these, 16 were approved in Canada by the third quarter of 2020.
- In total, 40% (19) of the new medicines received an orphan designation from the FDA and/or the EMA. Oncology treatments accounted for 23% (11) of the 2019 new medicines, while biologics made up nearly a third (14) of the approvals.
- Based on preliminary results, nine oncology medicines had treatment costs exceeding $5,000 per 28-day cycle.

(D) Spotlight on Canada

The number of new medicines that received their first Canadian approval in 2018 was in line with trends observed over the past five years.

- 40 new-to-Canada medicines were approved for market in 2018, of which 22 had reported sales by Q4-2019, accounting for 1.6% of the total Canadian pharmaceutical market.
- Four of the five internationally top-selling new medicines in 2018 received market authorization in Canada in the same year, including Biktarvy (bictegravir), which represented 21% of all Canadian 2018 new medicine sales by Q4-2019.
- An analysis of the rate of new medicine approvals in Canada found a steady annual trend of approximately nine approvals per quarter 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 four previous editions to provide a broad analysis of medicines that have received market approval since 2015, with a special focus on medicines approved in 2018 and 2019. 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.

The report consists of four main sections: Section A provides an overview of trends from 2015 to 2019; Section B focuses on new medicines that received international market approval in 2018; Section C presents a preliminary analysis of the new medicines approved internationally in 2019; and Section D spotlights Health Canada approvals in 2018.

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

METHODS

This report analyzes new medicines that have received initial market approval through the FDA, the EMA, and/or Health Canada since 2015, with a focus on those approved in 2018 and 2019. A new medicine is 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. For the purpose of the report, new medicines are identified at the medicinal ingredient level. Using these criteria, 175 new medicines were identified as new approvals between 2015 and 2018, including the 51 analyzed for the 2018 list in Section B, and 47 were identified for the preliminary analysis of 2019 medicines in Section C. The approval of these medicines in Canadian and international markets was assessed as of the end of 2019 or the third quarter of 2020 (Q3-2020), as specified.

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 2018. This includes a number of the medicines in the 2018 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 2018.

International markets examined include the Organisation for Economic Co-operation and Development (OECD) members, with a focus on Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom (UK), which will comprise the PMPRB11 comparator countries. Sales data for the United States (US) is also used where sales have not been reported in the PMPRB11.

The IQVIA MIDAS® Database (all rights reserved) is the main data source for the sales and list prices of new medicines in Canadian and international markets, as well as the volume 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 Resources section of the Analytical Studies page on the PMPRB website.

Canadian prices are based on MIDAS data, if available; otherwise, they are derived 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 are calculated using Canadian list prices where possible; if not, the foreign median price is used. Information on dosing regimens is taken from the product monographs published by Health Canada, or if not available, from the FDA or EMA. All medicines were reviewed as of Q3-2020, unless otherwise specified.

Prices and foreign-to-Canadian price ratios are reported for the highest-selling form and strength of each medicine in Canada, or in the PMPRB11 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 Resources section of the Analytical Studies page on the PMPRB website.

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

LIMITATIONS

New medicines reported in Sections A, B, and C are selected for analysis based on their date of market approval by the FDA, the EMA, and/or Health Canada. Some of the medicines reported may have earlier approval dates in other countries, such as Australia and Japan, which are governed by other regulatory bodies. Likewise, the medicines included in this analysis do not necessarily represent all of those introduced in 2018 and 2019, as other national regulatory bodies not examined in this report may have approved additional medicines. Nevertheless, as the FDA and EMA represent significant international markets, this is estimated to have little effect on the overall results.

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 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 skewed towards the United States 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, 2015–2019

This section reports on the number of new medicines approved from 2015 to 2019, and tracks the progress of those approved from 2015 to 2018 through to the end of 2019. Sales and pricing information is reported as of Q4-2019.

A greater number of new medicines have been approved in recent years, including many new specialty treatments. Medicines first approved between 2015 and 2018 accounted for approximately 12% of all brand-name sales by the end of 2019. Canadian sales had been recorded for over a third of these by Q4-2019, placing Canada eighth among the PMPRB11 countries and maintaining its position as tenth in the OECD. Canada ranked among the top countries in the OECD in terms of the share of total new medicine sales, which suggests that the highest-selling medicines were among those approved.

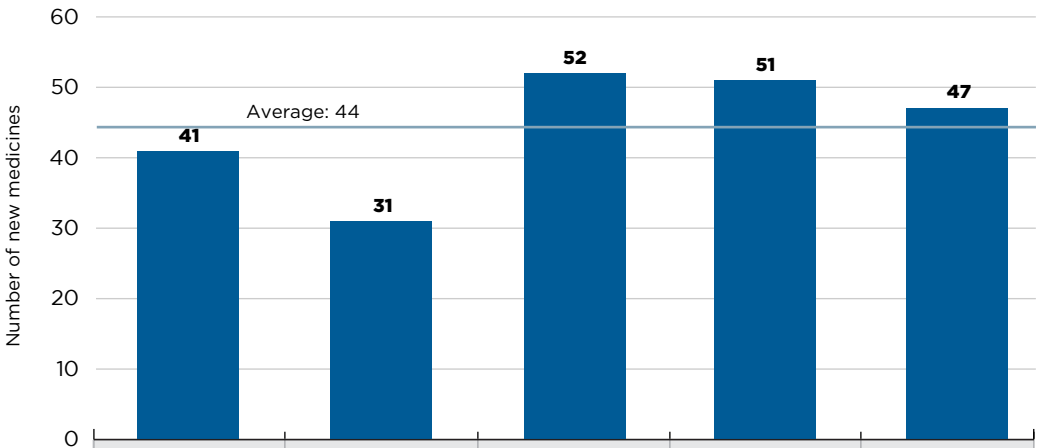
An average of 44 new medicines received first-time market approval through the FDA, the EMA, and/or Health Canada annually between 2015 and 2019 (Figure A1). In 2018, 51 new medicines were approved, of which over 60% (31) received an orphan designation from the FDA and/or EMA. Consistent with 2017 results, approximately one third of 2018 new medicines were indicated to treat cancer.

An additional 47 new medicines were approved in 2019, including a smaller share of orphan medicines (40%) and a slight decline in the proportion of new oncology medicines (23%).

New medicines have had a moderate year-over-year uptake in sales. By Q4-2019, those launched between 2015 and 2018 accounted for 12.8% of the total brand-name pharmaceutical market in Canada and 11.5% internationally (Figure A2). Medicines that were approved in 2018 represented 0.8% of all pharmaceutical sales in Canada and the PMPRB11.

In any given year, the impact of new medicines on pharmaceutical sales depends on their number, therapeutic relevance, and treatment costs. For instance, in 2018, the three highest-selling new medicines in Canada were velpatasvir, elbavisir, and grazoprevir, all approved in 2016 for the treatment of hepatitis C. Together, these three medicines accounted for 4.6% of brand-name medicine sales in 2018. By Q4-2019, spending on hepatitis C medicines had declined as a share of brand-name spending. As a result, sales of medicines approved in 2016 declined relative to medicines approved in other years, such as daratumumab (an oncology medicine launched in 2015) and semaglutide (a diabetes medicine launched in 2017). For more information on this group of medicines, see Appendix I.

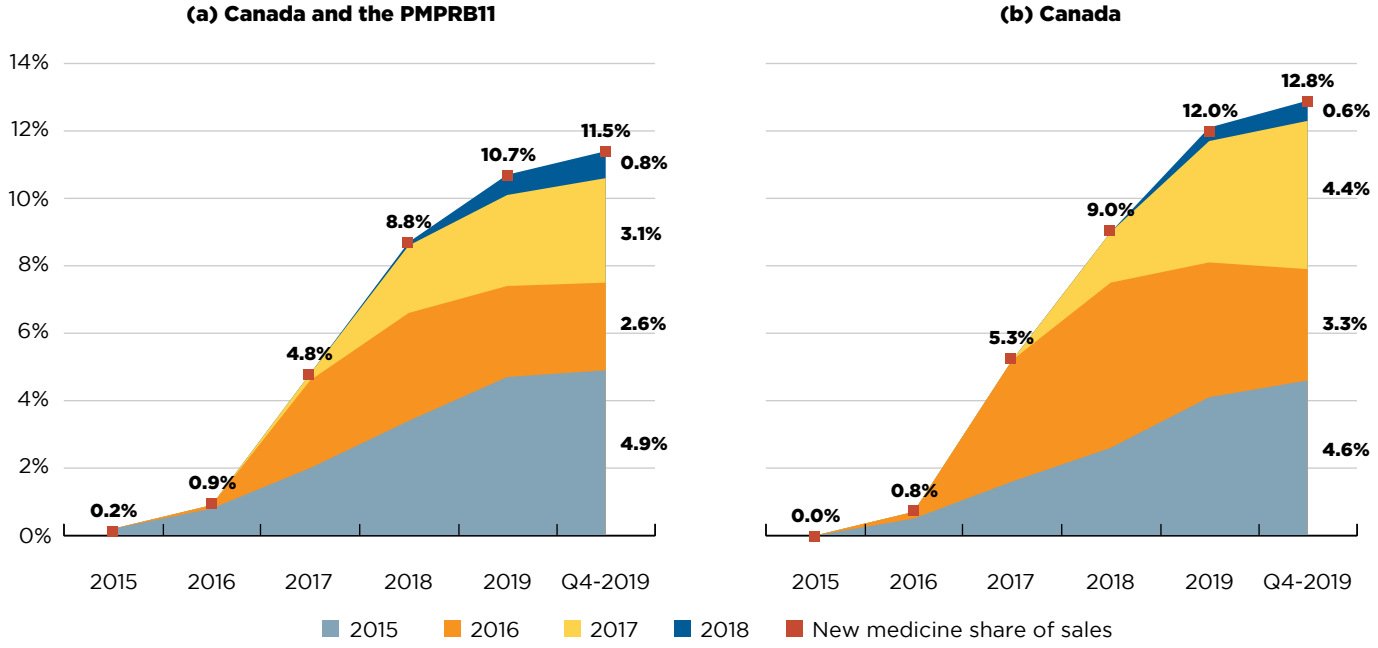
FIGURE A1 **New medicines approved by the US FDA, the EMA, and/or Health Canada, 2015 to 2019**



