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NPDUIS

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About the PMPRB

The Patented Medicine Prices Review Board (PMPRB) is a federal public agency that strives to make a unique contribution to sustainable spending on pharmaceuticals in Canada by:

- providing stakeholders with price, cost and utilization information to help them make timely and knowledgeable drug pricing, purchasing and reimbursement decisions; and
- acting as an effective check on the patent rights of pharmaceutical manufacturers through the responsible and efficient use of its consumer protection powers.

The NPDUI Initiative

The National Prescription Drug Utilization Information System (NPDUI) is a research initiative established by federal, provincial, and territorial Ministers of Health in September 2001 and 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 generate analysis that provides policy makers and public drug plan managers 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 patented and non-patented prescription drugs are being used and on sources of cost pressures.

The specific research topics and methodologies for the NPDUI reports are established with the guidance of the NPDUI Advisory Committee and reflect the priorities of the participating jurisdictions. 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, the Yukon, 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 Quebec, and the pan-Canadian Pharmaceutical Alliance (pCPA) Office.

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EXECUTIVE SUMMARY

The new PMPRB *Meds Entry Watch* annual publication explores the market entry dynamics of new drugs launched in Canada and other international markets. This first edition of the report provides both a retrospective analysis of the new drugs launched over a six-year period from 2009 to 2014, and an early analysis of drugs launched in 2015.

The retrospective analysis offers an overview of the historic availability, launch sequence, market penetration, sales and prices of new drugs launched in Canada and other foreign markets from 2009 to 2014. This analysis will be used as a benchmark for subsequent editions, which will report on new drug launches for each respective calendar year.

The early analysis of the drugs launched in 2015 provides detailed drug-level information on their therapeutic profile, international availability and introductory prices. Some of these drugs may already be available in Canada or may be coming soon. The next edition of the *Meds Entry Watch* will build on this analysis and provide additional up-to-date information on new drugs launched in 2016.

This publication is designed to inform decision makers, researchers and patients of the evolving market dynamics associated with emerging drug therapies in the Canadian and international pharmaceutical environment.

The international markets examined include the seven countries the PMPRB considers in reviewing the prices of patented drugs (PMPRB7): France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.



Key Findings

(A) Meds Entry Watch, 2009 to 2014

1. **New active substances (NASs) account for a sizable share of the Canadian and international pharmaceutical market.**
 - On average, 35 NASs were launched each year between 2009 and 2014, for a total of 210.
 - By the last quarter of 2015 (Q4-2015), the sales of these NASs amounted to 21.8% of the total brand-name pharmaceutical market in Canada and the PMPRB7.
 - An increasing share of NASs received an orphan drug designation and approval from the US Food and Drug Administration (FDA) and/or the European Medicines Agency (EMA) over the study period: 17% in 2009; an average of 32% from 2010 to 2013; and 47% in 2014.
2. **A comparable number of NASs are launched in Canada as in other foreign markets, and all top-selling NASs are available in Canada.**
 - NAS availability in Canada was similar to that in the PMPRB7 countries, with more than half of the NASs launched. The NASs available in Canada represented 97% of the total NAS sales for Canada and the PMPRB7 in Q4-2015.
 - The average lag time between the initial launch of a NAS and its launch in Canada was comparable to that observed in foreign markets; lag times were shorter for top-selling drugs.
 - Canadian list prices for NASs appeared to be in line with those of the European markets analyzed, and markedly lower than those in the US.
3. **The top-selling NASs account for most of the sales in Canada and the PMPRB7 and are dominated by the new direct-acting antiviral (DAA) treatments for hepatitis C.**
 - The 30 top-selling NASs accounted for 74% of the sales in Canada and the PMPRB7, while the 100 top-selling NASs accounted for 98% of sales in Q4-2015.
 - The new hepatitis C drugs accounted for 25% of NAS sales and 6% of all drug sales in Canada and the PMPRB7 in Q4-2015.
 - Twelve of the 30 top-selling NASs have list prices in hundreds or even thousands of dollars.

(B) Meds Entry Watch, 2015

4. **High-priced drugs dominate the NASs launched in 2015, many being biologic, orphan and/or oncology drugs.**
 - Thirty-five NASs were launched in 2015, consistent with the average in previous years.
 - More than half of the NASs launched in the PMPRB7 in 2015 were available in Canada by the end of 2016.
 - The share of new drug launches with orphan designations has been on the rise, with 15 (43%) of the NASs launched in 2015 having received an orphan drug designation and approval from the FDA and/or the EMA; this was similar to the share in 2014 but higher than the average in previous years.
 - The list prices of most NASs (24 out of 35) were in the hundreds or even thousands of dollars.

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INTRODUCTION

New drugs enter the Canadian and international markets each year, offering treatment options to patients. While some address unmet medical needs or provide significant therapeutic improvements, many new drugs offer only minor benefits over existing therapies. New drug launches fuel the growth in pharmaceutical costs and put pressure on drug plan expenditures (PMPRB 2017).

The *Meds Entry Watch* is a new PMPRB annual publication that provides detailed information on recently launched drugs, including their international availability, launch timing, market uptake, sales, and prices, as well as identifies new drugs that may soon be coming to Canada.

These analyses are designed to inform decision makers, researchers and patients of the evolving market dynamics of emerging drug therapies in the Canadian and international pharmaceutical environment.

This first edition of the *Meds Entry Watch* provides (A) a retrospective analysis of the new drugs launched over a six-year period from 2009 to 2014, which will provide a benchmark for later studies; and (B) a preliminary analysis of drugs launched in 2015. The next edition of the *Meds Entry Watch* will build on the analysis of the 2015 drug launches and present up-to-date information on new drugs launched in 2016. Subsequent editions of the report will focus on the new drugs launched in each respective calendar year.

