

Meds Entry Watch, 10th Edition

NPDUIS – National Prescription Drug Utilisation Information System



Patented
Medicine Prices
Review Board

Conseil d'examen
du prix des médicaments
brevetés

Canada 

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About the PMPRB

The Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial body responsible for protecting Canadians from patent abuse related to patented medicine prices. To do so, the PMPRB reviews the prices of these medicines and intervenes as necessary in the form of a hearing, during which a panel might determine that the prices are excessive. The PMPRB also contributes to a greater understanding of the biopharmaceutical ecosystem by publishing annual reports on trends in sales, pricing, and research and development spending.

Additionally, the PMPRB provides neutral, relevant, and timely ad hoc analysis on pharmaceutical trends, at the Minister's request.

The NPDUIS research initiative

The National Prescription Drug Utilization Information System (NPDUIS) research initiative was 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), and fulfills requests from the Minister of Health made pursuant to section 90 of the *Patent Act*.

For over twenty-five years, at the request of the Minister, the PMPRB has conducted an ongoing inquiry in the form of price, utilization, and post-marketing surveillance of medicines in Canada. This inquiry involves the analysis of prescribing patterns, budget impacts from newly launched or pending drug products, and cost trends. Reports of the findings are provided to the Minister of Health by the PMPRB, with the assistance of the NPDUIS group.

At the Minister's request, the specific research priorities and methodologies for the reports are established with the guidance of the NPDUIS Advisory Committee to ensure they align with the Minister's referral. 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, Canada's Drug Agency (CDA-AMC), Québec's Ministère de la Santé et des Services sociaux (MSSS), Nunavut, and the pan-Canadian Pharmaceutical Alliance (pCPA) Office.

This collective work supports Canada's health care system by delivering comprehensive and accurate information on medicine use and the factors driving cost pressures.

Acknowledgements

This report was prepared by the Patented Medicine Prices Review Board (PMPRB) as part of the National Prescription Drug Utilization Information System (NPDUIS) research initiative.

The PMPRB wishes to acknowledge and thank the members of the NPDUIS Advisory Committee for their expert oversight and guidance in the preparation of this report. Please note that the statements, findings, and conclusions do not necessarily reflect those of the members or their organizations.

Appreciation goes to Blake Wladyka for leading this project, with contributions from Dr. Étienne Gaudette.

Disclaimer

Analytical studies conducted by the PMPRB through the NPDUIIS research initiative are independent of the regulatory activities of the Board of the PMPRB. The research priorities, data, statements, and opinions expressed or reflected in NPDUIIS reports do not represent the position of the PMPRB with respect to any regulatory matter. NPDUIIS 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 an NPDUIIS 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 tenth edition of the *Meds Entry Watch* report, which explores the market entry of new medicines in Canada and other countries. Prior to sale, medicines must be approved by the appropriate national or regional health authority. Building on a retrospective analysis of trends since 2021, this report focuses on medicines that received first-time approval from the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada from 2021 to 2025 inclusive, and analyzes their uptake, pricing, sales, and availability as of the last quarter of 2024 (Q4-2024). Analysis of new medicines from 2025 is limited to approval and characteristics data due to the timing of data availability.

In addition to the international analysis, a Canadian-focused section provides sales and pricing information on medicines that received their first Health Canada approval between 2021 and 2024, regardless of prior international approval, as well as a retrospective review of approvals from 2021 to 2025.

The IQVIA MIDAS® database was the 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 were the Organisation for Economic Co-operation and Development (OECD) member countries.

Key Findings

A) Trends in New Medicine Approvals, 2021 to 2025

From 2021 to 2025, an average of 54 new medicines were first approved by either Health Canada, the FDA, or EMA each year. Over half of these medicines received an orphan designation from the FDA or EMA.

B) Trends in New Medicine Sales, 2021 to 2025

In Q4-2024, 77% of total OECD sales of new medicines were for medicines that had sales in Canada, indicating that Canada continues to approve and sell the highest-selling medicines approved internationally. Canada ranked twelfth among OECD member countries for this metric, above the average of 74%.

Diabetes medicine tirzepatide was the internationally highest-selling new medicine approved between 2021-2024, accounting for 47% of Q4-2024 sales.

C) Spotlight on Canada

Focusing on medicines receiving first Canadian approval, between 2021 and 2025, Health Canada granted market authorization to 41 medicines each year on average, of which an average of 14 (34%) were expensive drugs for rare diseases (EDRDs).

As of Q4-2024, the RSV vaccine Abrysvo was the highest-selling among Canada's 2021-2024 newly approved medicines with 12% of new-to-Canada sales.

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Introduction

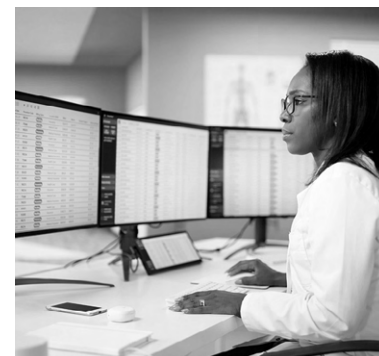


Meds Entry Watch is an annual publication that explores the dynamics of new medicines entering Canadian and international markets, providing information on their availability, sales, and prices.

This tenth edition provides a broad analysis of medicines that have received market approval since 2021, with a special focus on medicines approved in Canada from 2021 to 2025. New medicine approval cohorts are identified for each year based on the date of their first market authorization by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada.

The format of this report has been updated to provide more timely information on the most recent 2025 approvals. While sales data is not yet available, approval data and sales characteristics of 2025 new medicines have been included in this edition. The report consists of three main sections: Section A provides an overview of international approval trends from 2021 to 2025; Section B focuses on new international medicines sales trends from 2021 to 2024; and Section C spotlights Health Canada approvals from the same five-year period of 2021 to 2025. Complimentary data supplements, which include tables that capture most of the data presented throughout the report, are available on the [Canada.ca website](https://www.canada.ca). While some figures analyse different time periods, this new format helps to streamline data and better categorize information.

Methods



New medicines that received first-time market approval from the FDA, the EMA, and/or Health Canada between 2021 and 2025 were analyzed. A new medicine was selected for analysis if it received market authorization from any of these regulatory bodies during the calendar year for the first time, even if it was not yet listed for reimbursement or if there were no recorded sales in the available source data. For the purposes of this analysis, new medicines were identified at the medicinal ingredient level. The approval of these medicines in Canadian and international markets was assessed as of the fourth quarter of 2025 (Q4-2025).

Section C narrows the focus to Canadian approvals. Medicines analyzed in Section C included new and previously marketed medicinal ingredients that received their first Canadian market authorization through Health Canada between 2021 and 2025. Marketed status for Canadian approvals was sourced from Health Canada's Drug Product Database.

The IQVIA MIDAS® database (all rights reserved) was the data source for the sales and list prices of new medicines in Canadian and international markets, as well as the volume of units sold. The international markets examined were the Organisation for Economic Co-operation and Development (OECD) member countries. MIDAS® data reflects the national retail and hospital sectors for each country, including all sales (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 MIDAS® and other NPDUIS source materials, see the Resources section of the [NPDUIS Analytical Studies](#) webpage.

Canadian prices were based on MIDAS® data, if available; otherwise, they were obtained from publicly available results of the Reimbursement Review reports published by Canada's Drug Agency (CDA-AMC). 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 Q4-2025.

Prices and foreign-to-Canadian price ratios were reported for the highest-selling form and strength of each medicine in Canada, or in the OECD if no Canadian sales were available at the time of the analysis. The foreign-to-Canadian price ratios presented in this report were 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 [NPDUIS Analytical Studies](#) webpage.

Expensive drugs for rare diseases (EDRDs) are therapies with an orphan designation from the FDA or EMA and treatment costs exceeding \$100,000 CAD annually per patient¹. For oncology drugs the threshold used is \$7,500 per 28-day cycle. High-cost drugs are those with an average annual cost of \$10,000 or more per patient².

Prices and sales in foreign currencies were converted into Canadian dollars using the 12-month or 3-month average exchange rate published by the Bank of Canada for the year or quarter, in question.

1 British Columbia PharmaCare, 2026, *Exceptional funding of EDRDs*, Available: <https://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/what-we-cover/exceptional-funding-edrd>

2 Canadian Institute for Health Information, 2022. *Trends in public drug program spending in Canada*, Available: <https://www.cihi.ca/en/trends-in-public-drug-program-spending-in-canada>

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. The medicines included in this analysis do not necessarily represent all of those introduced from 2021 to 2025, 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 expected to have little effect on the overall results.

Market approval does not necessarily mean that the medicine is available for sale in the country or countries represented by the regulatory body granting approval. The availability of a new medicine in each country at any point in time is influenced by a variety of factors including the manufacturer's business decision to launch, as well as the timing of that decision; the regulatory approval process in place; and the existing market dynamics. The assessment of medicine availability in Canada does not consider non-marketed medicines available through exceptional programs such as the Special Access Program (SAP) for drugs in Canada. Because this report describes the initial market penetration of new medicines, availability and uptake are expected to increase in subsequent years.

Canadian and international sales and prices are based on manufacturer list prices as reported in MIDAS®, and do not capture price rebates, managed entry agreements (also known as product listing agreements), dispensing fees, or patient access schemes. The methodology used by MIDAS® for estimating sales volumes and revenue, which are used to calculate unit prices, varies by country and data availability.

Some medicines with sales may not be reported in IQVIA MIDAS®, and thus, the sales of new medicines may be under-reported.

Aggregated international sales and pricing data are skewed by the United States, which has the largest pharmaceutical market and generally approves more drugs than any other OECD country. As a result, the ranking of medicines by international sales generally reflects the order of sales in the US. In some cases, the US is shown separately from the OECD in order to better capture international trends.

Publicly available prices from Canada's Drug Agency (CDA-AMC) are based on the manufacturers' submitted list prices, which may differ from list prices upon market entry.