	2015	2016	2017	2018	2019
Share of orphan medicines	54%	42%	46%	61%*	40%
Share of oncology medicines	34%	16%	33%	31%*	23%

* This value has been corrected and as such does not match the value reported in previous editions.
Data source: US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

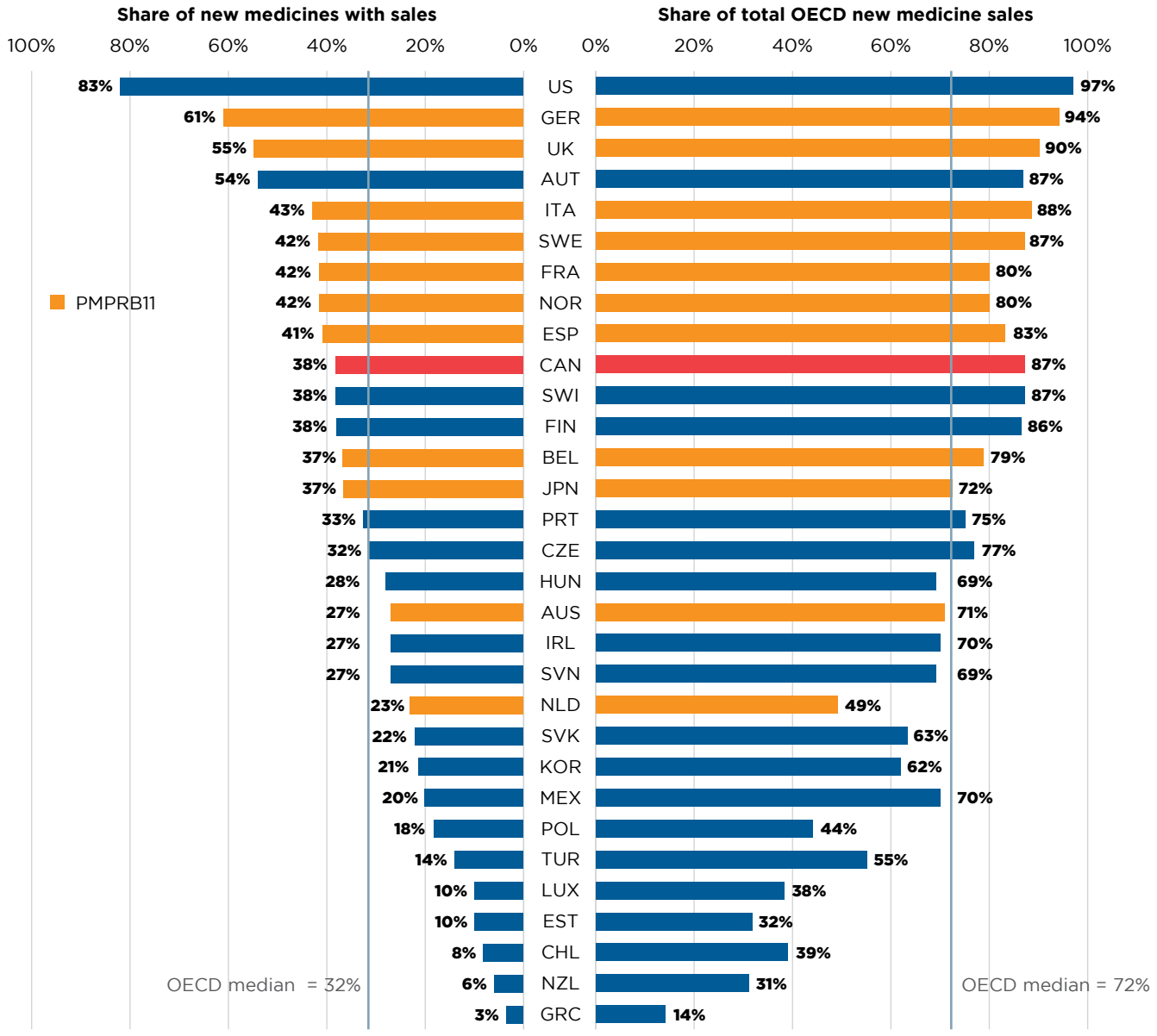
FIGURE A2 **New medicine cumulative share of all brand-name medicine sales by year of approval (2015 to 2018), Canada and the PMPRB11***



* Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and the United Kingdom.
Data source: IQVIA MIDAS® Database, 2019. All rights reserved.

Of the 175 medicines approved from 2015 to 2018, 66 (38%) had recorded sales in Canada by Q4-2019 (Figure A3). While this proportion was higher than the OECD median of 32%, it ranked below the median of the PMPRB11 countries, many of which have lower average list prices for patented medicines (PMPRB). The new medicines sold in Canada accounted for 87% of the OECD sales for all new medicines analyzed, representing the fifth highest share in the OECD, well above the median of 72%. These findings are similar to those of previous editions of this report and continue to suggest that although fewer new medicines were approved in Canada, the higher-selling new medicines were among those sold.

FIGURE A3 **Share of new medicines approved in Canada and the PMPRB11* from 2015 to 2018 with available sales, and their respective share of OECD sales, by country, Q4-2019**



Note: Sales are based on manufacturer list prices and include sales for all OECD countries.
* Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and the United Kingdom.
Data source: IQVIA MIDAS® Database, 2019. All rights reserved.

B NEW MEDICINE APPROVALS, 2018

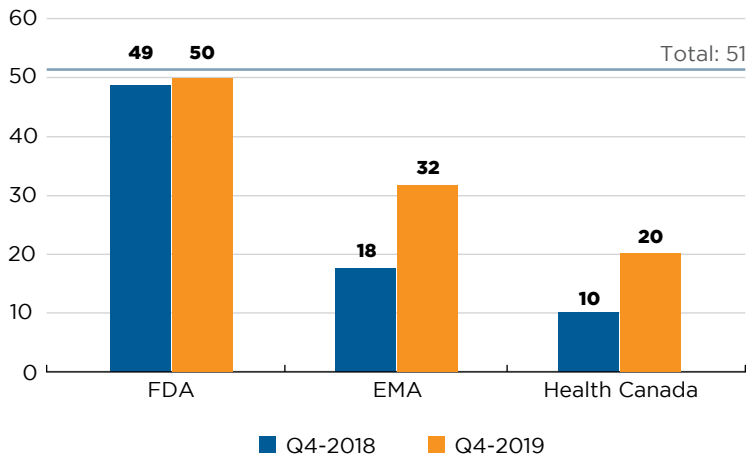
This section reports on new medicines approved in 2018 and tracks their progress through the first two years after approval. Sales and pricing data are provided as of Q4-2019 while assessments, recommendations, and reimbursement decisions are reported as of Q3-2020.

In addition to a relatively high number of total new approvals, 2018 brought a pronounced increase in the number of orphan medicines authorized for market. Sales for 2018 new medicines were highly concentrated, with a single antiviral accounting for the majority of revenues in the last quarter of 2019.

Fifty-one new medicines were approved in Canada, Europe, and the US in 2018. By the end of 2019, 20 of these had been approved in Canada. Both the FDA and the EMA approved more new medicines than Canada at 50 and 32, respectively (Figure B1).

Of the 20 medicines approved in Canada, 9 had sales data available in MIDAS by Q4-2019. This placed Canada ninth in the OECD in terms of the number of new medicines sold and seventh in terms of the corresponding OECD sales of these new medicines, at 75%. The US market, which ranked first among all OECD countries, recorded sales for 45 of the medicines approved in 2018, representing over 99% of OECD sales.

FIGURE B1 **Number of 2018 new medicines with market approval as of Q4-2018 and Q4-2019**



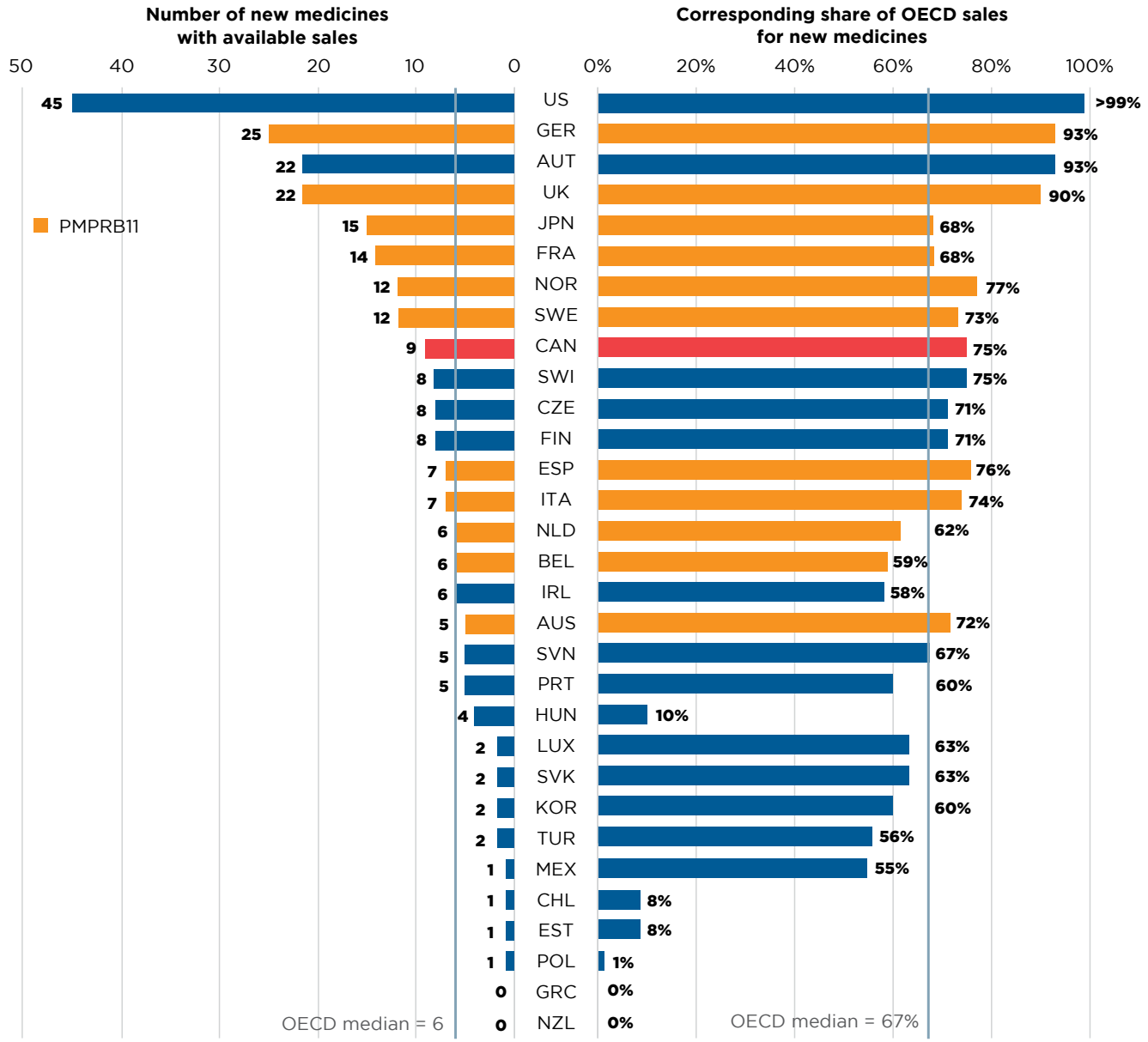
Data source: US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Health Canada databases.