METHODS

This report identifies the new active substances (NASs) launched in Canada and in other international markets between January 1, 2009, and December 31, 2014, and analyzes their uptake, pricing, sales and availability as of the last quarter of 2015 (Q4-2015). For the purpose of this study, drugs were reported at the active chemical substance level.

The international markets examined include the seven countries the PMPRB considers in reviewing the prices of patented drugs (PMPRB7): France, Germany, Italy, Sweden, Switzerland, the United Kingdom (UK) and the United States (US).

A NAS was considered to be launched if it recorded first sales in the retail or hospital sectors in Canada or in any of the international markets examined, based on data reported in IMS AG's MIDAS™ Database. For the Canadian market, NAS availability was further cross-referenced against Health Canada's Drug Product Database (DPD) and the Notice of Compliance (NOC) database to ensure that all NASs authorized for sale in Canada were accurately identified. Using these criteria, 210 drugs were selected for the retrospective analysis from 2009 to 2014 in Section A; and 35 drugs were identified for the preliminary analysis in Section B.

The main data source for launch dates, drug sales and pricing was IMS AG's MIDAS™ Database (all rights reserved). MIDAS™ data reflects the national retail and hospital sectors for each country and includes drug sales, list prices and the physical quantity of drugs used in the public, private and out-of-pocket market segments. The Canadian and international prices reported in MIDAS™ are manufacturer ex-factory list prices. Sales and volume data encompass all versions of a substance available in a particular country, produced by any manufacturer in any strength and form. International price comparisons at the individual drug level are restricted to molecules with the same form, strength and volume.

Market spot exchange rates were used to convert foreign currency prices into their Canadian dollar equivalents. Foreign currencies were converted to Canadian dollars using the 12-month or 3-month average exchange rate for the year or the quarter, respectively.

Supplementary information related to the definition and calculation of the measures of central tendency and average foreign-to-Canadian price ratios is available as an online resource (see the Reference Documents section of the Analytical Studies page of the PMPRB website).



LIMITATIONS

The identification of drug launches in each country was based on the availability of sales in the MIDAS™ Database. Drugs with low sales may not be reported in the database, and thus, the number of new active substances launched in any given country may be slightly under-reported. However, this should only have a minimal impact on the overall sales results.

While a substance was considered to be launched if it recorded first sales in Canada or in any other international market analyzed during the study period, the substance may have been launched at an earlier date than indicated by the available sales data. In addition, a NAS may have been launched at an earlier date in a foreign market not examined in this report.

For the Canadian market, NAS availability was further cross-referenced against Health Canada's drug approval information, and it may capture drugs not yet marketed in Canada over the study period.

Canadian and international sales and prices available in the IMS MIDAS™ Database are estimated manufacturer factory-gate list prices and do not reflect off-invoice price rebates and allowances, managed entry agreements, or patient access schemes. Manufacturer list prices may be different from other price points in the distribution chain, such as wholesaler or pharmacy retail prices.

The methodology that MIDAS™ uses for estimating drug prices varies by country depending on the distribution system and the availability of public data. This data includes the manufacturer's list price, the wholesale price, and the pharmacy price in specific markets. Manufacturer, wholesale or retail prices may represent estimates based on assumed regulated margins and/or markups.

The variations in utilization among countries may be due to differences in relevant market considerations, such as the demographic and disease profiles of the populations, or regulating and/or reimbursement policies.

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

Drugs accessed through the Special Access Program (SAP) in Canada are not captured in this report.

A MEDS ENTRY WATCH, 2009 TO 2014

A1 Overview of Canadian and international markets

On average, 35 new active substances (NASs) were launched annually in Canada and the PMPRB comparator countries from 2009 to 2014, with cumulative sales amounting to over one fifth (21.8%) of the entire brand-name pharmaceutical market by the last quarter of 2015 (Q4-2015). The sales of NASs were highly concentrated, with a small number of drugs accounting for a large proportion of the new drug sales.

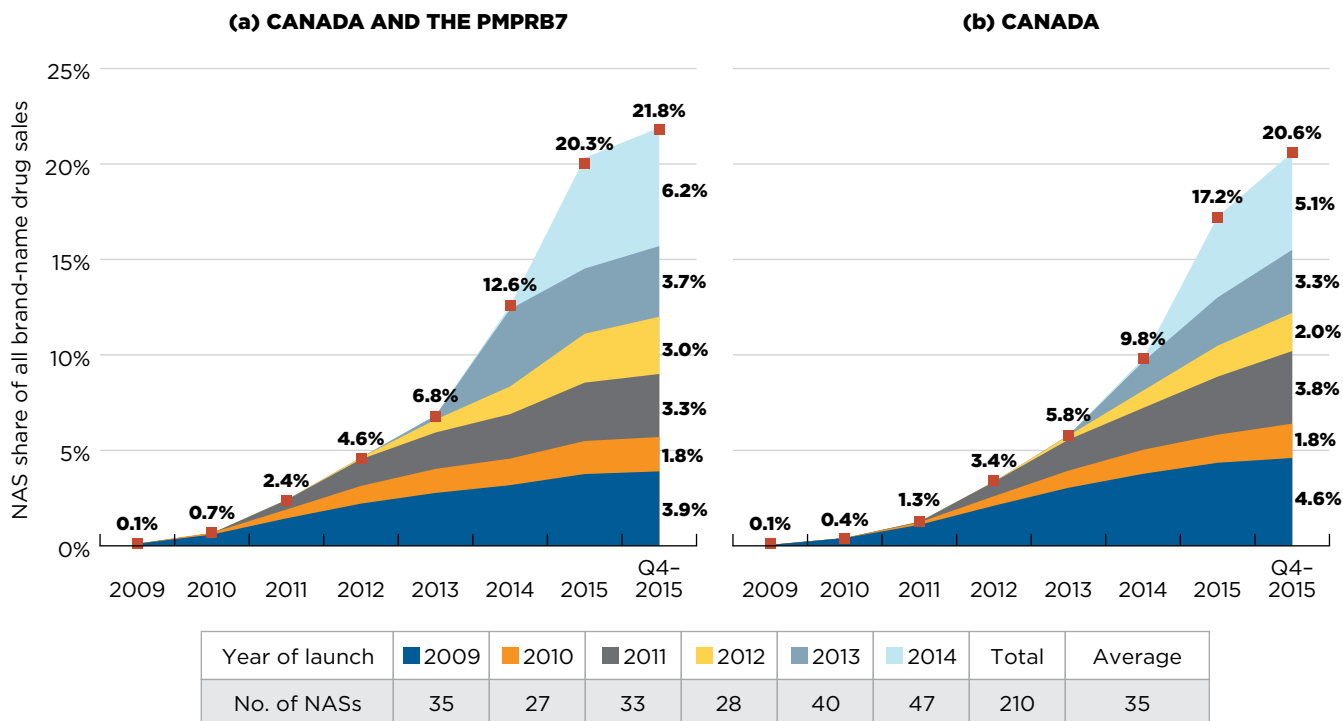
The majority of NASs that were launched internationally were also available in Canada; these drugs accounted for almost all (97%) of the NAS sales in the markets analyzed. Canada accounts for a sizable share of the international market for NASs.