A: Trends in International New Medicine Approvals, 2021–2025

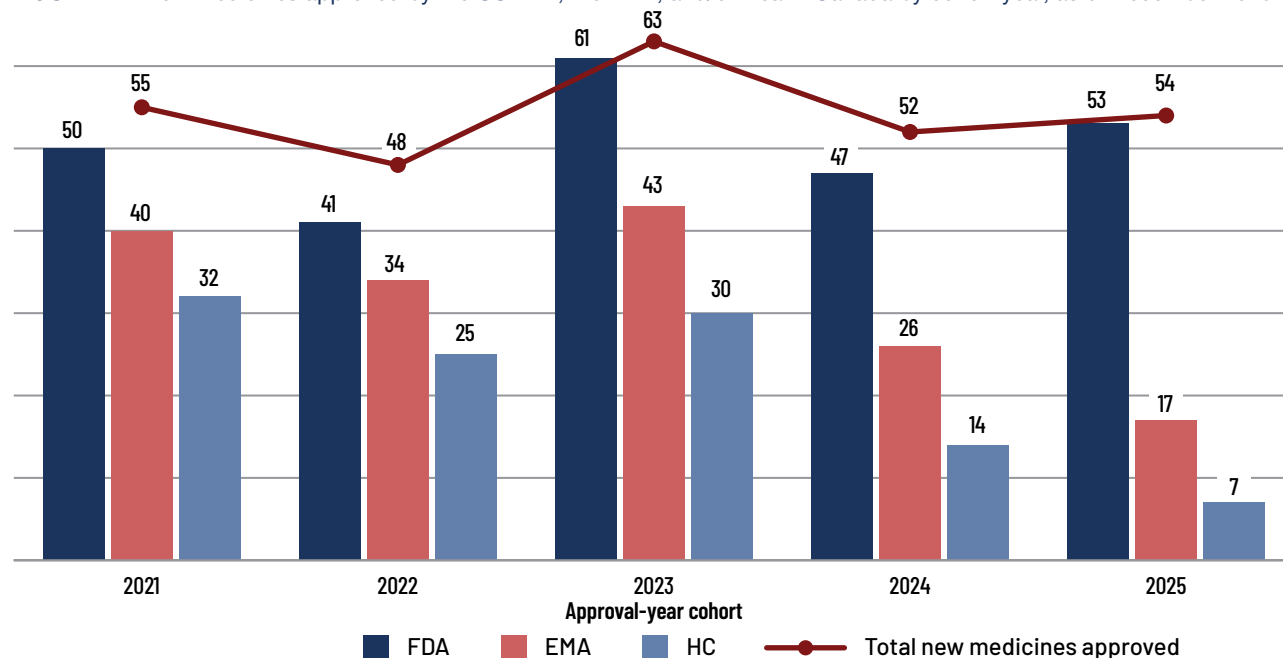


This section presents a five-year retrospective review of new medicine approvals by Health Canada, the FDA, and EMA. It reports on the number of new medicines approved from 2021 to 2025 and their characteristics as of Q4-2025. An average of 54 new medicines were approved by these agencies each year. Over half of these medicines received an orphan designation from the FDA or EMA.

Over the past five years, the FDA, EMA and Health Canada have approved a combined 272 new medicines. Roughly 50 to 60 new medicines were approved every year, which translates to an average of 54.

Figure A1 indicates that the FDA approves most of these medicines early and often, with 53 out of the 54 new medicines in the 2025 approval cohort. The EMA approves fewer medicines than the FDA but more than Health Canada, and as time passes both agencies narrow the gap with the FDA. By the end of 2025, Canada had approved 25 of the 2022 approval cohort and 32 of the 2021 group. For Canadian approval rates of new medicines regardless of prior international approval by the FDA or EMA, see figure C1.

FIGURE A1. New medicines approved by the US FDA, the EMA, and/or Health Canada by cohort year, as of December 2025

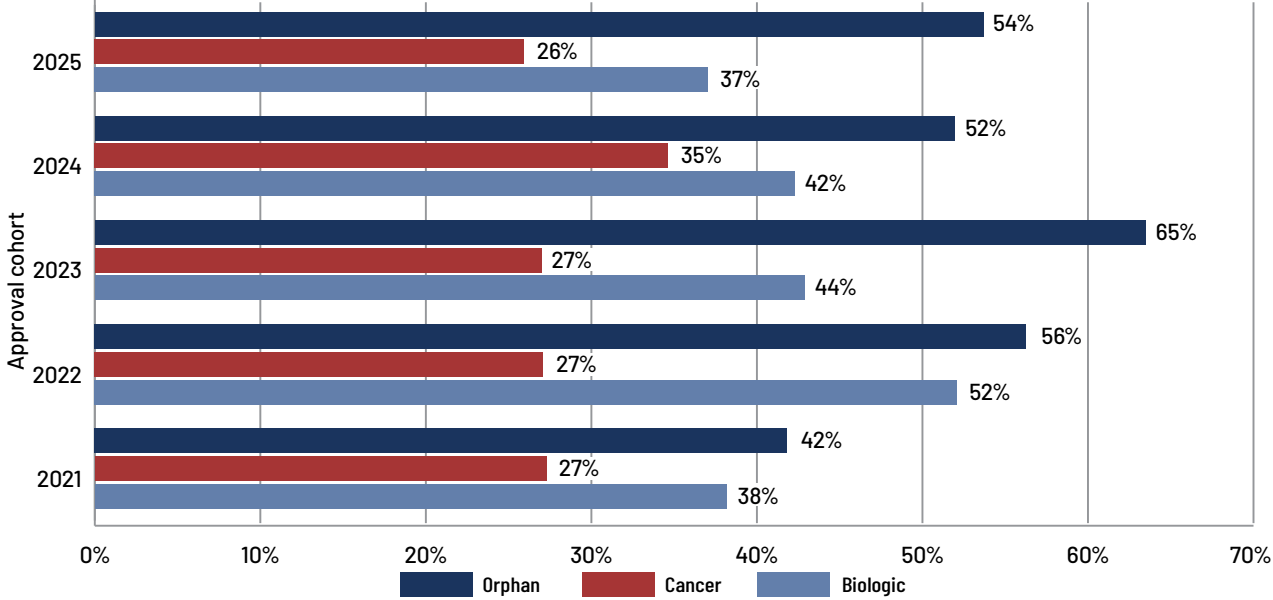


Data source: US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

For the past five years, most new medicine approvals have been biologic, oncology or orphan designated medicines. Combined, specialty medicines make between 70% and 80% of approvals in each of the past five years. The orphan designation produces the most popular specialty medicine attribute and was granted to over half of new medicine approvals in the past five years.

Manufacturers can submit to the FDA or EMA for orphan designation. Figure A2(a) illustrates the percentage of medicines with a specialty characteristic in each of the last five years. The orphan designation is the most common characteristic in every year followed by biologics, then cancer medicines.

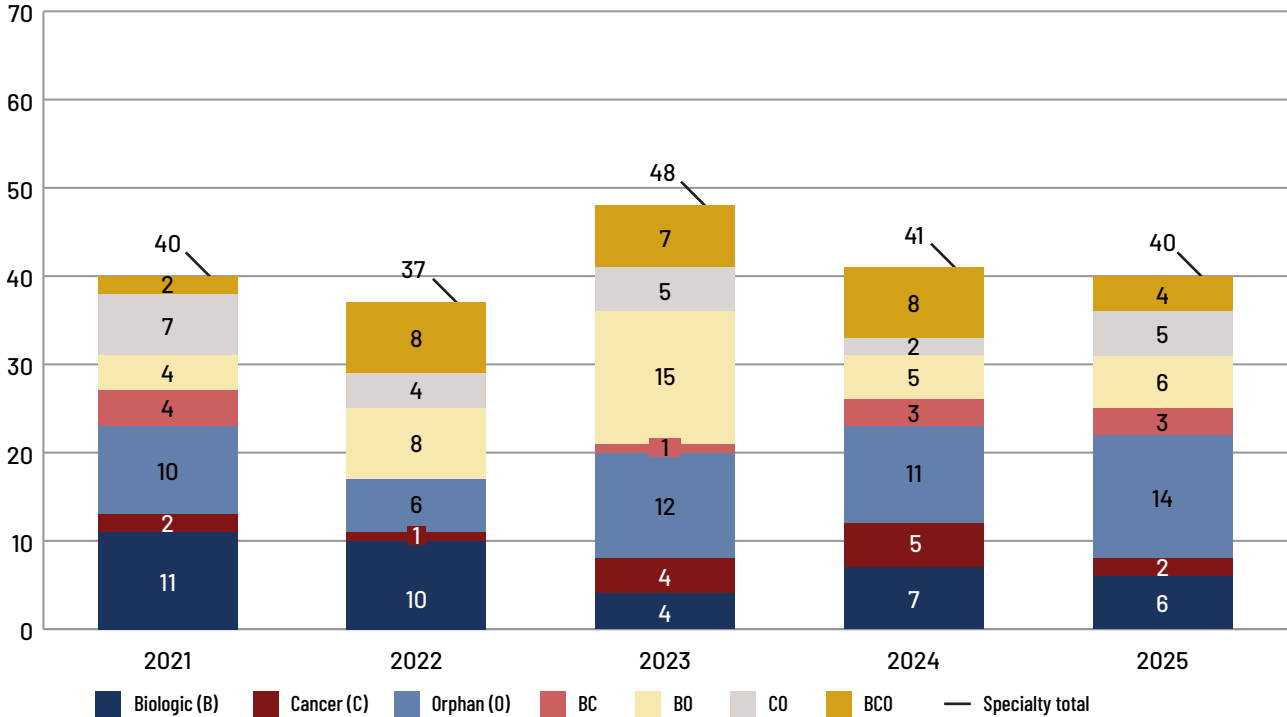
FIGURE A2(a). Specialty medicine designations for new medicines (%), 2021–2025



Note: Medicines can carry multiple specialty designations.
Data source: US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

Many specialty medicines approved over this time-period are a combination of two or all three characteristics. As shown in Figure A2(b), orphan designated biologics accounted for over a quarter of specialty medicines in 2023 and the combination of all three attributes accounted for almost a quarter of specialty medicines in 2024. In total, 206 out of the 272 medicines approved from 2021 to 2025 were specialized, which translates to more than 75% of all new medicines. The most prevalent specialties overall were orphan alone (25%), orphan designated biologics (19%) and biologics alone (18%).