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

Table B1 lists the new medicines approved in 2018. For each medicine, the country with the first reported sales is given, along with the availability in Canada, the share of sales in Q4-2019, 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.

Antineoplastics and antivirals continued to account for the greatest number of new medicines in 2018, with 14 and 4 medicines approved, respectively.

FIGURE B2 **Number of 2018 new medicines with market approval and their share of OECD sales as of Q4-2019**



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 with recorded sales data as of Q4-2019. Sales are based on manufacturer list prices and include sales for the selected new medicines in all OECD countries.
Data source: IQVIA MIDAS® Database, 2019 (all rights reserved); US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

1. 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.

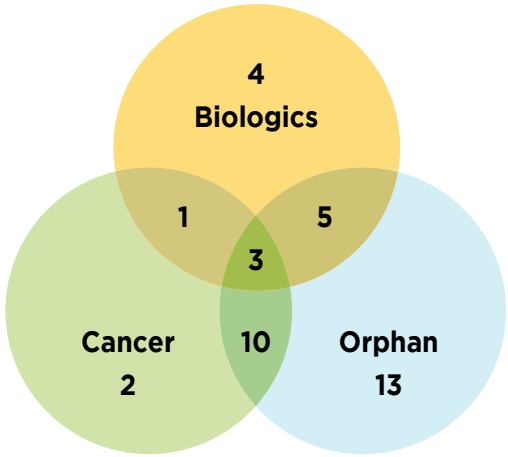
Several other therapeutic areas emerged as top contributors in 2018, including four new blood coagulation system products and three new analgesics, all of which were indicated for the treatment of migraines. In total, the list of 2018 new medicines spans 23 therapeutic classes.

Despite the range of therapeutic areas represented, sales for the 2018 new approvals were highly concentrated. The top three therapeutic classes, representing eight medicines, accounted for over three quarters of all new medicine sales across the OECD by Q4-2019 (Table B1). Antivirals topped the list with 53% of all sales, driven primarily by Biktarvy, an oral HIV medicine that alone accounted for over half of sales by the end of 2019. Analgesics followed with a 14% share of sales held by three medicines indicated for the treatment of migraines, half of which can be attributed to the top treatment in the class, erenumab (Aimovig). Respiratory system medicines were responsible for 10% of new medicine sales, attributed to two cystic fibrosis treatments containing the new medicine tezacaftor—Symdeko[2] and Trikafta[3]. Despite having the greatest number of new medicines, the antineoplastics class captured 5% of new medicine sales with no individual medicine capturing more that 1% of sales.

A considerable number of new medicines fell into specialty categories. In total, 61% (31) of the 2018 new medicines received an orphan designation from the FDA and/or the EMA and 31% (16) of new medicines were for the treatment of cancer. Approximately 25% (13) were biologics, which represents a decline over the previous year. As illustrated in Figure B3, there was considerable overlap among these categories: 13 of the new oncology medicines were orphan-designated, of which three were also classified as biologics.

As reported in Table B1, three new medicines had no recorded sales as of Q4-2019: tecoviramat, moxidectin, and calaspargase. Tecoviramat is an antiviral medicine for smallpox, a virus considered to be eradicated by the WHO in 1979. While sales have not been registered through typical supply chains, the US government purchased the product directly in case of an outbreak[4] and Canada followed suit shortly after with purchases by the Department of National Defense and a pending tender announcement from the Public Health Agency of Canada.[5,6,7] Moxidectin, a medicine previously used only in veterinary practice, has become indicated for human use in the treatment of onchocerciasis, commonly referred to as "river blindness" in the US. River blindness is predominantly found outside of the OECD in sub-Saharan Africa. While the medicine is novel for human use and presents benefits over current treatments, none of the OECD countries have reported sales as of Q4-2019. The third medicine, calaspargase, is a biologic indicated to treat acute lymphoblastic leukemia in children and young adults.

FIGURE B3 **Number of cancer, orphan, and biologic medicines first approved in 2018**



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

2. Symdeko was first authorized by the FDA in 2018 and received market authorization from Health Canada in June 2018. No Canadian sales were available in the MIDAS® Database as of the end of 2019, though the medicine is covered through Canadian private drug plans (Table B2).
3. Trikafta contains both tezacaftor and the 2019 new medicine elexacaftor. Despite receiving its first international authorization through the FDA in 2019, it was the top-selling product containing tezacaftor by Q4-2019.
4. SIGA. 2020. *SIGA Announces Deliveries of Oral TPOXX® to HHS Valued at Approximately $32 Million*. GlobeNewswire: June 25, 2020. Available at: https://www.globenewswire.com/news-release/2020/06/25/2053714/0/en/SIGA-Announces-Deliveries-of-Oral-TPOXX-to-HHS-Valued-at-Approximately-32-Million.html
5. SIGA. 2019. *SIGA Announces Canadian Department of National Defence Intent to Purchase Up To 15,325 Courses of Oral TPOXX®*. GlobeNewswire: Dec. 5, 2019. Available at : https://www.globenewswire.com/news-release/2019/12/05/1956971/0/en/SIGA-Announces-Canadian-Department-of-National-Defence-Intent-to-Purchase-Up-To-15-325-Courses-of-Oral-TPOXX.html
6. SIGA. 2020. *SIGA Announces Public Health Agency of Canada Intent to Purchase Up To 33,300 Courses of Oral TPOXX®*. GlobeNewswire: Oct. 8, 2020. Available at: https://www.globenewswire.com/news-release/2020/10/08/2105498/0/en/SIGA-Announces-Public-Health-Agency-of-Canada-Intent-to-Purchase-Up-To-33-300-Courses-of-Oral-TPOXX.html
7. TPOXX® (tecovirimat) (H1020-203092/A) Tender Notice. Public Works and Government Services Canada: Oct. 7, 2020. Available at: https://buyandsell.gc.ca/procurement-data/tender-notice/PW-PH-896-79143

TABLE B1 **New medicines approved in 2018, availability, share of sales, prices, and treatment costs, ranked by therapeutic class share of sales, Q4-2019**