Between 2009 and 2014, 210 NASs were launched in Canada and the PMPRB7, ranging from 27 to 47 NASs per year (Figure A1.1). An increasing share of NASs received an orphan drug designation and approval from the US Food and Drug Administration (FDA) and/or the European Medicines Agency (EMA) over the study period: 17% in 2009; an average of 32% from 2010 to 2013; and 47% in 2014. Figure A1.1 also depicts the cumulative market share for NASs launched in (a) both Canada and the PMPRB7, and (b) Canada only.

In any given year, the impact of NASs on pharmaceutical sales depends on the number and therapeutic relevance of the drugs being launched. For instance, the NASs launched in 2014 had a very high impact on sales, mainly driven by the new direct-acting antiviral (DAA) treatments for hepatitis C. Harvoni alone accounted for 4.0% of the total brand-name drug sales for all of the markets analysed in 2015. In Canada, the sales for Harvoni reached \$595 million in 2015, representing 3.8% of all brand-name drug sales.

Cumulatively, NASs had a steep year-over-year uptake in sales. By Q4-2015, NAS sales reached 21.8% of the total brand-name pharmaceutical market for Canada and the PMPRB7, and 20.6% for Canada.

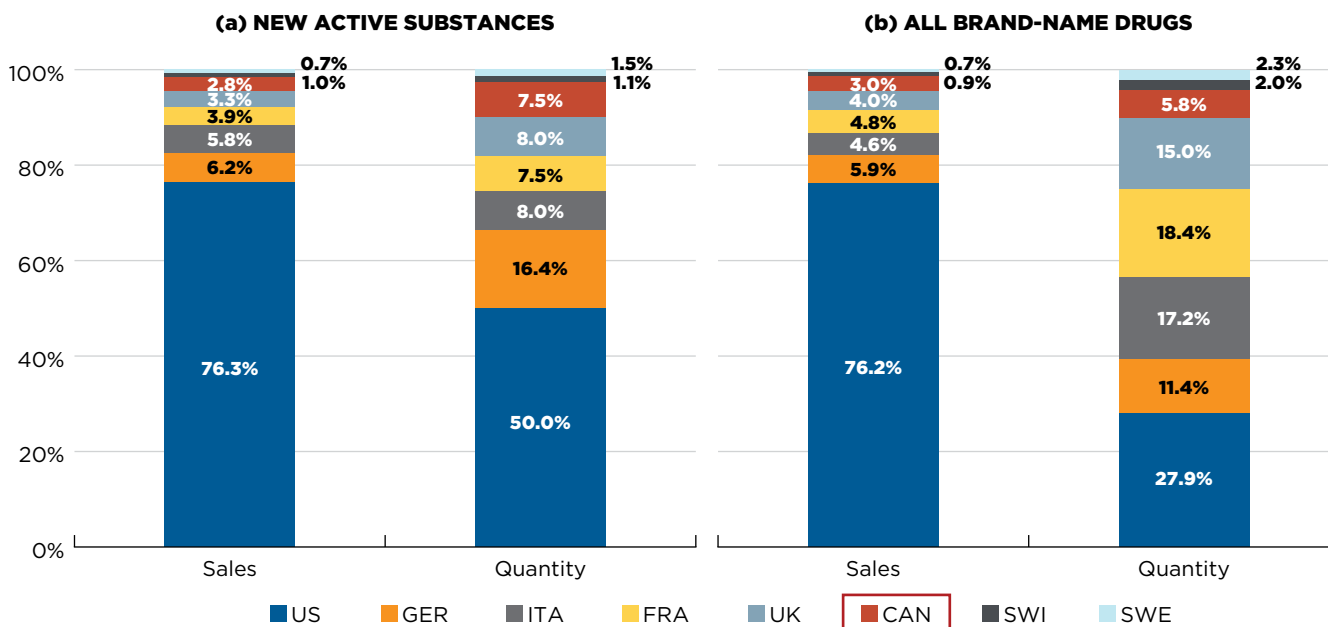
The international markets examined include the seven countries the PMPRB considers in reviewing the prices of patented drugs (PMPRB7): France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.

FIGURE A1.1 Cumulative NAS share of all brand-name drug sales, by launch year (2009–2014) Canada and the PMPRB7*

Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales. Sales are based on manufacturer list prices.

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

Source: MIDAS™ Database, 2009 to 2015, IMS AG. All rights reserved.