FIGURE A2(b). Specialty medicine mix for new medicines 2021–2025 (N)

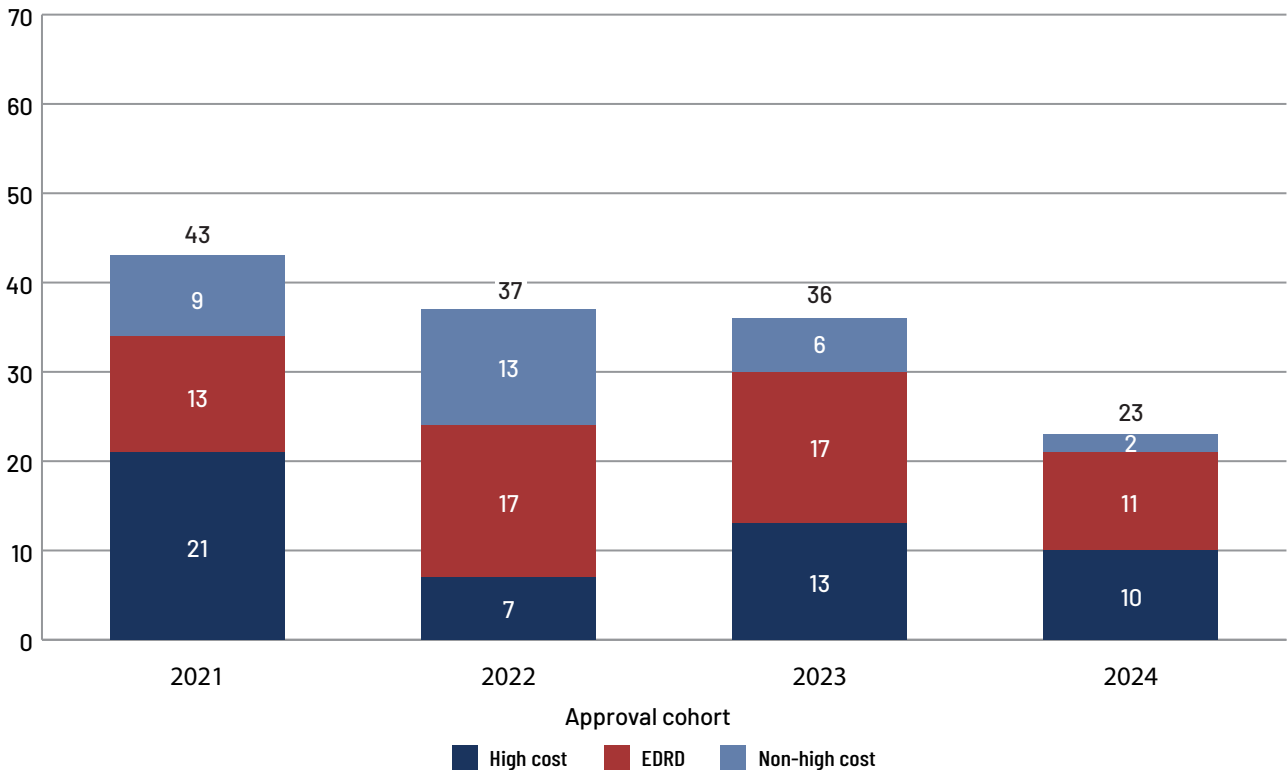


Data source: US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

Most new medicines approved over the past five years exceed the high-cost threshold of \$10,000 per year or \$5,000 per 28-day cycle for oncology. A majority of those medicines are also classified as expensive drugs for rare diseases (EDRDs)—orphan-designated therapies with treatment costs exceeding \$100,000 annually or \$7,500 per 28-day cycle for oncology. Over the past four years, more than three quarters

of new medicines surpassed the high-cost threshold and over half of those qualified as EDRDs. In any given year, at least half of new medicines were considered high-cost. In 2023, this figure rose to a five-year high of 83%, with 30 of 36 medicines considered high-cost. While annual treatment costs were only available for approximately half of 2024 new medicines, almost all were considered high-cost.

FIGURE A3. High-cost new medicines, 2021–2024 (N)

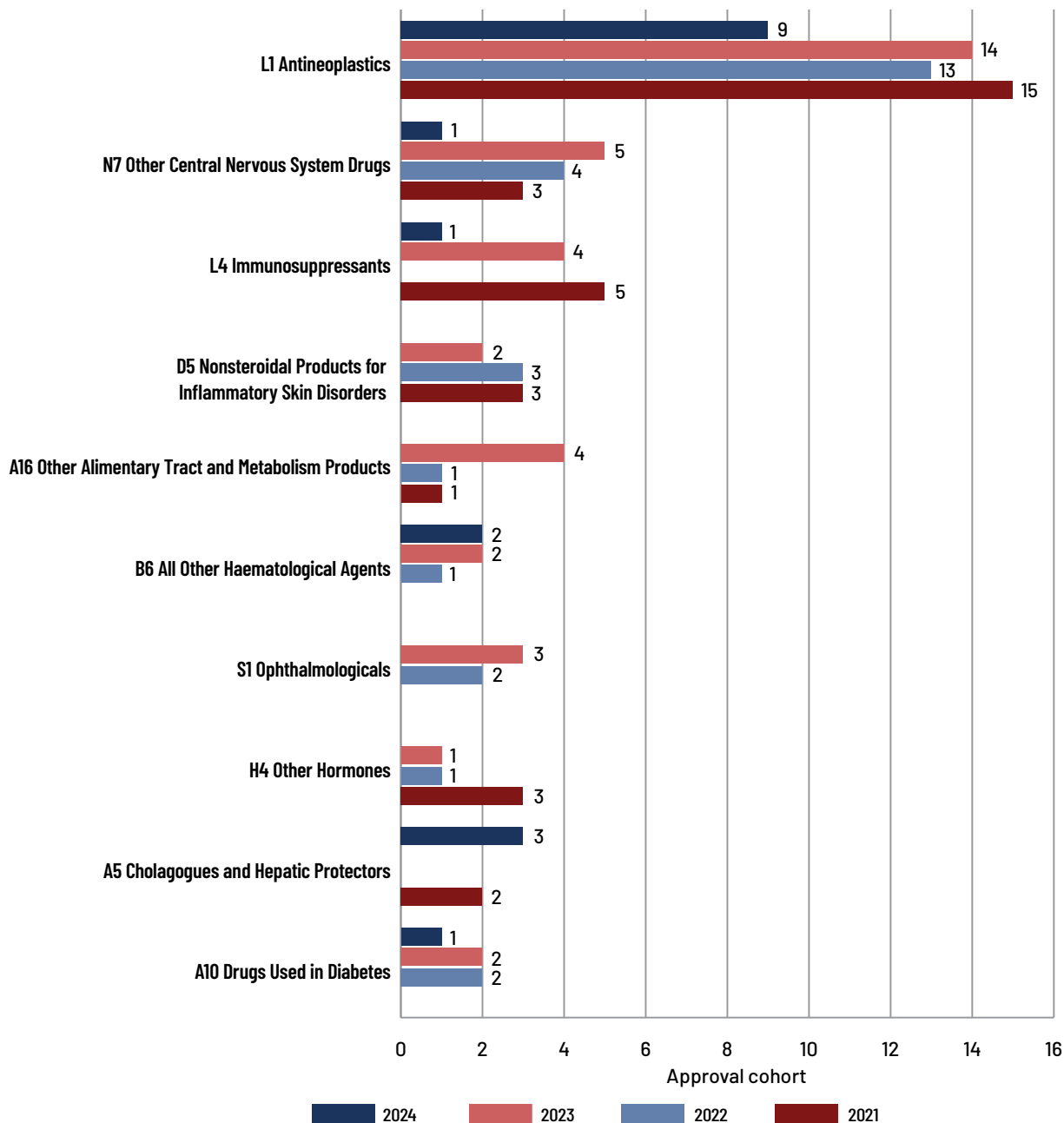


Note: This analysis considers new medicines approved between 2021 and 2025 with treatment costs available as of Q3-2025.
 *High-cost medicines are defined as those with treatment costs exceeding \$10,000 annually or \$5,000 per 28-day cycle.
 †Expensive drugs for rare diseases (EDRDs) are defined as those with an orphan designation through the FDA or EMA and treatment costs exceeding \$100,000 annually or \$7,500 per 28-day cycle for oncology.
 Data source: IQVIA MIDAS® Database, 2024 (all rights reserved); Canada’s Drug Agency (CDA-AMC) reports.

New medicines from the past five years are represented by 50 anatomical therapeutic classes (ATC). The top ten classes with the most approvals from 2021 to 2024 are shown in Figure A4. Antineoplastics, indicated for the treatment of cancer, have produced the most approvals in each of the past five years with annual totals of

9 approvals or more. Drugs for diabetes are tenth on the list with five approvals, but include blockbuster medicines such as semaglutide, which has a large sales and budgetary impact. These are topics that will be covered in section B.

FIGURE A4. New medicine ATC classes by approval cohort, 2021–2024 (N≥5)



Note: Vaccine class was omitted from this list.

Data source: World Health Organization, IQVIA MIDAS® Database, 2024 (all rights reserved).

B: Trends in International New Medicine Sales, 2021–2024



This section reports on the sales and relative pricing of new medicines approved from 2021 to 2024 and tracks their international sales through Q4-2024. Tirzepatide dominated new medicine sales as of Q4-2024, accounting for 47% of revenues for drugs approved between 2021 and 2024.

Figure B1(a) illustrates the proportion of new medicines with sales from each approval year. Canada’s sales mix shows a smaller percentage of 2023 and 2024 medicines than that of the US and the OECD. As a result, three quarters of Canada’s new medicines with sales come from 2021 and 2022. Figure B1(b) shows the proportional mix of sales in dollars of new medicines across approval years. Here we can

see that Canada derives almost half of its sales from 2022 medicines despite only accounting for a quarter of new medicines sold. Top-selling Faricimab (Vabysmo), indicated for treating wet age-related macular degeneration, accounted for over 38% of Q4-2024 sales in Canada for the 2022 approval year. Following that was another 2022 medicine tirzepatide (Mounjaro), indicated for diabetes and weight loss, which accounted for an additional 25%. Combined, these two medicines accounted for two thirds of 2022 new medicines sales in Canada in Q4-2024. Tirzepatide was also the highest selling new medicine globally, accounting for 47% of new medicine sales across the OECD.