Rank	Therapeutic class*	Medicine (trade name, form, strength, volume)	Availability: First sale in Canada, US, or PMPRB11†		Availability: First sale in Canada	Share of new medicine sales across the OECD: Medicine	Share of new medicine sales across the OECD: Therapeutic class	No. of countries with sales‡	Canadian price§ (CAD)	PMPRB11 price (CAD): Min	PMPRB11 price (CAD): Median	PMPRB11 price (CAD): Max	US price	Treatment cost**: Treatment cost (CAD)	Treatment cost**: Annual/ Course
1	J5-Antivirals for systemic use	Bictegravir (Biktarvy, film-ctd tab, 50 mg + 200 mg + 25 mg)	US	Feb-18	Oct-18	52%	53%	13	36	26	40	68	118	14,315	Annual
2		Baloxavir marboxil (Xofluza, film-ctd tab, 20 mg)[O]	JPN	Mar-18	–	1%		2	–	23	23	23	93	117	Dose
3		Doravirine (Pifeltro, film-ctd tab, 100 mg)	US	Sept-18	Nov-18	1%		9	17	12	22	26	53	6,077	Annual
4		Ibalizumab (Trogarzo, infus. vial/ bottle, 150 mg/ml, 1.33 ml)[B,O]	US	May-18	–	<1%		1	–	–	–	–	1,328	73,064	Annual
5	N2-Analgesics	Erenumab (Aimovig, prefill autoinj, 70 mg/ml, 1 ml)	US	May-18	Dec-18	7%	15%	9	545	471	591	783	674	6,543	Annual
6		Galcanezumab (Emgality, prefill autoinj, 120 mg/ml, 1 ml)[B]	US	Oct-18	Oct-19	5%		8	624	466	597	938	693	14,977	Annual
7		Fremanezumab (Ajovy, prefill syrng sc, 150 mg/ml, 1.5 ml)[B]	US	Sept-18	–	2%		5	–	–	634	783	701	7,664	Annual
8	R7-Other respiratory system products	Tezacaftor (Trikafta‡‡, film-ctd tab, various strengths)[O]	US	Feb-18	–	10%	10%	6	–	–	–	–	308	336,734	Annual
9	L1-Antineoplastics	Encorafenib (Braftovi, capsule, 75 mg)[C,O]	US	Jul-18	–	1%	5%	9	–	42	49	58	77	8,275	28-day cycle
10		Lorlatinib (Lorbrena, film-ctd tab, 100 mg)[C,O]	JPN	Nov-18	Apr-19	1%		7	343	220	265	326	654	88,958	28-day cycle
11		Binimetinib (Mektovi, film-ctd tab, 15 mg)[C,O]	US	Jul-18	–	1%		9	–	22	41	58	72	6,974	28-day cycle
12		Cemiplimab (Libtayo, infus. vial/ bottle, 50 mg/ml, 7 ml)[B,C]	US	Oct-18	May-19	1%		6	8,497	6,940	7,100	9,023	11,004	8,200	21-day cycle
13		Gilteritinib (Xospata, film-ctd tab, 40 mg)[C,O]	JPN	Dec-18	–	1%		4	325[ii]	189	242	322	282	7,328	28-day cycle
14		Mogamulizumab (Poteligeo, infus. vial/bottle, 4 mg/ml, 5 ml)[B,C,O]	JPN	May-12	–	<1%		3	–	1,633	1,887	2,140	3,852	32,104 to 16,052	28-day cycle
15		Larotrectinib (Vitrakvi, oral liquid, 100 mg/5 ml, 100 ml)[C,O]	US	Dec-18	Sept-19	<1%		4	334	392	392	392	888	17,967 to 23,956	28-day cycle
16		Talazoparib (Talzenna, capsule, 1 mg)[C]	FRA	Oct-18	–	<1%		4	–	192	220	248	600	6,948	28-day cycle
17		Duvelisib (Copiktra, capsule, 25 mg)[C,O]	US	Oct-18	–	<1%		1	–	–	–	–	248	13,887	28-day cycle
18		Tagraxofusp (Elzonris, infus. vial/ bottle, 1 mg/ml, 1 ml)[C,O]	US	Mar-19	–	<1%		1	–	–	–	–	29,518	557,885	21-day cycle
19		Glasdegib (Daurismo, film-ctd tab, 100 mg)[C,O]	US	Dec-18	–	<1%		1	–	–	–	–	694	19,436	28-day cycle
20		Dacomitinib (Vizimpro, film-ctd tab, 45 mg)[C,O]	US	Oct-18	Apr-19	<1%		5	117[ii]	103	127	189	519	3,267	28-day cycle
21		Moxetumomab pasudotox (Lumoxiti, infus. dry bottle, 1 mg)[B,C,O]	US	Nov-18	–	<1%		1	–	–	–	–	2,531	21,259	28-day cycle
22		Ivosidenib (Tibsovo, film-ctd tab, 250 mg)[C,O]	US	Aug-18	–	<1%		1	–	–	–	–	494	27,642	28-day cycle

(continued on the next page)

TABLE B1 **New medicines approved in 2018, availability, share of sales, prices, and treatment costs, ranked by therapeutic class share of sales, Q4-2019 *(continued)***

Rank	Therapeutic class*	Medicine (trade name, form, strength, volume)	Availability: First sale in Canada, US, or PMPRB11†		Availability: First sale in Canada	Share of new medicine sales across the OECD: Medicine	Share of new medicine sales across the OECD: Therapeutic class	No. of countries with sales‡	Canadian price§ (CAD)	PMPRB11 price (CAD): Min	PMPRB11 price (CAD): Median	PMPRB11 price (CAD): Max	US price	Treatment cost**: Treatment cost (CAD)	Treatment cost**: Annual/ Course
23	B6-All other haematological agents	Lanadelumab (Takhzyro, vial sc, 150 mg/ml, 2 ml)[O]	US	Sept-18	–	3%	4%	6	20,538[i]	18,479	19,049	20,710	25,658	533,988	Annual
24		Caplacizumab (Cablivi, vial dry, 11 mg)[O]	SWE	Aug-18	–	1%		7	6,200[i]	–	–	–	9,290	236,840	Annual
25		Fostamatinib (Tavalisse, film-ctd tab, 100 mg)[O]	US	Jun-18	–	<1%		1	–	–	–	–	215	12,031	28-day cycle
26	L2-Cytostatic hormone therapy	Apalutamide (Erleada, film-ctd tab, 60 mg)[C]	US	Feb-18	Jul-18	3%	3%	7	29	22	36	44	115	3,175	28-day cycle
27	L4-Immunosuppressants	Ravulizumab (Ultomiris, infus. vial/bottle, 10 mg/ml, 30 ml)[O]	US	Jan-19	–	2%	3%	3	–	6,491	6,731	6,971	7,709	62,738 to 76,680	Loading dose / Maintenance dose
28		Emapalumab (Gamifant, infus. vial/bottle, 5 mg/ml, 10 ml)[B,O]	US	Jan-19	–	1%		1	–	–	–	–	32,275	5,034,964	Annual
29	D10-Anti-acne preparations	Sarecycline (Seysara, film-ctd tab, 100 mg)	US	Jan-19	–	2%	2%	1	–	–	–	–	35	12,663	Annual
30	H1-Pituitary and hypothalamic hormones	Elagolix (Orilissa, film-ctd tab, 150 mg)	US	Aug-18	Oct-18	1%	1%	2	6	–	–	–	38	1,119	Annual
31	M5-Other drugs for disorders of the musculo-skeletal system	Burosumab (Crysvita, vial sc, 30 mg/ml, 1 ml)[B,O]	NLD	Feb-18	–	1%	1%	7	–	8,697	13,367	14,689	11,529	454,298 to 584,098	Annual
32	D5-Nonsteroidal products for inflammatory skin disorders	Tildrakizumab (Ilumya, prefill syrng sc, 100 mg/ml, 1 ml)[B]	US	Oct-18	–	1%	1%	5	–	2,671	2,671	2,671	16,583	41,685 to 57,762	Annual
33	R3-Anti-asthma and COPD products	Revefenacin (Yupelri, lung u-d liq, 175 mcg/dose, 3 ml)	US	Dec-18	–	1%	1%	1	–	–	–	–	40	14,642	Annual
34	N7-Other CNS drugs	Patisiran (Onpattro, infus. vial/bottle, 2 mg/ml, 5 ml)[O]	US	Aug-18	–	1%	1%	6	13,022[i]	11,028	11,942	12,467	11,149	677,145	Annual
35		Inotersen (Tegsedi, prefill syrng sc, 189 mg/ml, 1.5 ml)[O]	FRA	Aug-18	–	<1%		2	8,077[i]	7,887	8,351	8,816	–	420,000	Annual
36	B2-Blood coagulation system, other products	Damoctocog alfa pegol (Jivi, vial dry ret., 3000 IU)[B]	US	Sept-18	–	<1%	1%	6	516	2,923	3,582	6,477	5,283	287,540 to 364,129	Annual
37		Andexanet alfa (Ondexxya, vial dry, 200 mg)	US	Jun-18	–	<1%		3	–	3,716	4,197	4,677	–	36,930	Dose
38		Avatrombopag (Doptelet, film-ctd tab, 20 mg)[O]	US	Jun-18	–	<1%		1	–	–	–	–	366	3,661 to 5,491	5-day cycle
39		Lustrombopag (Mulpleta, film-ctd tab, 3 mg)	JPN	Oct-15	–	<1%		–	–	149	149	149	1,467	1,043	Annual
40	V3-All other therapeutic products	Zirconium cyclosilicate (Lokelma, oral u-d powder, 10 g/dose)	SWE	Mar-18	–	<1%	<1%	5	25[i]	16	23	24	26	2,283 to 9,131	Annual

(continued on the next page)

TABLE B1 **New medicines approved in 2018, availability, share of sales, prices, and treatment costs, ranked by therapeutic class share of sales, Q4-2019 *(continued)***

Rank	Therapeutic class*	Medicine (trade name, form, strength, volume)	Availability: First sale in Canada, US, or PMPRB11†		Availability: First sale in Canada	Share of new medicine sales across the OECD: Medicine	Share of new medicine sales across the OECD: Therapeutic class	No. of countries with sales‡	Canadian price§ (CAD)	PMPRB11 price (CAD): Min	PMPRB11 price (CAD): Median	PMPRB11 price (CAD): Max	US price	Treatment cost**: Treatment cost (CAD)	Treatment cost**: Annual/ Course
41	A16-Other alimentary tract and metabolism products	Elapegademase (Revcovi, vial im, 1.6 mg/ml)B,O	US	Nov-18	–	<1%	<1%	1	–	8,222	8,222	8,222	–	2,493,892	Annual
42		Velmanase alfa (Lamzede, infus. dry bottle, 10 mg)O	FRA	Mar-18	–	<1%		2	–	–	1,336	1,558	–	486,477	Annual
43		Pegvaliase (Palynziq, prefill syrng sc, 20 mg/ml, 1 ml)B,O	US	Jul-18	–	<1%		2	–	585	585	585	567	206,911	Annual
44	J1-Systemic antibacterials	Omadacycline (Nuzyra, film-ctd tab, 150 mg)	US	Feb-19	–	<1%	<1%	1	–	–	–	–	226	19,159	14-day cycle
45		Eravacycline (Xerava, infus. dry bottle, 50 mg)	US	Oct-18	–	<1%		1	–	–	–	–	64	764 to 2,675	4- to 14-day treat-ment
46	G3-Sex hormones and products with similar desired effects, systemic action only	Segesterone acetate (Annovera, vaginal mech. pessary with substance, 10 mcg + 150 mcg)	US	Sept-19	–	<1%	<1%	1	–	–	–	–	2,507	2,507	Annual
47	G4-Urologicals	Plazomicin (Zemdri, infus. vial/ bottle, 50 mg/ml, 10 ml)	US	Jul-18	–	<1%	<1%	1	–	–	–	–	411	3,700 to 6,475	4- to 7- day treat-ment
48	P1-Antiprotozoals and anthelmintics	Tafenoquine (Krintafel, film-ctd tab, 150 mg)O	US	Feb-19	–	<1%	<1%	1	–	–	–	–	12	25	Dose
49	Not assigned as of Q3-2020	Calaspargase (Asparlas)B,C,O	FDA	Dec-18	–										
50	P02-Anthelmintics	Moxidectin§§ (Moxidectin)O	FDA	Jun-18	–										
51	J05-Antivirals for systemic use	Tecovirimat (Tpoxx)O	FDA	Jul-18	–										

No sales data in MIDAS® as of Q4-2019 – date of approval by FDA, EMA, and/or Health Canada.