FIGURE A1.2 Market share by country for NASs and all brand-name drugs, by volume of sales and units Canada and the PMPRB7*, Q4-2015

Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales. Sales are based on manufacturer list prices.

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

Source: MIDAS™ Database, 2015, IMS AG. All rights reserved.

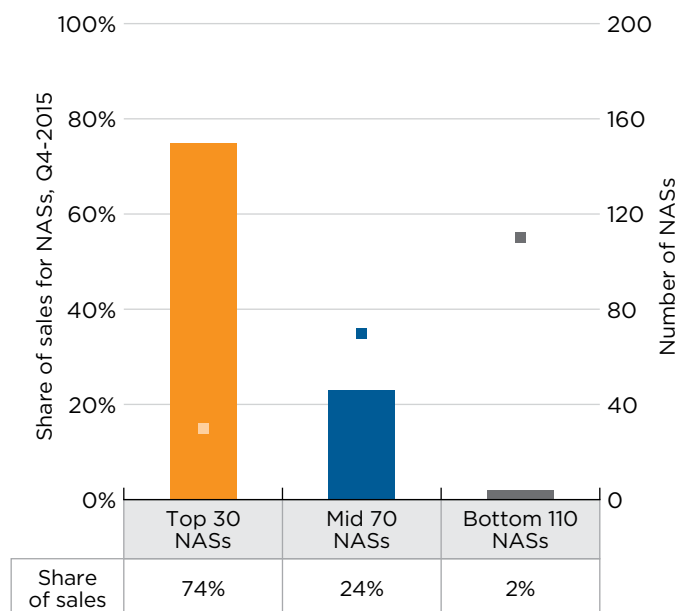
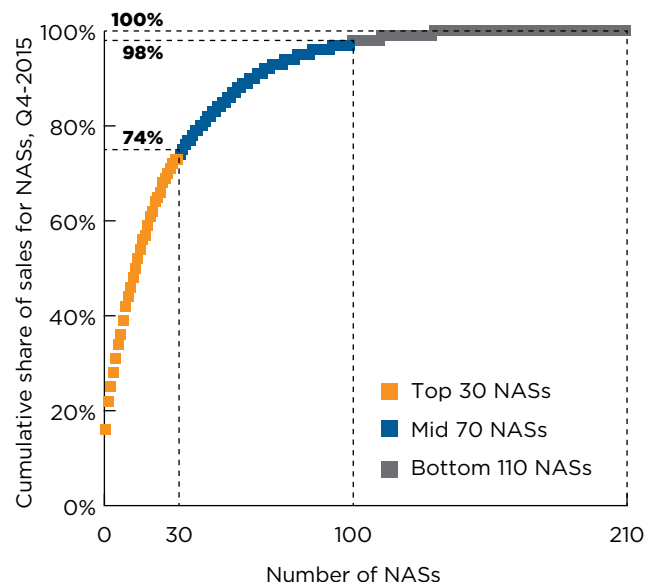
Canada accounts for a sizable share of the international market for NASs. Figure A1.2 reports the country-specific market share for (a) NASs and (b) all brand-name drugs in Q4-2015. In terms of sales, Canada's share of the international market for NASs (2.8%) is comparable to its share of the brand-name drug market in general (3.0%). Canada's share of the PMPRB7 market in terms of utilization (quantity) is greater than its share of sales both for NASs and for all brand-name drugs (7.5% and 5.8%, respectively).

In general, pharmaceutical sales are highly concentrated, with a small number of drugs accounting for a large proportion of sales. This also applies to NASs.

Figure A1.3 depicts the sales concentration of the 210 NASs launched from 2009 to 2014. The 30 top-selling NASs accounted for three-quarters (74%) of the total NAS sales in Q4-2015. These drugs had individual drug-level sales exceeding \$250 million in Canada and the PMPRB7 in Q4-2015.

Most of the remaining sales (24%) were accounted for by the 70 NASs with Q4-2015 sales ranging from \$25 million to \$250 million. NASs with drug-level sales of less than \$25 million made up the majority (110) of the drugs, but only represented 2% of the total sales.

**FIGURE A1.3 Sales concentration of NASs
Canada and PMPRB7*, Q4-2015**



Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales. Sales are based on manufacturer list prices.

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

Source: MIDAS™ Database, 2009 to 2015, IMS AG. All rights reserved.

A closer look at the availability of NASs by country suggests that while larger markets tend to launch more drugs, Canada launched an appreciable number of NASs relative to its population. Furthermore, the drugs launched in Canada accounted for all but 3% of the total NAS sales in the markets analyzed.

Figure A1.4 reports the number and share of NASs launched between 2009 and 2014 by country, along with their corresponding share of total NAS sales for Canada and the PMPRB7 in Q4-2015. The countries are ranked by the number of NASs launched, and the population of each country is given in the accompanying table.