FIGURE B1(a). Sales distribution of 2021 to 2024 new medicines, Q4-2024

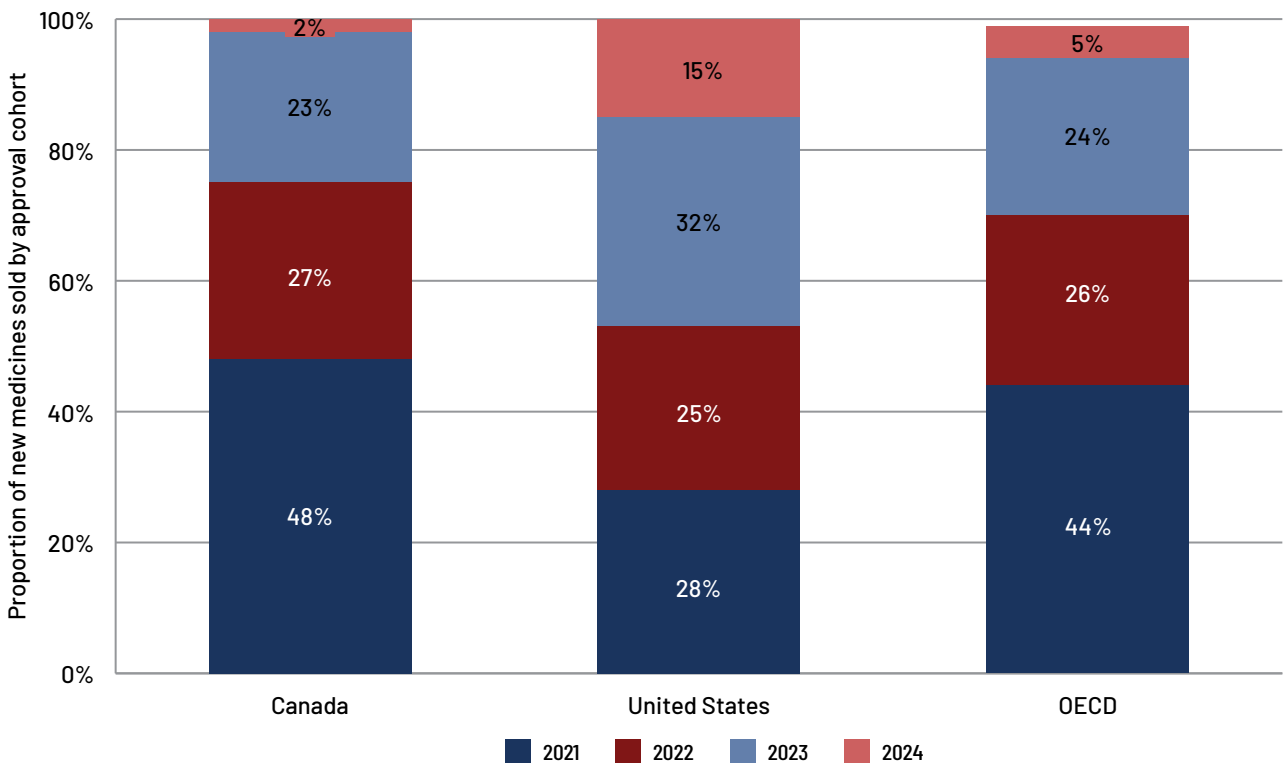
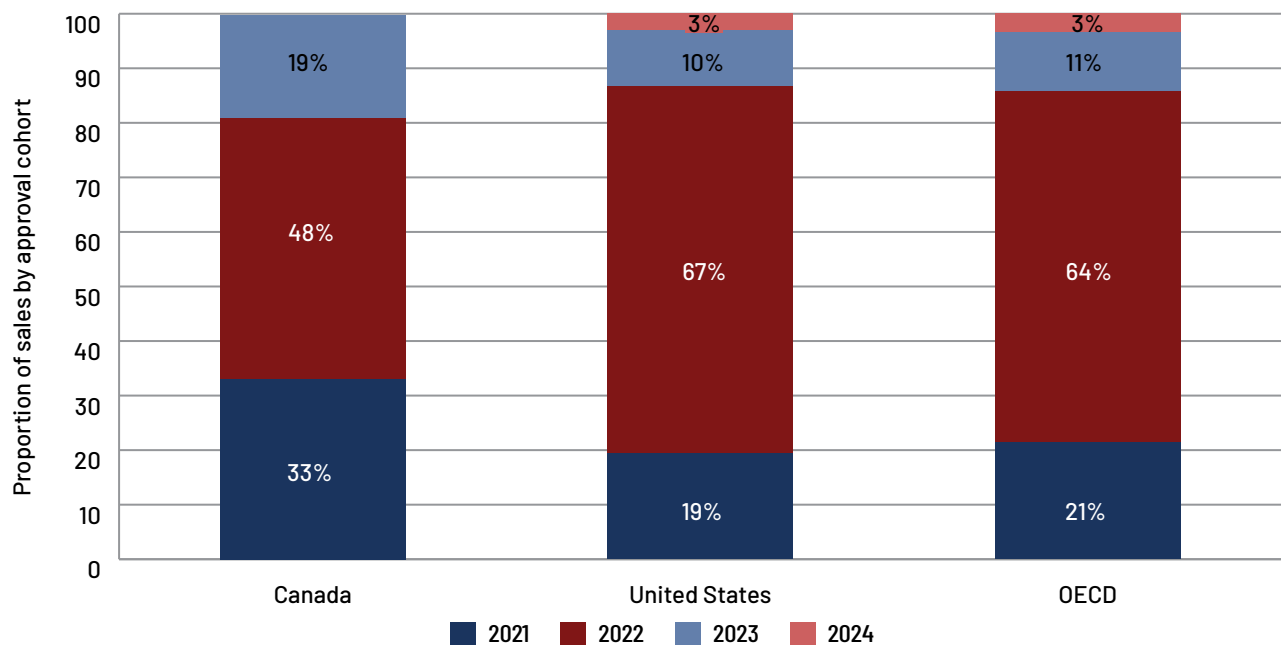


FIGURE B1(b). Sales revenue by approval cohort, Q4-2024

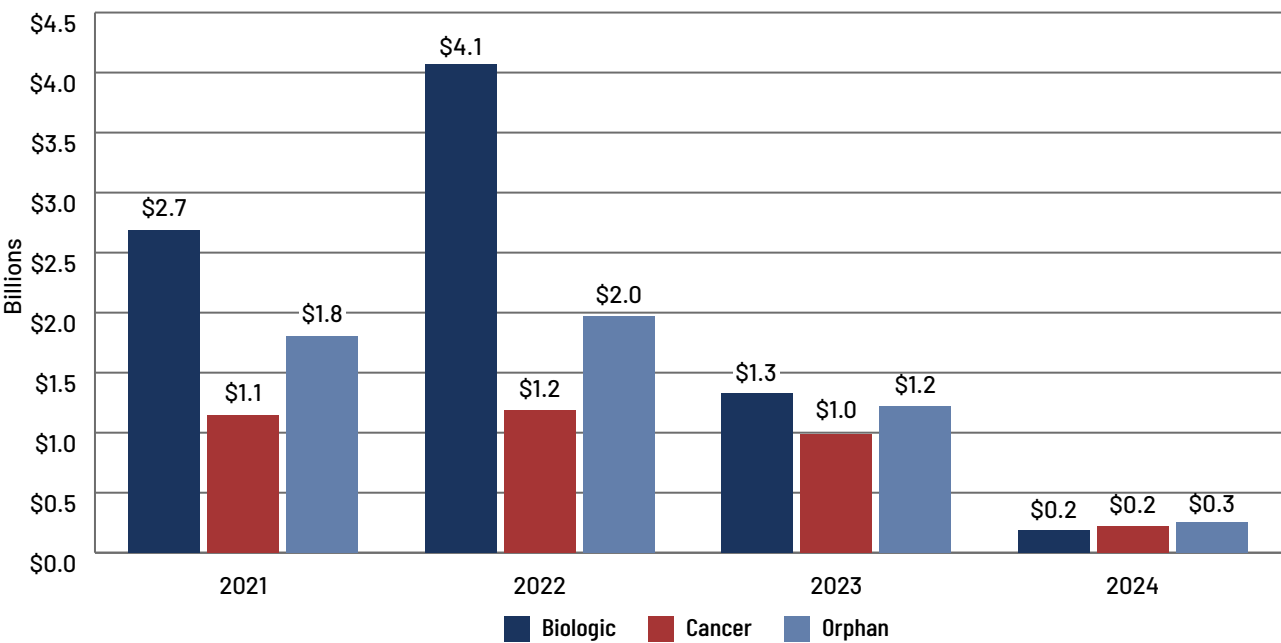


Data source: IQVIA MIDAS® Database, 2024 (all rights reserved).

Biologic, oncology and orphan medicines represent a significant proportion of new medicine sales every year. Figure B2(a) provides a simple illustration of each specialized category of medicine’s sales for each approval year from 2021 to 2024. The sales of biologics tend to outpace those of oncology and orphan medicines in most approval years. Oncology medicine is the lowest-selling specialty category in every approval year.

Figure B2(b) provides more depth to the analysis by accounting for medicines that fall into either multiple categories or none. It shows the percentage of new medicine sales at the intersection of the biologic and orphan categories as well as for medicines which carry no specialization. In each approval year, at least 20% of Q4-2024 sales are generated by non-specialized medicines. This includes the 2022 diabetes medicine tirzepatide.