Note: A medicine was considered to be new in 2018 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.

Specialty medicines are indicated using the following abbreviations: B: biologic; C: cancer; O: orphan medicine.

* 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).

† Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and the United Kingdom.

‡ Includes all PMPRB11 countries, as well as the US and Canada.

§ 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.

‡‡ Trikafta is included in both the 2018 and 2019 lists because it contains both the 2018 new medicine tezacaftor and the 2019 new medicine elexacaftor. Despite being released in 2019, Trikafta was the top-selling product for both of the new medicines by Q4-2019.

§§ Approvals and sales for moxidectin only reflect human use and do not include veterinary indications.

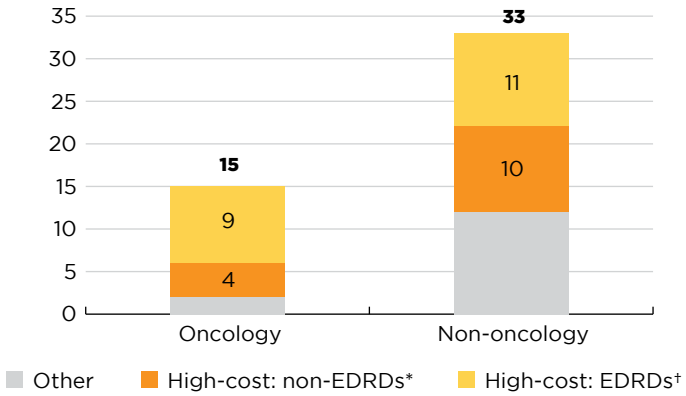
Data source: IQVIA MIDAS® Database, 2019 (all rights reserved); US Food and Drug Administration Novel Drugs 2018; European Medicines Agency Human Medicines Highlights 2018; Health Canada databases.

More than two thirds of the 2018 new medicines were high-cost, with treatment costs over $10,000 per year or $5,000 per 28-day cycle for oncology medicines. Eleven non-oncology and nine oncology medicines were identified as expensive drugs for rare diseases (EDRDs)—orphan-designated therapies exceeding $100,000 in annual treatment costs, or $7,500 per 28-day cycle for oncology. Combined, these 20 EDRDs accounted for 19% of 2018 new medicine sales.

As of Q3-2020, 24 of the medicines first approved in 2018 had been authorized for market in Canada. Of this group, 15 had been reviewed through CADTH's Common Drug Review (CDR) or the pan-Canadian Oncology Drug Review (pCODR) processes, which provide drug listing guidance to Canada's drug programs. Eleven medicines were given a "Reimburse with conditions" recommendation, while four were recommended as "Do not reimburse". None of the medicines received a recommendation to "Reimburse" without conditions.

The pan-Canadian Pharmaceutical Alliance (pCPA) is a consortium of public drug plans which conducts joint negotiations for brand name and generic drugs in Canada. Of the 24 new medicines approved in Canada, four had completed pCPA negotiations as of Q3-2020 and six others had negotiations underway.

FIGURE B4 **Distribution of new medicines approved in 2018 by treatment cost**



Note: This analysis considers the 48 new medicines approved in 2018 with treatment costs available as of Q3-2020.
* 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.
Data source: IQVIA MIDAS® Database, 2019 (all rights reserved); Canadian Agency for Drugs and Technologies in Health (CADTH) reports.

Negotiations were not pursued in three cases, two of which were for oncology products, and eight medicines had no record of negotiation. An agreement was not reached in the case of dacomitinib.

A review of private drug plan data found that over half (13) of the 24 new medicines were reimbursed by at least one private drug plan in Canada by Q3-2020. Note that these are preliminary results and the rates of reimbursement for new medicines can be expected to increase in the coming years.

The PMPRB's Human Drug Advisory Panel (HDAP), which conducts scientific reviews of new patented medicines, found that 75% of the new medicines assessed demonstrated slight or no improvement over their therapeutic comparators.[8]

Table B2 provides an overview of the recommendations and negotiation status for the 24 approved medicines, as well as information on whether these medicines have recorded sales through private drug plans in Canada.

Table B3 provides further details on the pharmacoeconomic assessments conducted by CADTH through the CDR and pCODR processes, 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 reviewed by CADTH were not cost-effective at the submitted price. Accordingly, the majority were recommended to be approved on the condition that their price be reduced; price reductions needed to reach the $50,000/QALY level were estimated in 12 of the 15 available reports, ranging from 22% to 98%. Of the 15 medicines, only erenumab had an ICER range that fell within $50,000/QALY ($39,000 to $153,000).

8. Results of the HDAP reviews are published in the PMPRB's *Annual Report*. The upcoming 2019 edition will include information on assessments for this list of medicines.

TABLE B2 Assessments, recommendations, and reimbursement decisions for 2018 new medicines approved in Canada by Q3-2020

ATC*	Medicine (trade name)†	Health Canada approval	CADTH recommendation				pCPA negotiation status				Private plans
		Notice of Compliance	Reimburse	Reimburse with conditions	Do not reimburse	Review in progress	Active	Completed and closed	Concluded without agreement	No negotiations	Covered
L2	Apalutamide (Erleada)[C]	Jul-18		■				■			
J5	Bictegravir (Biktarvy)	Jul-18		■				■			
M5	Burosumab (Crysvita)[B,O]	Dec-18		■			■				
B6	Caplacizumab (Cablivi)[O]	Feb-20			■						
L1	Cemiplimab (Libtayo)[B,C]	Apr-19		■			■				
L1	Dacomitinib (Vizimpro)[C,O]	Feb-19		■					■		
J5	Doravirine (Pifeltro)	Oct-18		■				■			
H1	Elagolix (Orilissa)	Oct-18									
N2	Erenumab (Aimovig)	Aug-18		■			■				
N2	Fremanezumab (Ajovy)[B]	Apr-20				■					
N2	Galcanezumab (Emgality)[B]	Jul-19									
L1	Gilteritinib (Xospata)[C,O]	Dec-19		■			■				
L1	Glasdegib (Daurismo)[C,O]	Apr-20				■					
N7	Inotersen (Tegsedi)[O]	Oct-18		■				■			
B6	Lanadelumab (Takhzyro)[O]	Sept-18		■			■				
L1	Larotrectinib (Vitrakvi)[C,O]	Jul-19			■					■	
L1	Lorlatinib (Lorbrena)[C,O]	Feb-19			■					■	
N7	Patisiran (Onpattro)[O]	Jun-19		■			■				
L1	Talazoparib (Talzenna)[C]	Sept-19									
R7	Tezacaftor, ivacaftor (Symdeko)[O]	Jun-18									
V3	Zirconium cyclosilicate (Lokelma)	Jul-19			■					■	
J5	Baloxavir marboxil (Xofluza)[O]	Feb-20									
B2	Damoctocog alfa pegol (Jivi)[B]	Oct-18									
L4	Ravulizumab (Ultomiris)[O]	Aug-19									

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 medicine.

Data source: IQVIA Private Drug Plan database, 2019; Health Canada Notice of Compliance Database; Canadian Agency for Drugs and Technologies in Health (CADTH) reports; pan-Canadian Pharmaceutical Alliance (pCPA) reports; and IQVIA MIDAS® Database (all rights reserved).

TABLE B3 Summary of Common Drug Review and pan-Canadian Oncology Drug Review assessments for 2018 new medicines approved in Canada by Q3-2020

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)
Apalutamide (Erleada)[C]	Nov-18	Castrate-resistant prostate cancer	Yes	CUA/CEA	198,826	–
Apalutamide (Erleada)[C]	Apr-20	Metastatic castration-sensitive prostate cancer	Yes	CUA/CEA	Dominated**	50% to 80%
Bictegravir (Biktarvy)	Oct-18	HIV-1 infection	Yes	CUA	–	–
Burosumab (Crysvita)[B,O]	May-20	X-linked hypophosphatemia	Yes	CUA	2,703,146 to 3,523,922	93% to 94%
Caplacizumab (Cablivi)[O]	Sept-20	Acquired thrombotic thrombocytopenic purpura (aTTP)	Do not reimburse	CUA	237,053	75%
Cemiplimab (Libtayo)[B,C]	Jan-20	Cutaneous squamous cell carcinoma	Yes	CUA/CEA	166,221	40% to 80%
Dacomitinib (Vizimpro)[C,O]	May-19	Non-small cell lung cancer	Yes	CUA	103,979 to 188,631	–
Doravirine (Pifeltro)	May-19	HIV-1 infection	Yes	CUA	168,387	>40%
Erenumab (Aimovig)	Jul-20	Migraine	Yes	CUA	39,640 to 153,635	22% to 64%
Gilteritinib (Xospata)[C,O]	May-20	Acute myeloid leukemia (AML)	Yes	CUA/CEA	168,451	90%
Inotersen (Tegsedi)[O]	Dec-19	Hereditary transthyretin amyloidosis	Yes	CUA	1,322,377	88%
Lanadelumab (Takhzyro)[O]	Nov-19	Hereditary angioedema, prevention	Yes	CUA	Dominant** to 6,981,558	59% to 84%
Larotrectinib (Vitrakvi)[C,O]	Oct-19	Neurotrophic tyrosine receptor kinase (NTRK) locally advanced or metastatic solid tumours	Do not reimburse	CUA/CEA	70,619 to 1,295,244	>55%
Lorlatinib (Lorbrena)[C,O]	Jan-20	Non-small cell lung cancer	Do not reimburse	CUA	237,125	>75%
Patisiran (Onpattro)[O]	Jul-19	Polyneuropathy in hereditary transthyretin-mediated amyloidosis	Yes	CUA	4,818,778	98%
Zirconium cyclosilicate (Lokelma)	Mar-20	Hyperkalemia, adults	Do not reimburse	CUA	106,137 to 187,924	85% to 90%

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 medicine.