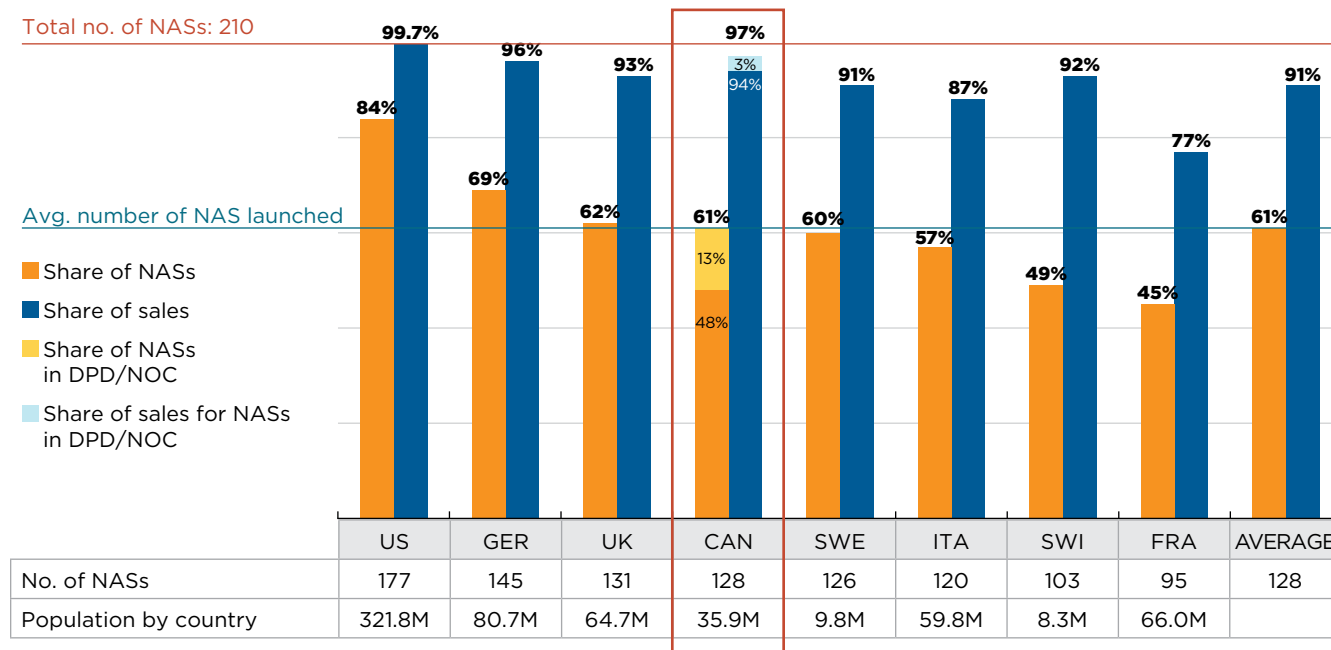
The results indicate that Canadian NAS availability is in line with the other markets analyzed. Of the 210

NASs launched, 61% (128) were available in Canada. Of these drugs, 101 had MIDAS™ sales data and the other 27¹ were identified as either marketed or approved for sale in Canada based on Health Canada's Drug Product Database and the Notice of Compliance database. While the US market launched the most new drugs (84%), the results suggest that no country launched all NASs.

The drugs that were available in Canada accounted for 97% of the total NAS sales, while those that were not available as of Q4-2015 represented only 3% of the NAS sales.

These results suggest that while the size of the market may be an important consideration in where a NAS is launched, it is not the only one.

FIGURE A1.4 Number of NASs launched and their respective share of NAS sales in Canada and the PMPRB7*, Q4-2015



Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For the Canadian market, Health Canada's Drug Product Database (DPD) and the Notice of Compliance (NOC) database were cross-referenced to ensure that all NASs authorized for sale in Canada were accurately identified. Sales are based on manufacturer list prices.

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

Sources: MIDAS™ Database, 2009 to 2015, IMS AG. All rights reserved.

Health Canada's Drug Product Database and Notice of Compliance database.

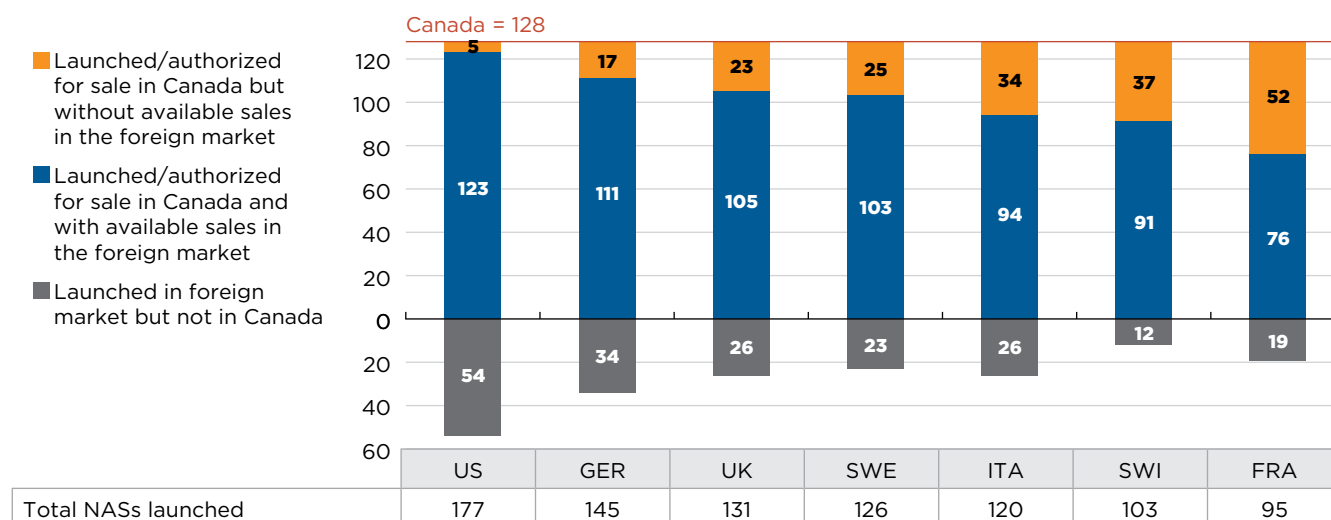
1. 10 of these drugs have been approved for sale (issued a Notice of Compliance) and 17 have been marketed.

Appendix I reports the share of the 210 NASs launched between 2009 and 2014 by OECD country (Organisation for Economic Co-operation and Development), along with their corresponding share of total NAS OECD sales in Q4-2015.