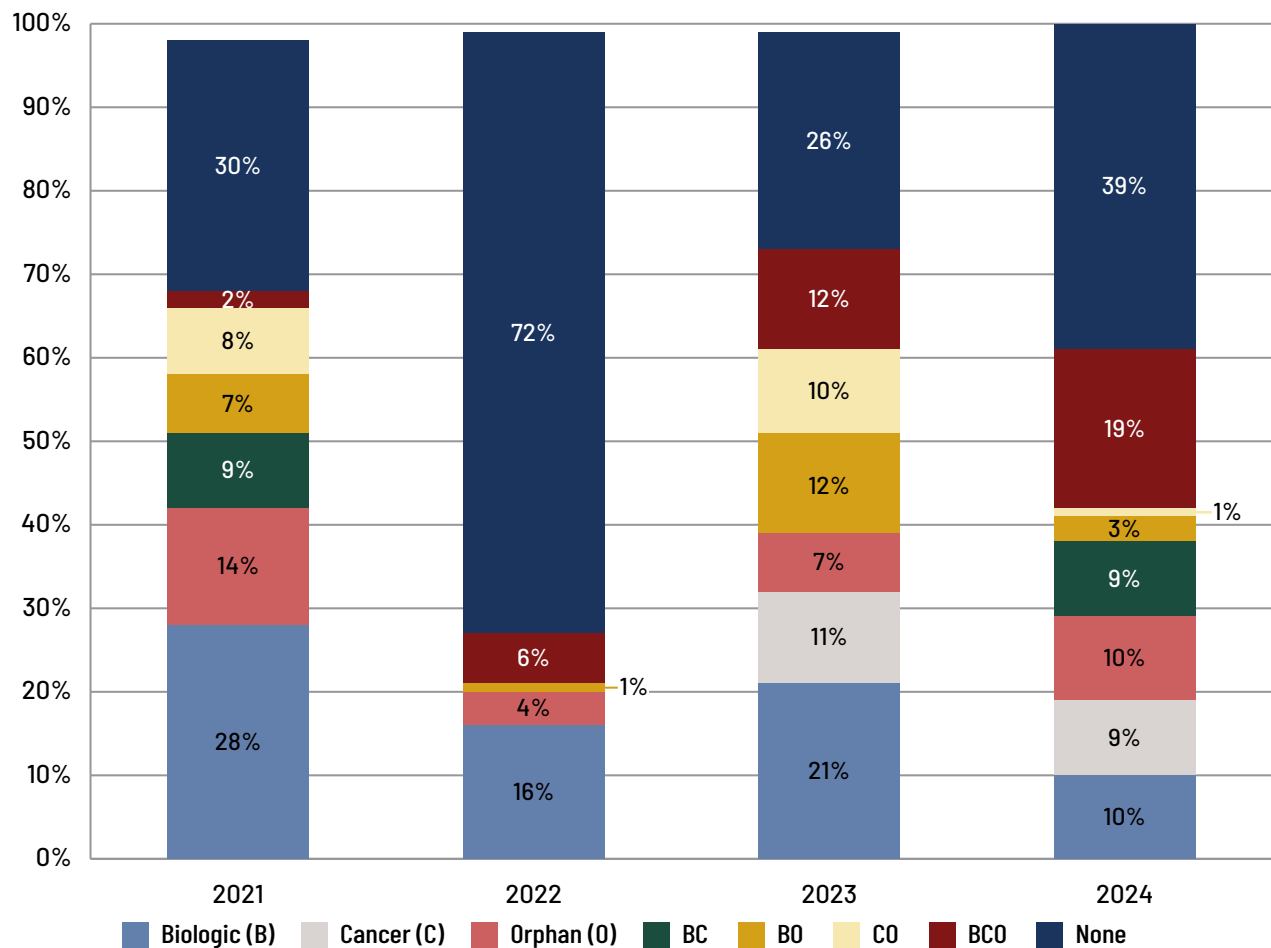
FIGURE B2(a). OECD sales of new medicines by specialty medicine category, Q4-2024



Note: Medicines can carry multiple specialty designations.

Data source: US Food and Drug Administration, European Medicines Agency, and Health Canada databases. IQVIA MIDAS® Database, 2024 (all rights reserved).

FIGURE B2(b). OECD sales of new medicines by specialty categories, Q4-2024 (%)

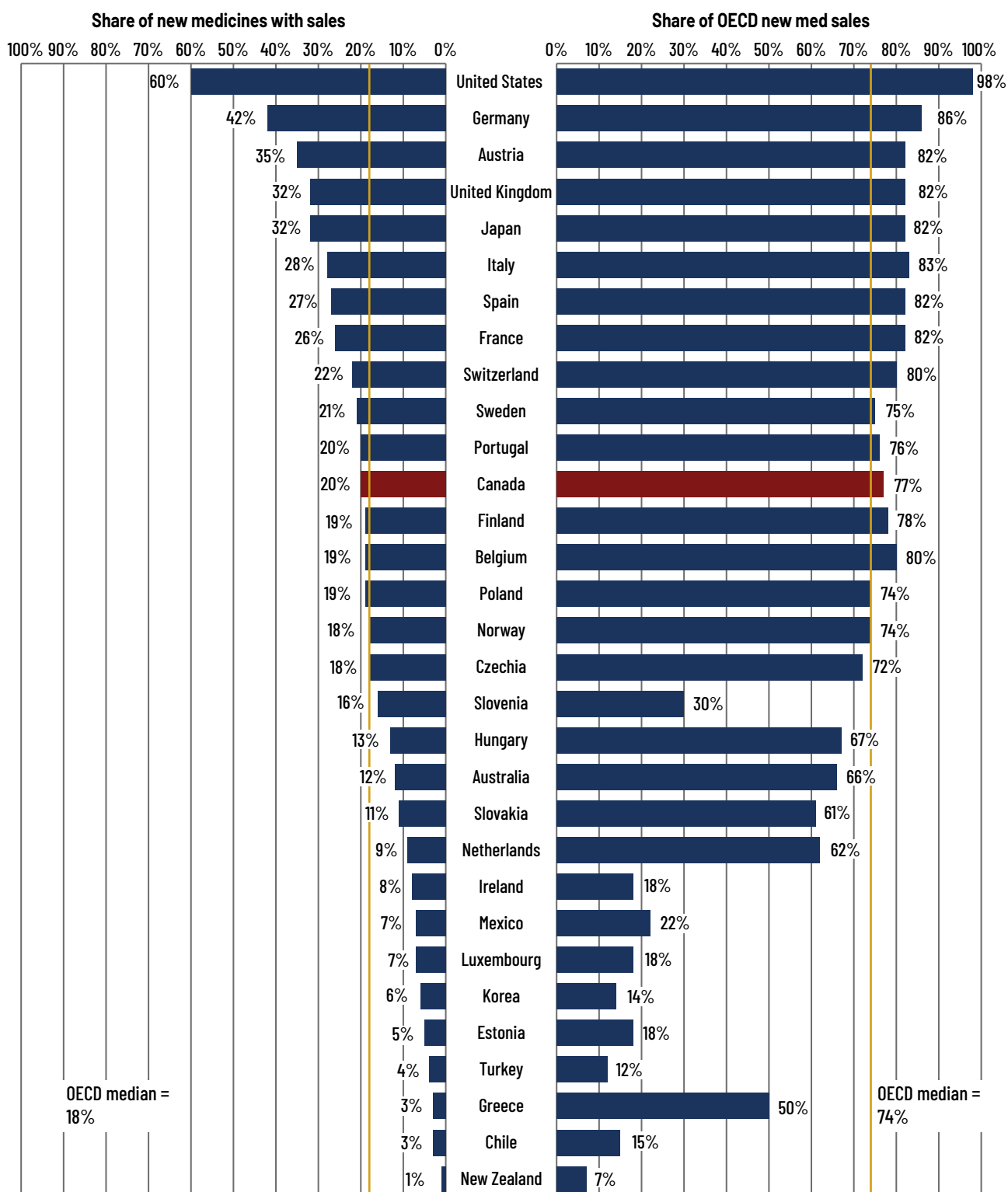


Data source: US Food and Drug Administration, European Medicines Agency, and Health Canada databases. IQVIA MIDAS®, Database, 2024 (all rights reserved).

Of the 218 medicines approved from 2021 to 2024, 44 (20%) had sales in Canada by Q4-2024 (Figure B3). This ranks Canada slightly higher than the OECD median of 18%. The US leads the way with sales for 60% of new medicines. In Q4-2024, 77% of total OECD sales of new medicines were generated from

the 44 medicines that had sales in Canada, as shown on the right side of Figure B3. This indicates that over three quarters of international spending on new medicines was concentrated in the subset available in Canada. This was the twelfth-highest share in the OECD and above the median of 74%.

FIGURE B3. Share of new medicines* from 2021 to 2024 with available sales and their respective share of OECD sales, Q4-2024



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

* For the purposes of this analysis, new medicines were defined as those that received their first market authorization through the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), or Health Canada.

Data source: IQVIA MIDAS® Database, 2024 (all rights reserved).

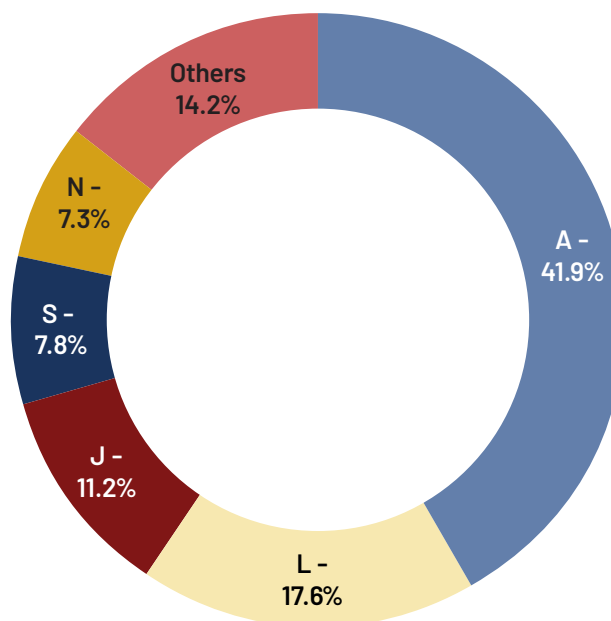
Below, new medicines are grouped by therapeutic class and measured by Q4-2024 sales. Sales were recorded for classes at the ATC1 level. Figure B4(a) shows the top-selling classes as a percentage of total new medicine sales. The alimentary tract and metabolism class accounted for 42% of sales alone. This is in large part due to the sales of the 2022 diabetes medicine tirzepatide. Figure B4(b) shows the sales value of each therapeutic class for each new medicine cohort year. Alimentary tract medicines account for the majority of sales at \$11B, almost all from tirzepatide sales (\$10.6B).