† Initial or final recommendation issued as of Q3-2020.

‡ Price was explicitly defined as a condition for reimbursement.

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

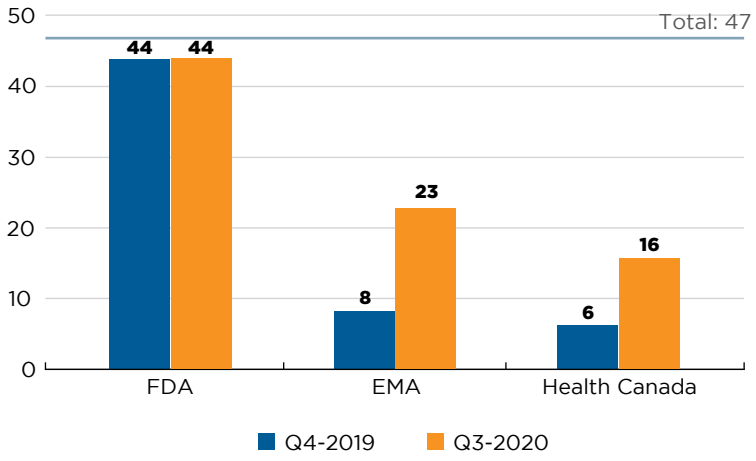
C NEW MEDICINE APPROVALS, 2019

This section provides a preliminary analysis of the new medicines approved internationally in 2019, including information on approval status as of Q3-2020 and pricing as of Q4-2019.

Slightly fewer medicines were authorized for market in 2019 though the total number of approvals continued to be historically high. The 2019 approvals introduced a number of high-cost medicines, most notably in the oncology market, as well as a smaller number of orphan medicines.

Forty-seven new medicines received first-time market approval through the FDA, the EMA, and/or Health Canada in 2019. As of the third quarter of 2020, Health Canada had approved 16 of these new medicines, trailing the EMA (23) and the FDA (44) (Figure C1).

FIGURE C1 **Number of 2019 medicines with market approval as of Q4-2019 and Q3-2020**



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 2019.
Data source: US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

Table C1 provides a full list of the 47 new medicines approved in 2019 along with their country with first reported sales, availability in Canada, and price and treatment cost where available.[9] Prices are reported for the highest-selling form and strength of each medicine. Note that this information reflects the early availability and uptake of these medicines in the markets analyzed.

By Q4-2019, 27 new medicines had sales in Canada, the US, and/or the PMPRB11. Over two thirds (20) of these came with treatment costs exceeding $10,000 per year or $5,000 per 28-day course. Notably, the 2019 group of new medicines mirrored the trends observed in 2018, introducing elexecaftor, which is used in combination with tezacaftor and ivacaftor in the cystic fibrosis treatment Trikafta, as well as two analgesics indicated for the treatment of migraines: lasmiditan and ubrogepant.

9. For more detailed supplementary information regarding the indication and manufacturer of each of the 2019 new medicines, see the *Meds Entry Watch* publication section of the Analytical Studies page on the PMPRB website.

TABLE C1 New medicines approved in 2019, availability, prices, and treatment costs, Q4-2019

Medicine (trade name, form, strength, volume)	Therapeutic class*	Availability: First sale in Canada, US, or PMPRB11†		Availability: First sale in Canada	No. of countries with sales	Canadian price‡ (CAD)	PMPRB11 price (CAD): Min	PMPRB11 price (CAD): Median	PMPRB11 price (CAD): Max	US price (CAD)	Treatment cost**: Treatment cost (CAD)	Treatment cost**: Annual/Course
Alpelisib (Piqray, film-ctd tab, 300 mg)[C]	L1-Antineoplastics	US	Jun-19	–	1	–	–	–	–	345	126,104	Annual
Brexanolone (Zulresso, infus. vial/bottle, 5 mg/ml, 20 ml)	N6-Psychoanaleptics	US	Jul-19	–	1	–	–	–	–	8,642	27,221	60-hour infusion
Brolucizumab (Beovu, ophthal. vial, 120 mg/ml, 0.05 ml)[B]	S1-Ophthalmologicals	US	Oct-19	–	1	1,418[i]	–	–	–	2,284	8,508/ 5,672	First year/ Subsequent years
Crizanlizumab (Adakveo, vial, 10 mg/ml, 10 ml)[B,O]	B6-Other haematological agents	US	Nov-19	–	1	–	–	–	–	2,943	14,347	Annual
Darolutamide (Nubeqa, film-ctd tab, 300 mg)[C]	L2-Cytostatic hormone therapy	US	Aug-19	–	1	28[i]	–	–	–	112	3,175	28-day course
Elexacaftor (Trikafta‡‡, film-ctd tab, various strengths)[O]	R7-Other respiratory products	US	Oct-19	–	1	–	–	–	–	308	336,734	Annual
Enfortumab vedotin (Padcev, infus. dry bottle, 20 mg)[B,C]	L1-Antineoplastics	US	Dec-19	–	1	–	–	–	–	2,769	38,935	28-day course
Entrectinib (Rozlytrek, capsule, 200 mg)[B,C,O]	L1-Antineoplastics	US	Aug-19	–	2	95	96	96	96	232	254,469	Annual
Erdafitinib (Balversa, film-ctd tab, 4 mg)[C]	L1-Antineoplastics	US	Apr-19	–	1	–	–	–	–	459	376,652	Annual
Fedratinib (Inrebic, capsule, 100 mg)[C,O]	L1-Antineoplastics	US	Aug-19	–	1	–	–	–	–	204	297,876	Annual
Istradefylline (Nouriast/Nourianz, film-ctd tab, 20 mg)	N4-Anti-Parkinson drugs	JPN	May-13	–	2	–	8	8	8	52	19,157	Annual
Lefamulin (Xenleta, film-ctd tab, 600 mg)	J1-Systemic antibacterials	US	Sept-19	–	1	–	–	–	–	171	1,709	10 days (in lieu of infusion)
Luspatercept (Reblozyl, vial dry, 75 mg)[B,O]	B3-Anti-anaemic preparations	US	Nov-19	–	1	–	–	–	–	12,556	217,633	Annual
Onasemnogene abeparvovec (Zolgensma, infus. vial/bottle)[B,G,O]	N7-Other central nervous system drugs	US	Jul-19	–	1	–	–	–	–	93,606	–	–
Pexidartinib (Turalio, capsule, 200 mg)[C,O]	L1-Antineoplastics	US	Aug-19	–	1	–	–	–	–	188	274,980	Annual
Polatuzumab vedotin (Polivy, infus. dry bottle, 140 mg)[B,C,O]	L1-Antineoplastics	US	Jun-19	–	1	–	–	–	–	17,935	103,765	Six 21-day cycles
Pretomanid (Pretomanid), tablet, 200 mg)[O]	J4-Antimycobacterials	US	Dec-19	–	1	–	–	–	–	20	3,647	26 weeks
Risankizumab (Skyrizi, prefill syrng sc, 90 mg/ml, 0.83 ml)[B]	D5-Nonsteroidal products for inflammatory skin disorders	US	Apr-19	May-19	8	2,523	2,251	2,400	3,611	–	14,805	Annual
Romosozumab (Evenity, prefill syrng sc, 90 mg/ml, 1.17 ml)[B]	M5-Other drugs for disorders of the musculo-skeletal system	JPN	Mar-19	Aug-19	3	331	–	–	–	1,131	7,935	Annual
Selinexor (Xpovio, film-ctd tab)[C,O]	L1-Antineoplastics	US	Jul-19	–	1	–	–	–	–	796	331,106	Annual

(continued on the next page)

TABLE C1 New medicines approved in 2019, availability, prices, and treatment costs, Q4-2019 *(continued)*

Medicine (trade name, form, strength, volume)	Therapeutic class*	Availability: First sale in Canada, US, or PMPRB11†		Availability: First sale in Canada	No. of countries with sales	Canadian price‡ (CAD)	PMPRB11 price (CAD): Min	PMPRB11 price (CAD): Median	PMPRB11 price (CAD): Max	US price (CAD)	Treatment cost**: Treatment cost (CAD)	Treatment cost**: Annual/Course
Siponimod (Mayzent, film-ctd tab, 2 mg)	N7-Other central nervous system drugs	US	May-19	–	1	89[i]	–	–	–	308	32,622	Annual (maintenance)
Solriamfetol (Sunosi, film-ctd tab, 150 mg)[O]	N7-Other central nervous system drugs	US	Jun-19	–	1	–	–	–	–	28	10,046	Annual (at max. dose)
Trifarotene (Aklief, cream, 45 g)	D10-Anti-acne preparations	US	Nov-19	–	1	2	–	–	–	15	NA	Topical use
Turoctocog alfa pegol (Esperoct, vial dry ret., 3000 IU)[B]	B2-Blood coagulation system	GER	Aug-19	–	1	–	5,262	5,262	5,262	–	516,854	Annual
Upadacitinib (Rinvoq, ret. tablet, 15 mg)	M1-Anti-inflammatory and anti-rheumatic products	US	Aug-19	–	1	49[i]	–	–	–	197	17,770	Annual
Voxelotor (Oxbryta, film-ctd tab, 500 mg)[O]	B6-Other haematological agents	US	Dec-19	–	1	–	–	–	–	131	143,272	Annual
Zanubrutinib (Brukinsa, capsule, 80 mg)[C,O]	L1-Antineoplastics	US	Dec-19	–	1	–	–	–	–	122	178,637	Annual
Air polymer-type A (ExEm Foam)	Not assigned as of Q4-2019	FDA	Nov-19	–								
Betibeglogene autotemcel (Zynteglo)[B,O,G]	B06-Other haematological agents	EMA	May-19	–								
Bremelanotide (Vyleesi)	G2-Other gynaecologicals	FDA	Jun-19	–								
Brilliant blue G opthalmic (TissueBlue)[O]	Not assigned as of Q4-2019	FDA	Dec-19	–								
Cefiderocol (Fetroja)	J01-Antiinfectives and antiseptics for local oral treatment	FDA	Nov-19	–								
Cenobamate (Xcopri)	N03-Antiepileptics	FDA	Nov-19	–								
Ebola Zaire vaccine (Ervebo)[B,O]	J07-Vaccines	EMA	Dec-19	–								
Fam-trastuzumab deruxtecan (Enhertu)[B,C]	L01-Antineoplastic agents	FDA	Dec-19	–								
Fluorodopa F-18	V09-Diagnostic radiopharmaceuticals	FDA	Oct-19	–								
Givosiran (Givlaari)[O]	A16-Other alimentary tract and metabolism products	FDA	Nov-19	–								
Golodirsen (Vyondys 53)[O]	M09-Other drugs for disorders of the musculo-skeletal system	FDA	Dec-19	–								
Relebactam (Recarbrio)	J01-Antibacterials for systemic use	FDA	Jul-19	–								
Lasmiditan (Reyvow)	Not assigned as of Q4-2019	FDA	Oct-19	–								
Lemborexant (Dayvigo)	Not assigned as of Q4-2019	FDA	Dec-19	–								

No sales data in MIDAS® as of Q4-2019 – date of approval by FDA, EMA, and/or Health Canada.