A drug-level analysis indicates that all 30 top-selling drugs depicted in Figure A1.3 were launched in Canada, as well as in the United States, Germany and Switzerland. The remaining PMPRB7 countries launched fewer top-selling drugs, ranging from 23 to 29 NASs. Section A4 provides additional insight into the uptake and timing of the launches of the 30 top-selling NASs.

In terms of which NASs are available, Canada has the greatest similarity to the United States². Figure A1.5 provides bilateral results of the overlap between the NASs launched in Canada and in each of the PMPRB7 countries. For example, of the 128 NASs available in Canada, 123 were also launched in the US; 5 were launched in Canada but not in the US; and 54 additional NASs were launched in the US but not in Canada.

FIGURE A1.5 Comparison of the number of NASs available in Canada with those launched in PMPRB7*, Q4-2015



Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For the Canadian market, Health Canada's Drug Product Database and the Notice of Compliance database were cross-referenced to ensure that all NASs authorized for sale in Canada were accurately identified.

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

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.

2. Canada and the United States have established a Common Electronic Submission Gateway to reduce the regulatory burden for health products.

A2 International launch sequence and lag time

Canada falls well within the range of the PMPRB7 countries with respect to both the launch sequence and lag time of NASs. Drugs are generally launched in Canada before Switzerland, Italy and France, but after the United States, Sweden, Germany and the United Kingdom. The time taken between the initial launch of an NAS internationally and its launch in Canada is comparable to the average launch lag time for the PMPRB7 countries. Top-selling drugs tend to have a shorter lag time to launch in Canada.

The first country of launch for 86% of the NASs was either the United States or Sweden. The US market, which had the highest share of NAS sales in Q4-2015 (76.3% - see Figure A1.2), was the first market of launch for 67.1% of the NASs. In contrast, Sweden, which was the smallest market analyzed (0.7% of sales), was the first market for most of the remaining launches (19.0%). Germany, the second largest market in Q4-2015 (6.2% of NAS sales), was the first country of launch for a smaller share of the drugs (3.8%). Two drugs were first launched in Canada, one of which is a top-selling product. Section A4 provides detailed information on the launch sequence for the top-selling NASs (Table A4.2).

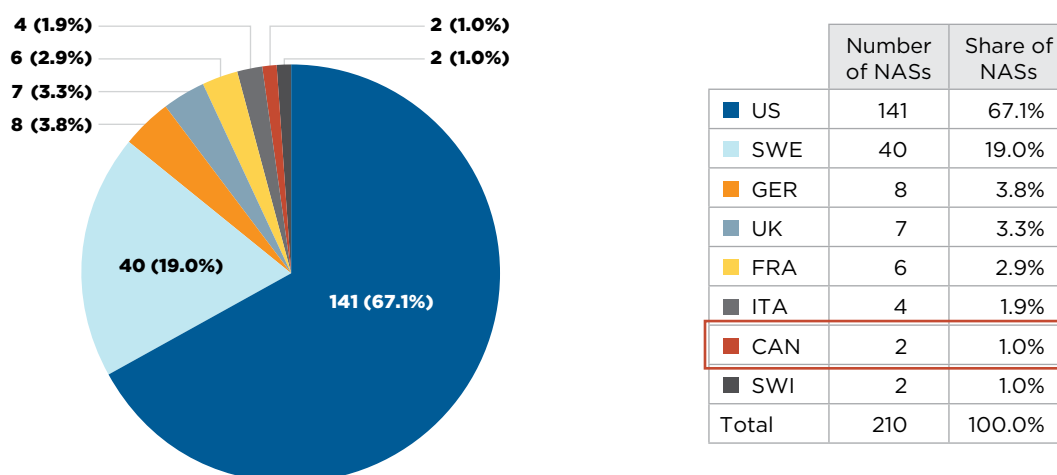
These results suggest that the size of the market is not always a determinant in the launching sequence, which may also depend on other business and market dynamic considerations.

The majority of NASs were launched in Canada before they were launched in Switzerland, Italy and France; while the United States, Sweden, Germany and the United Kingdom tended to have earlier availability than Canada. Table A2.1 reports the number and share of NASs launched in Canada before being launched in a specific foreign market. For instance, of the 101 NASs launched in Canada between 2009 and 2014, 6 drugs (6%) were launched in Canada before the US, while 57 drugs (69%) were launched in Canada before being launched in Italy.

For the 210 NASs analyzed, the median lag time to launch in Canada fell within the middle of the range for the PMPRB7. The lag time is the number of months from the first launch in any of the markets analyzed to the launch in a particular country. The lag time was determined at the product level.

For this analysis, launches in the Canadian market were solely based on the 101 NASs with sales data available in the MIDAS™ Database.

FIGURE A2.1 Number of NASs launched by the country of first launch and respective market share Canada and the PMPRB7*, Q4-2015



Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales. Sales are based on manufacturer list prices.

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

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.

TABLE A2.1 Number and share of NASs launched in Canada before foreign markets
By country, PMPRB7*

	Number of NASs	Share of NASs	Sample size (NASs available in both Canada and comparator country)
United States	6	6%	99
Sweden	17	19%	88
United Kingdom	30	33%	92
Germany	36	39%	92
France	47	68%	69
Switzerland	50	58%	86
Italy	57	69%	83
Any PMPRB7 country	2	2%	101

Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales.

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

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.

Table A2.2 reports the sales-weighted average and median lag time to launch by country for the NASs in each sample. The country of first launch was excluded from the analysis for that market. For instance, the small sample size for the US market (36) is due to the fact that the United States was the country of first launch for most NASs (141).

The United States, Sweden, Germany and the United Kingdom, which were among the first countries to launch NASs, have the shortest lag times to launch for the remaining drugs, with a weighted average and a median of up to 9 months. The Canadian weighted average lag time was 8 months and the median was 11 months, which was similar to Switzerland and shorter than France and Italy (up to 15 months).