The L class representing antineoplastic oncology medicines accounts for the second highest sales at approximately 18%. As was shown in Section A, this is also the largest group by far based on number of approvals, with a total of 59 new medicines from 2021 to 2024.

Timing and the product life cycle are important to note when interpreting figure B4(b). Medicines approved in 2021 and 2022 have had time to produce sales across many countries and thus have a heavy influence on the overall class sales. Medicines approved in more recent years have had less time to come to market and garner sales or in many cases, have not made it to market at all. For those medicines that have generated significant sales, distribution across approval cohorts can vary. The alimentary tract class derives almost all of its sales from tirzepatide and the rest of the 2022 approval cohort, while playing a much less significant role in the other three cohort years. In contrast, the antineoplastics class, with 59 medicines spread over four approval cohorts, shows more consistent sales.

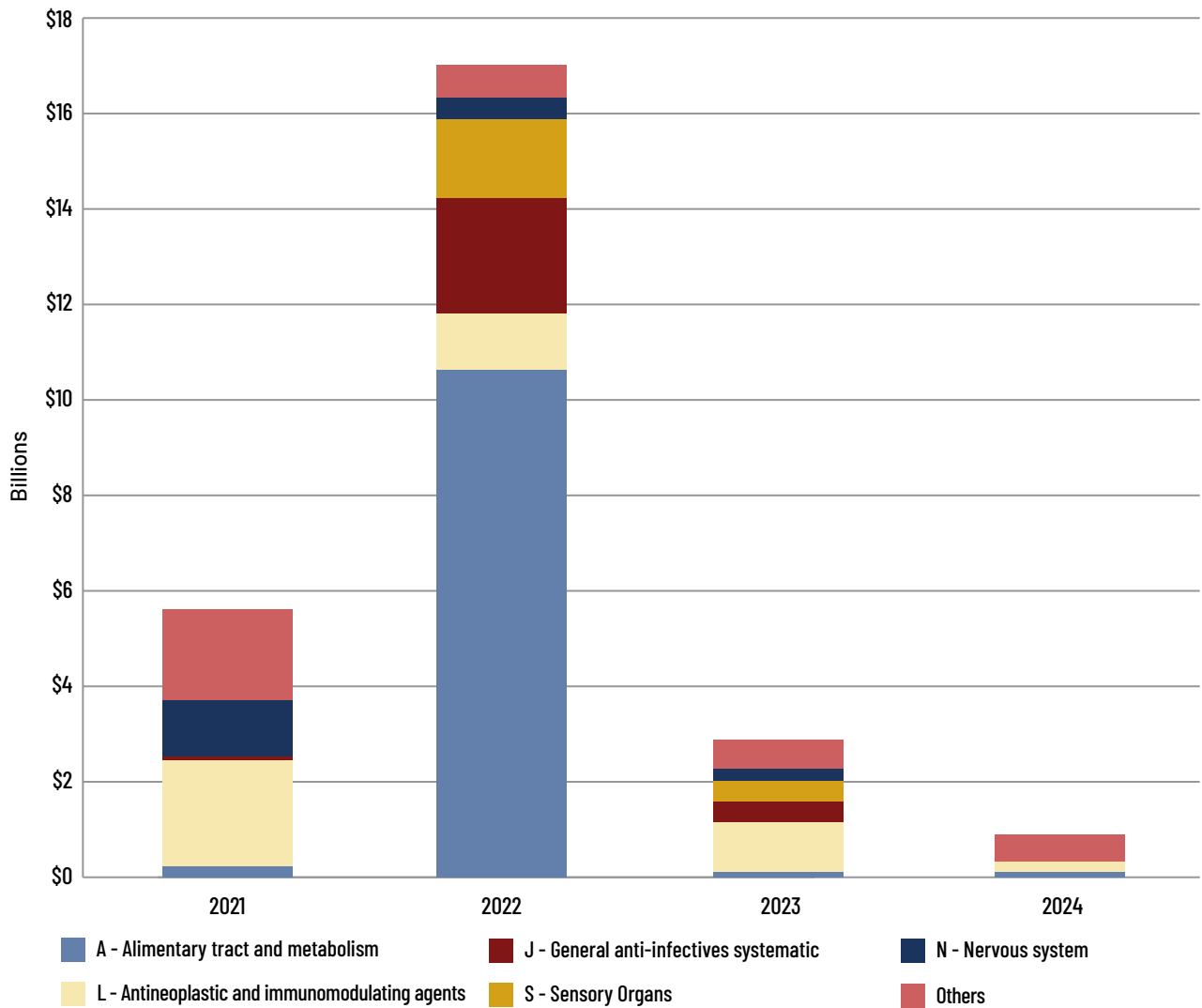
FIGURE B4(a). OECD sales of 2021-2024 new medicines by ATC class, Q4-2024

- A - Alimentary tract and metabolism
- L - Antineoplastic and immunomodulating agents
- J - General anti-infectives systematic
- S - Sensory Organs
- N - Nervous system
- Others



Data source: IQVIA MIDAS® Database, 2024 (all rights reserved).

FIGURE B4(b). OECD sales of new medicines by ATC class and approval cohort, Q4-2024



Data source: IQVIA MIDAS® Database, 2024 (all rights reserved).

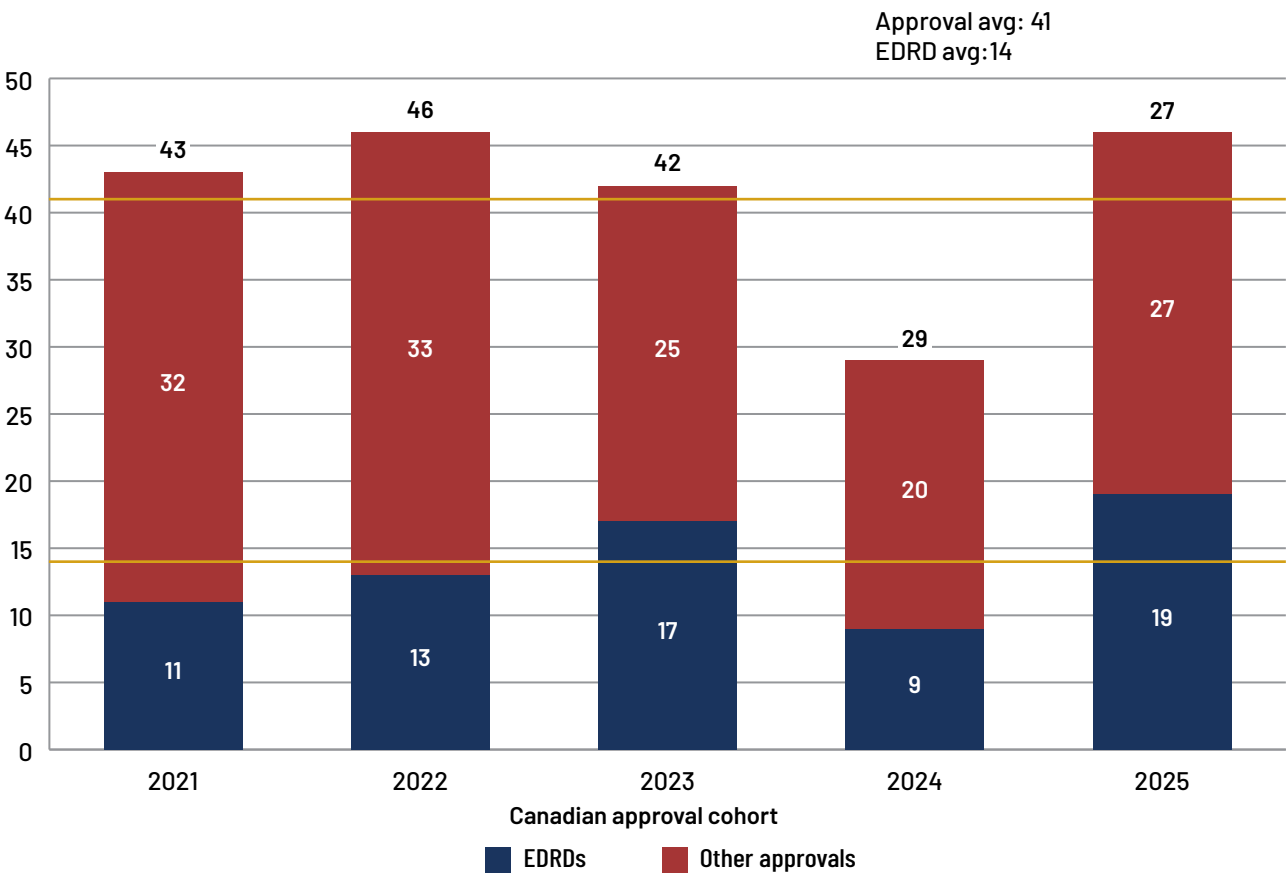
C: Spotlight on Canada



While Sections A and B reported new medicines approved internationally, this section reports on medicines new to Canada, approved between 2021 and 2025. Between 2021 and 2025, Health Canada approved 41 new medicines each year on average, of which an average of 14 (34%) were expensive drugs for rare diseases.

Between 2021 and 2025, Health Canada granted initial market authorization to an average of 41 new medicines each year, of which 14 (35%) were expensive drugs for rare diseases (EDRDs)—orphan-designated therapies with treatment costs exceeding \$100,000 annually or \$7,500 per 28-day cycle for oncology. A full list of EDRDs approved in Canada is provided in data supplement C.