(continued on the next page)

TABLE C1 New medicines approved in 2019, availability, prices, and treatment costs, Q4-2019 *(continued)*

Medicine (trade name, form, strength, volume)	Therapeutic class*	Availability: First sale in Canada, US, or PMPRB11†		Availability: First sale in Canada	No. of countries with sales	Canadian price‡ (CAD)	PMPRB11 price (CAD): Min	Median	Max	US price (CAD)	Treatment cost**: Treatment cost (CAD)	Annual/Course
Lumateperone tosylate (Caplyta)	Not assigned as of Q4-2019	FDA	Dec-19	–								
Sotagliflozin (Zynquista)	A10-Drugs used in diabetes	EMA	Apr-19	–								
Tenapanor (Ibsrela)	A06-Drugs for constipation	FDA	Sept-19	Apr-20§§								
Ubrogepant (Ubrely)	N02-Analgesics	FDA	Dec-19	–								
Modified Vaccinia Ankara (Jynneos)B	J05-Antivirals for systemic use	FDA	Sept-19	–								
Volanesorsen (Waylivra)O	C10-Lipid-regulating/anti-atheroma preparations	EMA	May-19	–								

Note: A medicine was considered to be new in 2019 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. Specialty medicines are indicated using the following abbreviations: B: biologic; C: cancer; O: orphan medicine; G: gene therapy.

* 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).

† Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and the United Kingdom.

‡ Includes all PMPRB11 countries, as well as the US and Canada.

§ 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.

** 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. If PMPRB11 prices were not available, the US price was used.

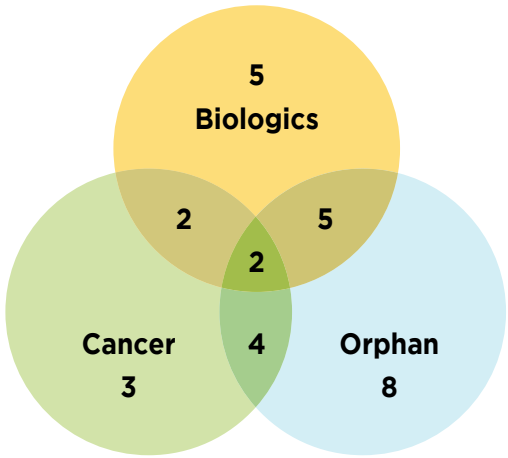
‡‡ Trikafta is included in both the 2018 and 2019 lists because it contains both the 2018 new medicine tezacaftor and the 2019 new medicine elexacaftor. Despite being released in 2019, Trikafta was the top-selling product for each of the new medicines by Q4-2019.

§§ Notice of Compliance issued as of Q3-2020.

Data source: IQVIA MIDAS® Database, 2019 (all rights reserved); US Food and Drug Administration Novel Drugs 2019; European Medicines Agency Human Medicines Highlights 2019; Health Canada Notice of Compliance Database.

Figure C2 illustrates the overlap between the number of new specialty medicines authorized for market in 2019. Orphan-designated medicines continued to represent an important share of the new medicines market in 2019, accounting for 40% (19) of new approvals, down from a 61% share in 2018. Similarly, orphan oncology treatments made up 10% (6) of the total new medicines, a decrease over their 25% share the year before. Approximately 30% (14) of the 2019 new medicines were biologics.

FIGURE C2 **Number of cancer, orphan, and biologic medicines first approved in 2019**



Data source: IQVIA MIDAS® Database, 2019 (all rights reserved).

D SPOTLIGHT ON CANADA

While sections B and C report new medicines approved internationally, this section focuses on the medicines that received their first Canadian market authorization in 2018.

The number of new-to-Canada medicines approved in 2018 was in line with recent years and included many of the top-selling new medicines on the international list of approvals from the same year.

Health Canada granted initial market authorization to 40 medicines in 2018, of which 22 had sales by the end of 2019. This volume of approvals was in line with the three previous years, during which time an average of nine new medicines were approved per quarter (Figure D1).

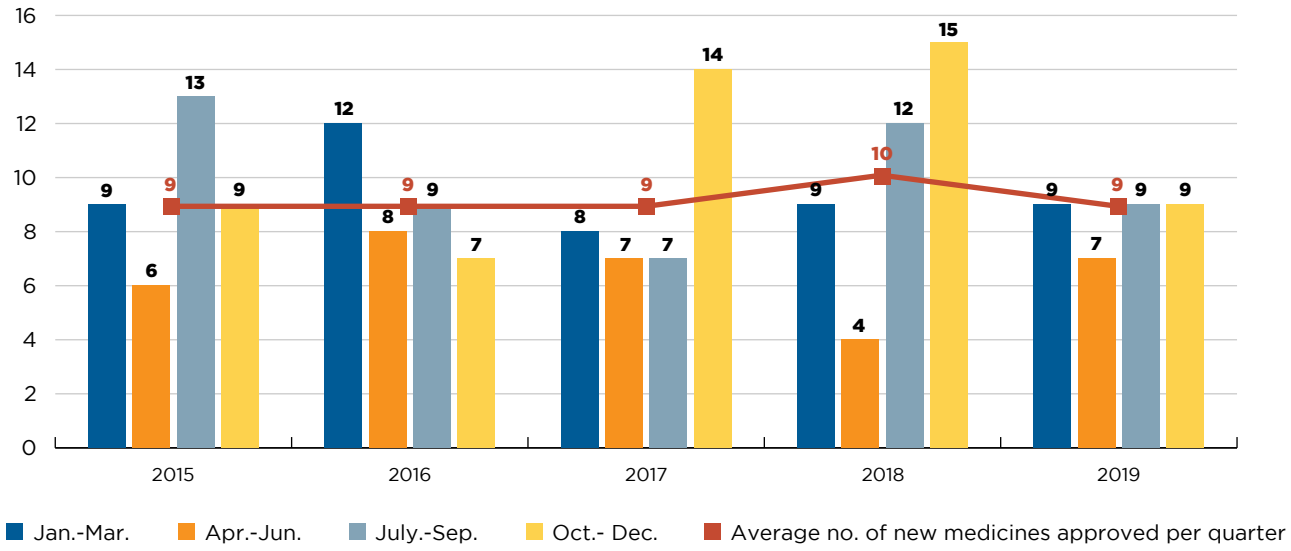
Table D1 reports on the availability, sales, and pricing of these 40 new-to-Canada medicines as of Q4-2019. Notably, four of the five highest-selling medicines reported in the list of 2018 new medicines in Table B1 were also reported here, indicating that Canadian approval occurred in the same year as international approval. Overall, new-to-Canada medicines accounted for 1.6% of branded pharmaceutical sales in Canada in 2018.

For each medicine, Table D1 also provides foreign-to-Canadian price ratios, which compare the median price of medicines in the PMPRB11 countries and the US price with the Canadian price. The average price of the medicine in Canada is set to a value of one and the corresponding foreign prices are reported relative to this value. The resulting ratios reflect how much more or less Canadians would have paid for a new medicine if they had paid the median international price or the US price.

The median PMPRB11 to Canadian price ratio reported across all new medicines was 0.81, indicating that international prices in Q4-2019 were approximately 19% lower than Canadian prices. In contrast, the median US price ratios show that the US pays about three times more than Canada for the same medicines.[10]

10. Note that previous editions of *Meds Entry Watch* reported median foreign-to-Canadian price ratios relative to the PMPRB7 countries and were heavily influenced by prices in the US. As such, results from this edition of the report are not comparable to those reported previously.

FIGURE D1 **Quarterly approvals for new medicines in Canada, 2015 to 2019**



Data source: Health Canada Notice of Compliance database (NOC).