TABLE A2.2 Lag time to launch* for NASs
By country, Canada and the PMPRB7†

	Weighted average lag (months)	Median lag (months)	No. of NASs in sample‡
United States	9	8	36
Sweden	5	6	86
France	13	15	89
Canada	8	11	99
Switzerland	11	11	101
Italy	14	15	116
United Kingdom	7	7	124
Germany	8	6	137
Total Canada and PMPRB7	10	10	210

Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales.

* The number of months from the first launch in any of the markets analyzed (Canada and the PMPRB7) determined at the product and country level.

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

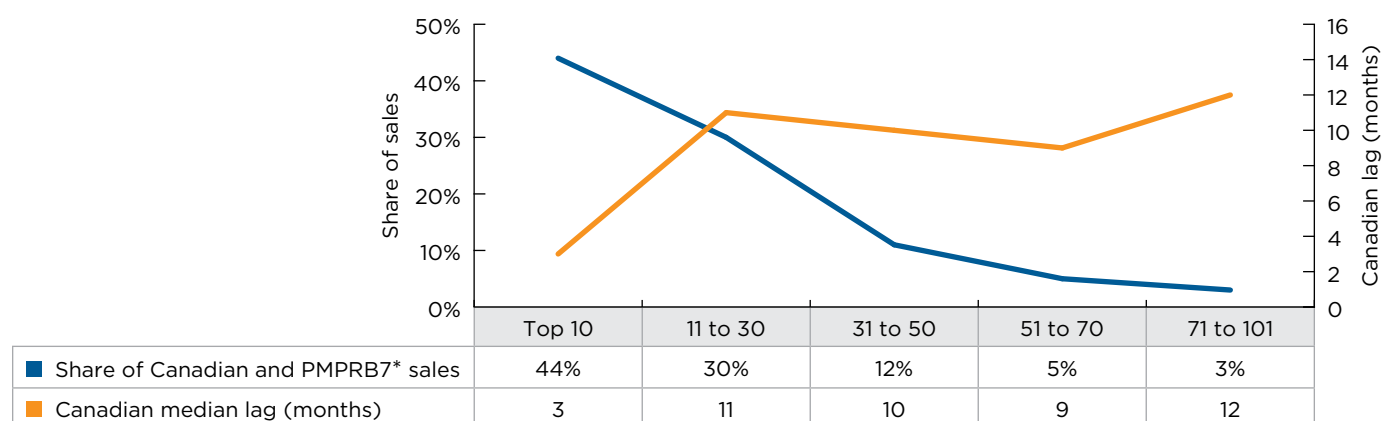
‡ The country of first launch was excluded from the analysis for that market.

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.

While Table A2.2 provides an overall assessment of the lag time to launch for all NASs, results vary greatly by drug. Figure A2.2 reports the Canadian lag time to launch for NASs by market share and indicates that lag times are shorter for drugs with higher sales. The 10 top-selling NASs, which accounted for 44% of all NAS sales in Q4-2015, were launched in Canada within approximately 3 months of their first international launch. In contrast, the rest of the drugs had a median lag time of 11 months.

The PMPRB's scientific review process provides recommendations on the level of therapeutic improvement of new patented drug products³. Based on this information, an analysis of the launch lag time by level of therapeutic improvement was also carried out. The results suggest that there is no appreciable difference in the lag time to launch based on the level of therapeutic improvement over existing drugs. The 10 NASs that were categorized as *breakthrough* drugs or as providing a *substantial improvement* had a median lag time of 10 months; while the NASs categorized as having a *moderate improvement* or *slight to no improvement* also had a median lag of 10 months.

FIGURE A2.2 Canadian lag time to launch for NASs by market share, Q4-2015



Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales.

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

Source: MIDAS™ Database, 2009 to 2015, IMS AG. All rights reserved.

3. The PMPRB website explains the categories in detail: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492#1637>

A3 International price comparison

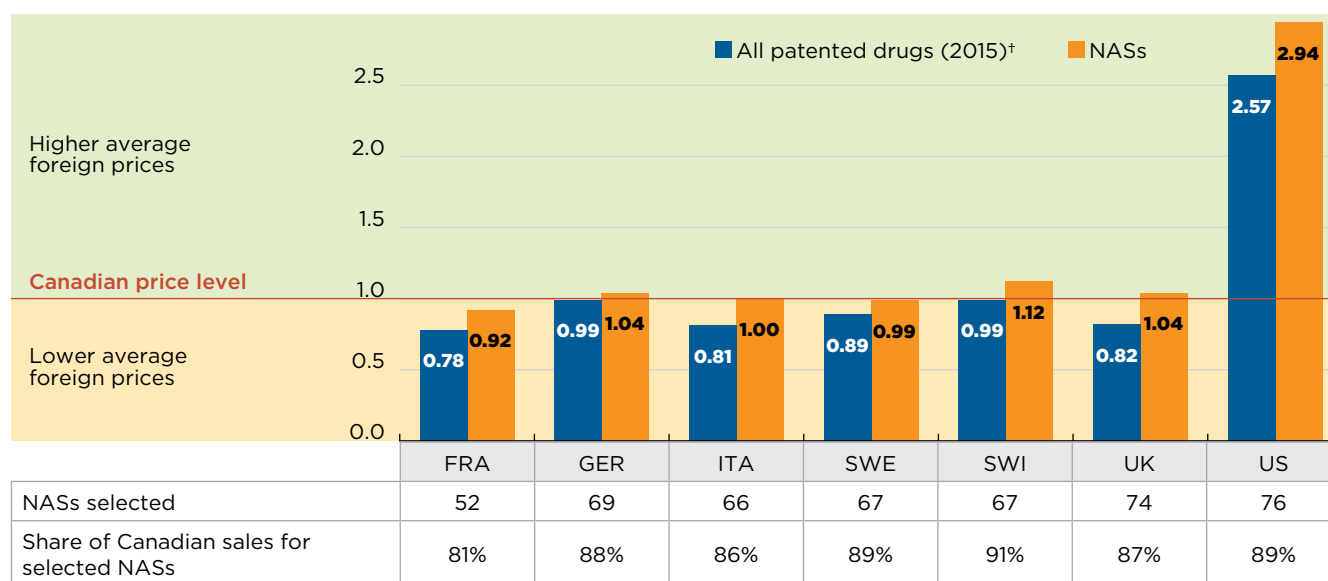
Canadian prices for new drugs are generally in line with those observed in the European markets analyzed, and considerably below those in the US market.