FIGURE C1. New medicine approvals by Health Canada, 2021-2025



Note: Expensive drugs for rare diseases (EDRDs) are defined as those with an orphan designation through the FDA or EMA and treatment costs exceeding \$100,000 annually or \$7,500 per 28-day cycle for oncology.

Data source: Health Canada Notice of Compliance database, drugs@FDA database, EMA drug database, CDA-AMC databases.

Prior to being marketed in Canada, medicines must be reviewed and authorized by Health Canada. However, to be considered for listing on the formulary of public insurers, medicines must also be assessed and recommended for listing by Canada’s Drug Agency (CDA-AMC), an independent, not-for-profit health technology assessment organization. In Quebec, health technology assessments are performed by the Institut national d’excellence en santé et en services sociaux (INESSS). Depending on the results of these assessments, the pan-Canadian Pharmaceutical Alliance (pCPA)—an alliance of public drug plans that conducts joint negotiations for brand-name and generic drugs in Canada—may then choose to enter price negotiations with pharmaceutical manufacturers prior to the drugs being considered for listing on public formularies.

Table C1 provides an overview of the CDA-AMC recommendation and pCPA negotiation status for the 29 new medicines approved in Canada in 2024, as well as information on whether these medicines have recorded sales through private drug plans in Canada. Of this group, 20 had completed CDA-AMC’s Reimbursement Review process, with 17 receiving a recommendation to “reimburse with conditions” and three receiving a “do not reimburse” recommendation. Fifteen of the 29 new medicines approved in Canada had completed pCPA negotiations by Q3-2025. Two were concluded without reaching an agreement. Three medicines had negotiations underway and the remaining eleven medicines had no record of negotiation.

A review of private drug plan data shows that nine of the 29 new medicines had been reimbursed by a private drug plan in Canada by Q3-2025. These rates of reimbursement for new medicines could increase in the coming years as medicines complete the reimbursement process.

TABLE C1. Assessments, recommendations, and reimbursement decisions for 2024 new medicines approved in Canada by Q3-2025

Medicine (trade name)	Health Canada approval	CDA-AMC recommendation‡					pCPA negotiation status§				Private plans
	Notice of Compliance	List	List with conditions	Do not list	Review in progress	Not reviewed	Active	Concluded with agreement	Concluded without agreement	No negotiations	Covered
Ethinyl estradiol (Ringza)	12/18/2024					x				x	
Zolbetuximab (Vyloy) ^{B,C,O}	12/13/2024		x					x			
Fezolinetant (Veozah)	12/2/2024					x				x	
Momelotinib (Ojjaara) ^{C,O}	11/8/2024		x					x			
RSV F-protein mRNA, 5' (m7G-5' - ppp-5' -Gm), 3' poly(A) (Mresvia) ^B	11/6/2024					x				x	
Avapritinib (Ayvakyt) ^{C,O}	9/18/2024		x					x			
Tarlatamab (Imdelltra) ^{B,C,O}	9/11/2024		x				x				
Fruquintinib (Fruzaqla) ^C	9/10/2024		x					x			
Perfluorohexyloctane (Miebo)	9/4/2024					x				x	
Ferric Maltol (Accrufer)	8/21/2024					x				x	
Ivosidenib (Tibsovo) ^{C,O}	7/19/2024		x					x			
Danicopan (Voydeya) ^O	7/19/2024		x						x		
Zilucoplan (Zilbrysq) ^O	7/11/2024		x					x			
Lebrikizumab (Ebglyss) ^B	6/24/2024			x				x			x
Vaccine, Chikungunya (Ixchiq) ^B	6/20/2024					x				x	x
Eplontersen (Wainua) ^O	6/19/2024		x					x			
Talquetamab (Talvey) ^{B,C,O}	4/30/2024			x			x				
Insulin icodec (Awiqli) ^B	3/12/2024		x						x		x
Ferric carboxymaltose (Ferinject)	3/11/2024		x					x			x
Etrasimod (Velsipity)	1/31/2024		x					x			x
Capivasertib (Truqap) ^C	1/26/2024		x					x			x

Vaborbactam (Vabomere)	12/20/2024					x				x	
Trofinetide (Daybue)	10/11/2024			x						x	
Exagamglogene autotemcel (Casgevy) ^{B,G,O}	9/23/2024		x				x				
Sotatercept (Winrevair) ^{B,O}	8/28/2024		x					x			
Vorasidenib (Vorango) ^{C,O}	8/27/2024		x							x	x
Corynebacterium diphtheriae CRM-197 protein (Capvaxine) ^B	7/15/2024					x				x	x
Olipudase alfa (Xenpozyme) ^{B,O}	2/28/2024					x				x	
Metreleptin (Myalepta)	1/17/2024		x					x			x

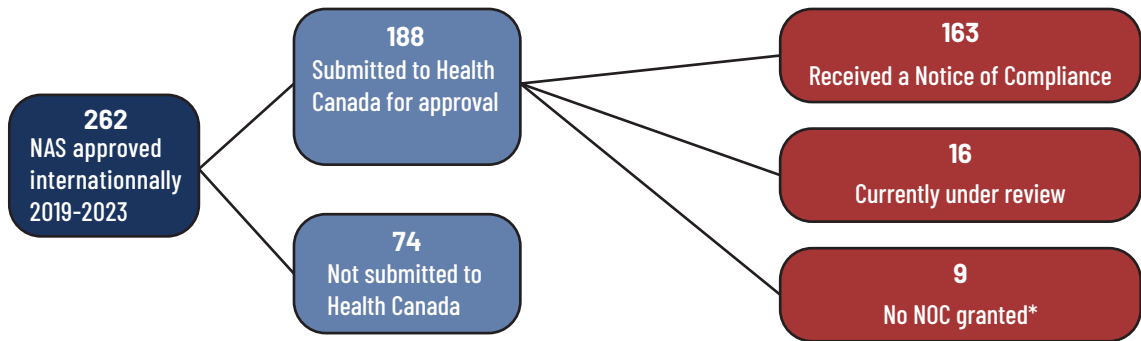
Note: Medicines were assessed through Canada's Drug Agency (CDA-AMC)'s Reimbursement Review process.† B: biologic; C: cancer; G: gene therapy; O: orphan.

Data source: IQVIA Private Drug Plan database; Health Canada Notice of Compliance database; Canada's Drug Agency Reimbursement Review reports; pan-Canadian Pharmaceutical Alliance (pCPA) reports; and IQVIA MIDAS® Database, 2024 (all rights reserved).

A retrospective analysis of the Health Canada submission status of the new medicines approved internationally from 2019 to 2023 is presented in Figure C2(a). Of 262 new active substances, 188 (72%) had been submitted for Health Canada review by December 2025.

Of those, 163 received a Notice of Compliance (NOC), sixteen were still under review, and 9 had an unsuccessful review process. The remaining 74 medicines (28%) had not yet been submitted for review.

FIGURE C2(a). Health Canada review status of new active substances with an international approval between 2019 and 2023, as of December 2025

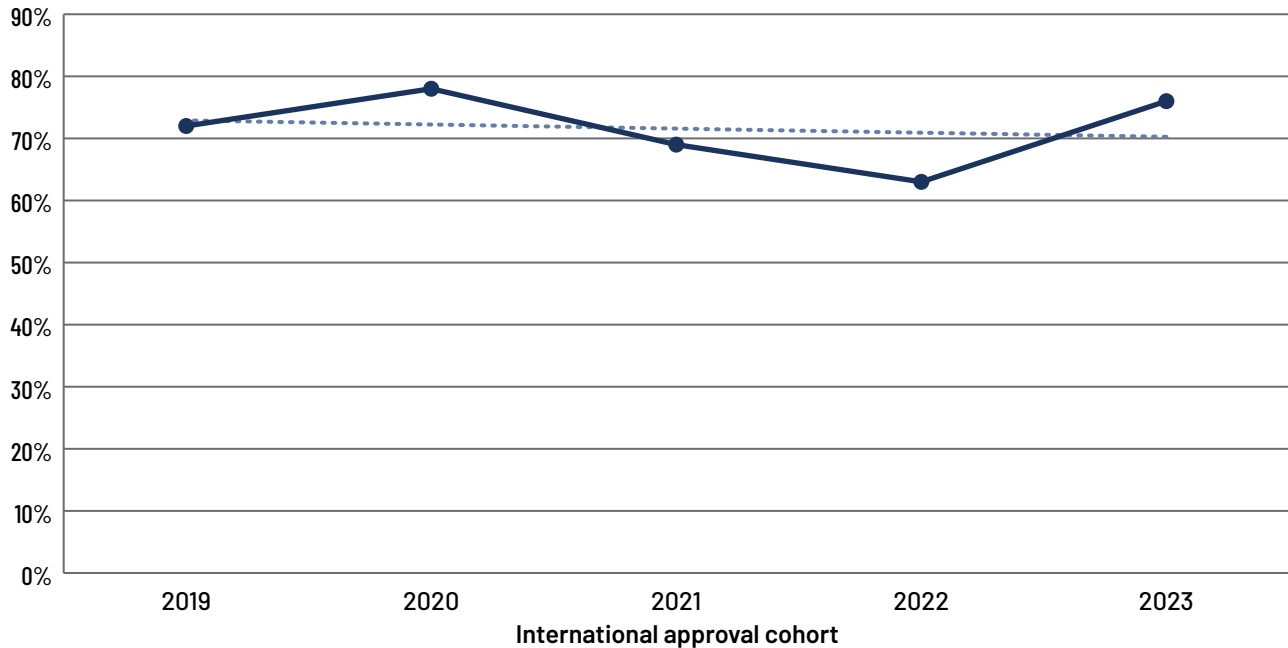


Note: Review statuses were last updated on December, 2025.
 *The submission resulted in a Notice of Non-Compliance or the review was cancelled by the sponsor.
 Data source: Health Canada’s Notice of Compliance database; Health Canada’s New Drug Submissions Completed website; and Health Canada’s New Drug Submissions Under Review website.

While some of these may still be submitted in the future, others may never come. Figure C2(b) shows that there are few additional submissions beyond the first two years since first international approval.