TABLE D1 Medicines first approved in Canada in 2018, availability, sales, and prices as of Q4-2019

Medicine (trade name, form, strength, volume)	Therapeutic class*	Availability			Share of Canadian new medicine sales	No. of countries with sales‡	Price (CAD)				
		First sale in the PMPRB11†	First sale in Canada	First sale in US			Canada	PMPRB11 median	US	Median PMPRB11-to-Canadian price ratio	US-to-Canadian price ratio
Apalutamide (Erleada, film-ctd tab, 60 mg)[C]	L2B2-Cytostatic anti-androgens	Jan-19	Jul-18	Feb-18	6%	5	29	36	115	1.26	3.95
Baricitinib (Olumiant, film-ctd tab, 2 mg)[O]	M1C0-Specific anti-rheumatic agents	Feb-17	Sept-18	Jun-18	1%	10	48	40	86	0.85	1.80
Benralizumab (Fasenra, prefill syrng sc, 30 mg/ml, 1 ml)[B]	R3M0-Interleukin inhibitor anti-asthmatics	Jan-18	Mar-18	Dec-17	13%	10	3,746	3,115	5,934	0.83	1.58
Bictegravir (Biktarvy, film-ctd tab, 50 mg + 200 mg + 25 mg)	J5C9-HIV antivirals, other	Jun-18	Aug-18	Feb-18	21%	11	36	40	118	1.10	3.24
Brigatinib (Alunbrig, film-ctd tab, 180 mg)[C,O]	L1H3-Protein kinase inhibitor (PKI) antineoplastics, ALK	Jun-18	Dec-18	May-17	<1%	4	330	242	590	0.73	1.79
Brodalumab (Siliq, prefill syrng sc, 140 mg/ml, 1.5 ml)[B]	D5B0-Systemic antipsoriasis products	Sept-16	Jul-18	Aug-17	1%	6	622	791	2,118	1.23	3.40
Burosumab (Crysvita, vial sc, 30 mg/ml, 1 ml)[B,O]	M5X0-All other musculoskeletal products	Feb-18	–	May-18	<1%	5	–	13,367	11,529	–	–
Cabozantinib (Cometriq, film-ctd tab, 40 mg)[C,O]	L1H9-Protein kinase inhibitor (PKI) antineoplastics, other	Mar-14	Oct-18	May-16	2%	9	439	280	629	0.64	1.43
Calcifediol (Rayaldee, ret. capsule, 30 mcg)	H4F0-Antiparathyroid products	Sept-78	–	Dec-16	<1%	0	–	–	45	–	–
Cerliponase alfa (Brineura, other infus., 30 mg/ml, 5 ml)[B,O]	N7X0-All other CNS drugs	May-17	–	Jun-17	<1%	1	–	25,710	30,513	–	–
Crisaborole (Eucrisa, ointment, 2%, 60 g)	D5X0-Other nonsteroidal products for inflammatory skin disorders	–	Nov-18	Feb-17	1%	1	2	2	13	0.79	5.51
Dalbavancin (Dalvance, infus. dry bottle, 500 mg)	J1X1-Glycopeptide antibacterials	Feb-15	–	Jul-14	<1%	0	–	–	1,348	–	–
Damoctocog alfa pegol (Jivi, vial dry ret., 3000 IU)[B]	B2D1-Factor VIII, including substitutes	Mar-19	–	Sept-18	<1%	5	–	4,193	6,974	–	–
Dinutuximab (Unituxin, infus. vial/bottle, 3.5 mg/ml)[B,C,O]	L1G9-Monoclonal antibody antineoplastics, other	Nov-16	–	Jul-15	<1%	0	–	–	14,074	–	–
Doravirine (Pifeltro, film-ctd tab, 100 mg)	J5C3-Non-nucleoside reverse transcriptase inhibitors	Nov-18	Nov-18	Sept-18	<1%	7	17	22	53	1.30	3.21
Edaravone (Radicava, infus. bag, 300 mcg/ml, 100 ml)[O]	N7X0-All other CNS drugs	Jun-01	–	Aug-17	<1%	0	–	–	681	–	–

(continued on the next page)

TABLE D1 Medicines first approved in Canada in 2018, availability, sales, and prices as of Q4-2019 *(continued)*

Medicine (trade name, form, strength, volume)	Therapeutic class*	Availability			Share of Canadian new medicine sales	No. of countries with sales‡	Price (CAD)				
		First sale in the PMPRB11†	First sale in Canada	First sale in US			Canada	PMPRB11 median	US	Median PMPRB11-to-Canadian price ratio	US-to-Canadian price ratio
Elagolix (Orilissa, film-ctd tab, 150 mg)	H1C3-Antigonadotrophin-releasing hormones	–	Oct-18	Aug-18	1%	0	6	–	38	–	6.15
Emicizumab (Hemlibra, vial sc, 150 mg/ml, 0.7 ml)[B,O]	B2D1-Factor VIII, including substitutes	Feb-18	–	Dec-17	<1%	9	–	11,838	11,769	–	–
Erenumab (Aimovig, prefill autoinj., 70 mg/ml, 1 ml)	N2C9-All other anti-migraine preparations	Jul-18	Dec-18	May-18	4%	5	545	591	674	1.08	1.24
Ertugliflozin (Steglatro, film-ctd tab, 15 mg)	A10P1-SGLT2 inhibitor antidiabetics, plain	Mar-18	May-18	Jan-18	<1%	6	3	2	11	0.61	4.31
Flibanserin (Addyi, film-ctd tab, 100 mg)	G2X9-Other gynaecologicals	–	Feb-19	Oct-15	<1%	0	8	–	17	–	2.08
Follitropin delta (Rekovelle, cartridges, 33.3 mcg/ml, 2.16 ml)[B]	G3G0-Gonadotrophins, including other ovulation stimulants	Feb-17	Sept-18	–	<1%	5	1,085	718	–	0.66	–
Hemin (Panhematin, infus. dry bottle, 350 mg)[B]	B6C0-Other haematological agents	Nov-90	–	Nov-83	<1%	0	–	–	9,057	–	–
Inotersen (Tegsedi, prefill syrng sc, 189 mg/ml, 1.5 ml)[O]	N7X0-All other CNS drugs	Aug-18	–	–	<1%	2	–	8,351	–	–	–
Inotuzumab ozogamicin (Besponsa, infus. dry bottle, 900 mcg)[B,C,O]	L1G9-Monoclonal antibody antineoplastics, other	Apr-17	May-18	Aug-17	1%	0	14,119	–	–	–	–
Iron ferric (Monoferric, vial IV, 100 mg/ml, 10 ml)	B3A1-Plain iron	–	Jan-19	–	1%	1	444[i]	–	–	–	–
Isavuconazole (Cresemba, capsule, 100 mg)[O]	J2A0-Systemic agents for fungal infections	Oct-15	Jul-19	Apr-15	<1%	8	77	66	–	0.85	–
Lanadelumab (Takhzyro, vial sc, 150 mg/ml, 2 ml)[O]	B6D0-Hereditary angioedema products	Oct-18	–	Sept-18	<1%	5	–	19,049	25,658	–	–
Latanoprostene bunod (Vyzulta, eye drops, 0.02%, 5 ml)	S1E2-Miotics and antiglaucoma preparations, topical	–	May-19	Dec-17	<1%	0	<1	–	5	–	17.41
Patiromer calcium (Veltassa, oral u-d powder, 8.4 g/dose)	V3G1-Hyperkalaemia products	Jul-17	–	Dec-15	<1%	6	–	12	35	–	–
Pralatrexate (Folotyn, vial IV, 20 mg/ml, 2 ml)[C,O]	L1B0-Antimetabolites	Aug-17	–	Jan-10	<1%	0	–	–	8,923	–	–
Ribociclib (Kisqali, film-ctd tab, 200 mg)[C]	L1H5-Protein kinase inhibitor (PKI) antineoplastics, CDK 4/6	Apr-17	Apr-18	Mar-17	3%	8	82	72	243	0.87	2.95
Semaglutide (Ozempic, prefill pens, 1.34 mg/ml, 3 ml)	A10S0-GLP-1 agonist antidiabetics	Feb-18	Feb-18	Jan-18	40%	8	199	125	–	0.63	–
Sucroferric oxyhydroxide (Velphoro, chew tab, 500 mg)	V3G2-Hyperphosphataemia products	Aug-14	–	Mar-14	<1%	10	–	2	14	–	–

(continued on the next page)

TABLE D1 Medicines first approved in Canada in 2018, availability, sales, and prices as of Q4-2019 *(continued)*

Medicine (trade name, form, strength, volume)	Therapeutic class*	Availability			Share of Canadian new medicine sales	No. of countries with sales‡	Price (CAD)				
		First sale in the PMPRB11†	First sale in Canada	First sale in US			Canada	PMPRB11 median	US	Median PMPRB11-to-Canadian price ratio	US-to-Canadian price ratio
Suvorexant (Belsomra, film-ctd tab, 15 mg)	N5B1-Non-barbiturates, plain	Nov-14	–	Jan-15	<1%	1	–	1	14	–	–
Telotristat etiprate (Xermelo, film-ctd tab, 250 mg)[O]	A7X0-Intestinal disorder products, other	Sept-17	Dec-18	Mar-17	<1%	8	88	18	83	0.21	0.95
Tezacaftor (Symdeko, film-ctd tab, 150 mg + 100 mg)[O]	R7X0-All other respiratory system products	Dec-18	–	Feb-18	<1%	5	–	331	418	–	–
Tipiracil (Lonsurf, film-ctd tab, 8.19 mg + 20 mg)[C]	L1B0-Antimetabolites	May-14	Mar-18	Oct-15	2%	8	83	49	246	0.59	2.97
Tisagenlecleucel (Kymriah, infus. bags)[B,C,O,G]	L1X5-CAR T-cell therapy antineoplastics	Jul-18	–	–	<1%	5	–	401,958	–	–	–
Anthrax antigen filtrate (Biothrax)[B]	J6BB19-Anthrax immunoglobulin	Dec-18	–								

No sales data in MIDAS® as of Q4-2019 – date of approval by Health Canada.

Note: Specialty medicines are indicated using the following abbreviations: B: biologic; C: cancer; O: orphan medicine.

* 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).

† Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden and the United Kingdom.

‡ Includes all PMPRB11 countries, as well as the US and Canada.

§ 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.

Data source: IQVIA MIDAS® Database, 2019, all rights reserved; Health Canada Notice of Compliance Database.

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APPENDIX I

Share of brand-name medicine sales for select medicines in Canada, 2018 and Q4-2019

Medicine	Year of approval	2018		Q4-2019	
		Rank of sales among new medicines*	Share of brand-name sales	Rank of sales among new medicines*	Share of brand-name sales
Velpatasvir	2016	1	3.3%	1	1.8%
Elbasvir	2016	2	0.7%	20	0.2%
Grazoprevir	2016	3	0.7%	21	0.2%
Semaglutide	2017	17	0.1%	5	0.7%
Daratumumab	2015	21	0.1%	2	1.0%

* New medicines 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.