The trend line indicates that an additional 5 years of lead time garners less than an additional 4% increase in submissions. Overall, for the period of 2019 to 2023, first international approvals are submitted for NOCs roughly 70% of the time.

FIGURE C2(b). Proportion of new medicines submitted to Health Canada by internationals approval cohort year

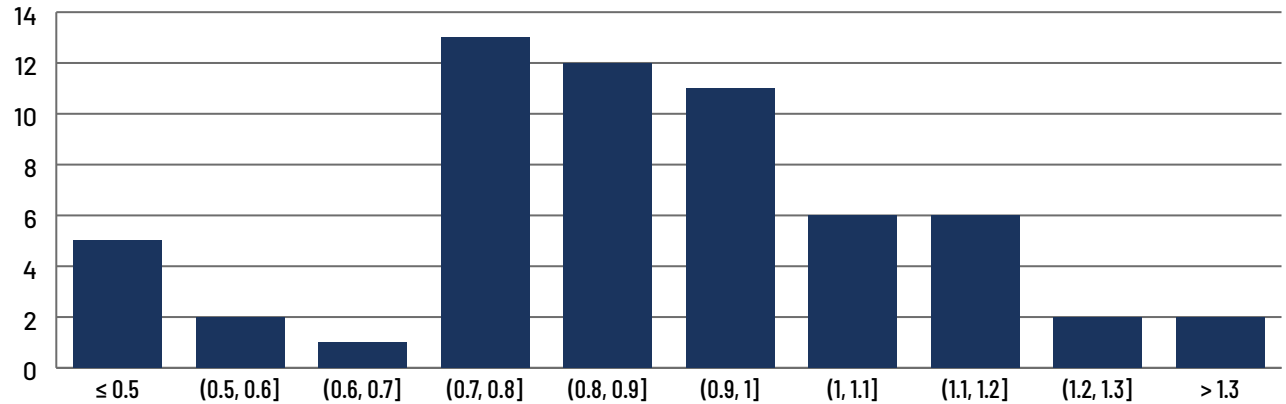


Note: Review statuses were last updated on December, 2025.
 Data source: Health Canada’s Notice of Compliance database; Health Canada’s New Drug Submissions Completed website; and Health Canada’s New Drug Submissions Under Review website

Foreign-to-Canadian price ratios compare the median price of medicines in the OECD member countries and the US price with the Canadian price. The 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. Due to the number of medicines not yet sold outside of the US, the US has been analyzed separately from the OECD. A total of 55 and 60 price ratios were compiled from the US and remaining OECD member countries respectively. The median OECD-to-Canadian price ratio reported across new medicines was 0.87, indicating that international prices in Q42024 of newly approved medicines in Canada from 2021 to 2024 were approximately 13% lower than Canadian prices at introduction.

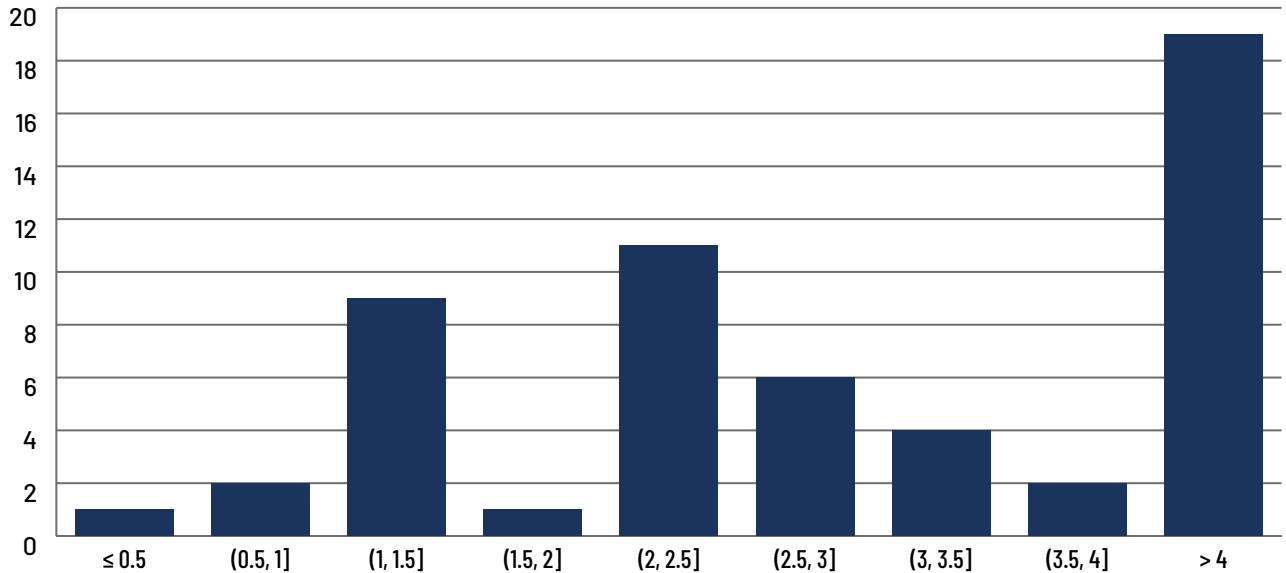
In contrast, the median US price ratio was 2.84 for the same period, indicating that the US pays nearly three times more than Canada for the same medicines. The distribution of data points for these price ratios is shown below. Figure C3(a) is a histogram of OECD-to-Canadian price ratios and displays a mostly normal distribution with a mean and median within the 0.8 to 0.9 bar. The left tail does show some abnormality with a drop off in medicines at the 0.7 mark, indicating that while Canadians are paying more for medicines on average and at the median, most medicines are at most approximately 40% more expensive in Canada than in the OECD. In contrast, Figure C3(b) shows the distribution of US-to-Canadian price ratios. This graph is defined by many outliers in the far-right bin, indicating that many new medicines cost at least four times more in the US compared to Canada.

FIGURE C3(a). Distribution of median OECD*-to-Canada price ratios for 2021-2024 new medicines, Q4-2024



* Excluding US.
 Data source: IQVIA MIDAS® Database, 2024 (all rights reserved).

FIGURE C3(b). Distribution of US-to-Canada price ratios for 2021-2024 new medicines, Q4-2024

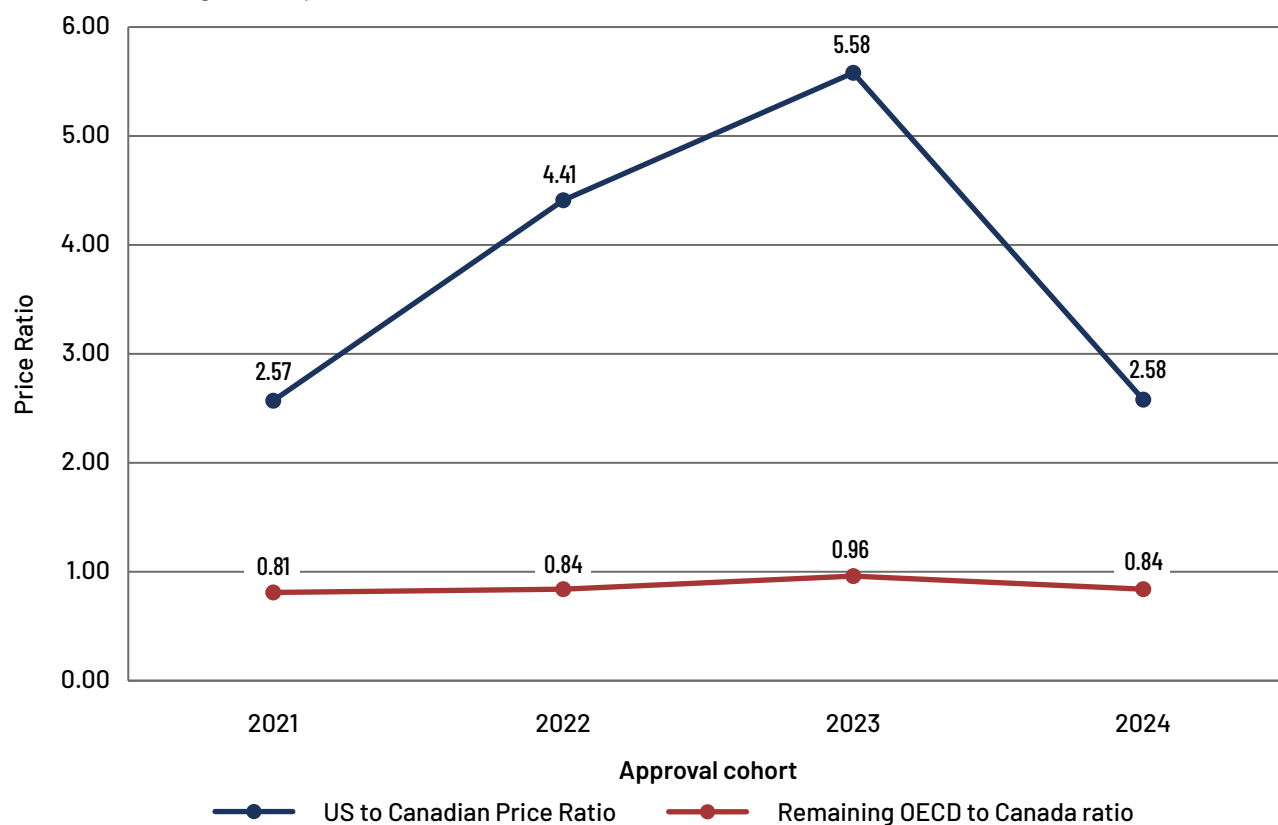


Data source: IQVIA MIDAS® Database, 2024 (all rights reserved).

Figure C4 displays an annual breakdown of average price ratios for both the US and remaining OECD member countries. The OECD shows little variation year after year and never goes over 1.0 or below 0.8.

The US shows much more variability with values of 2.57 in 2021 and 5.58 in 2023. Much of this can be attributed to the effect of outliers highlighted in the previous figure.

FIGURE C4. Average annual price ratios for 2021–2024 new medicines, Q4-2024



Note: OECD excludes US.

Data source: IQVIA MIDAS® Database, 2024 (all rights reserved).

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