This section reports the average foreign-to-Canadian price ratios for a variety of bilateral and multilateral measures⁴. Bilateral price ratios compare the list price levels for an individual country to those available in Canada. Multilateral ratios compare the list prices across all countries analyzed to those available in Canada.

The bilateral foreign-to-Canadian price ratios for Q4-2015 are reported in Figure A3.1. The results are expressed as an index with the Canadian price set to a value of one, and the international measures reported relative to this value; a result above the value of one indicates correspondingly higher average prices in foreign markets.

While the prices of patented drugs in most of the foreign markets analyzed generally tend to be lower than in Canada (PMPRB 2016), the foreign prices for NASs are either in line or slightly above the Canadian levels. These results suggest that at introduction Canadian prices are in line with international levels, but as drug markets mature, foreign prices decline relative to Canadian levels. Prices in the United States are markedly higher than in Canada and the other PMPRB7 markets for both NASs and patented drugs in general.

FIGURE A3.1 Average bilateral foreign-to-Canadian price ratios for NASs PMPRB7*, Q4-2015



Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales.

Prices reported are manufacturer list prices.

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

† PMPRB Annual Report 2015.

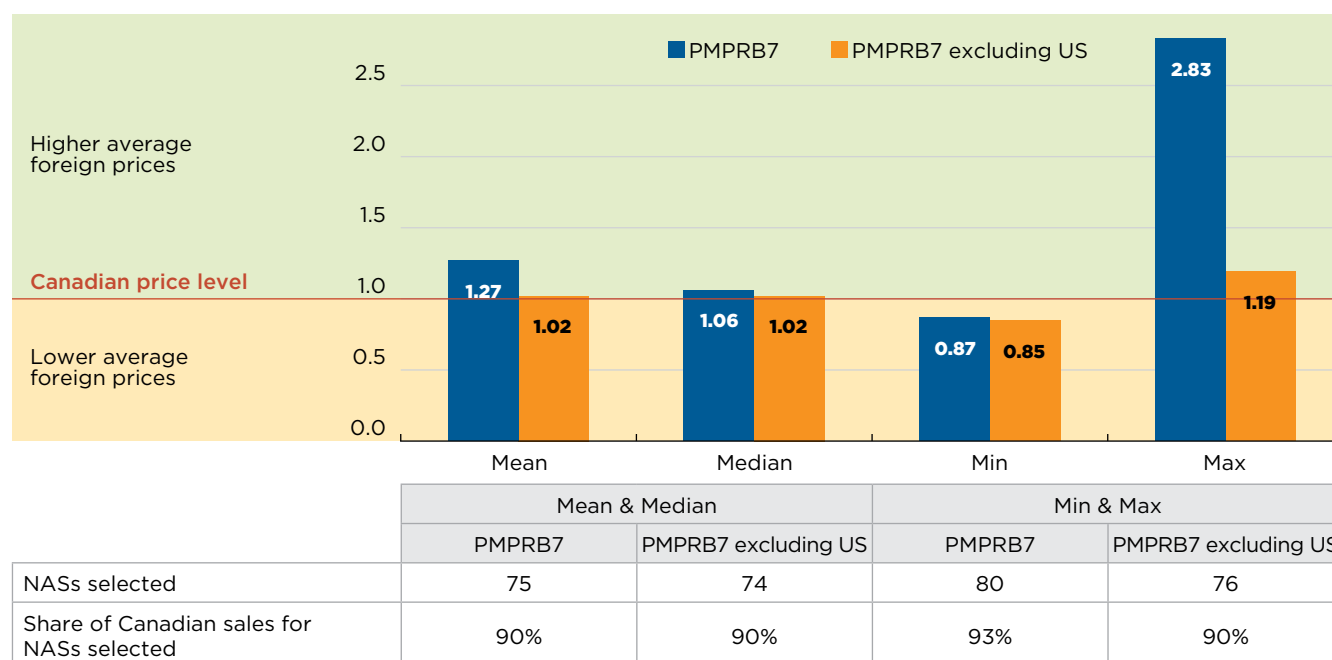
Source: MIDAS™ Database, October-December 2015, IMS AG. All rights reserved.

4. A detailed description of how foreign-to-Canadian price ratios are calculated is available on the PMPRB website—see the Reference Documents section on the NPDUIS Analytical Studies page.

The Q4-2015 multilateral foreign-to-Canadian price ratios are reported in Figure A3.2 and include results based on the mean, median, minimum and maximum foreign prices. Two sets of results are presented: (i) for all PMPRB7 markets; and (ii) for all PMPRB7 markets except the United States, which limits the results to markets with price regulations.

The median foreign prices for new drugs are 6% above the Canadian levels when all PMPRB7 countries are considered, but only 2% above when the United States is excluded.

FIGURE A3.2 Average multilateral foreign-to-Canadian price ratios for NASs PMPRB7*, Q4-2015



Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales. The minimum and maximum values were calculated for drugs with prices available in at least two foreign markets. The mean and median values were calculated for drugs with prices available in at least three foreign markets. Prices reported are manufacturer list prices.

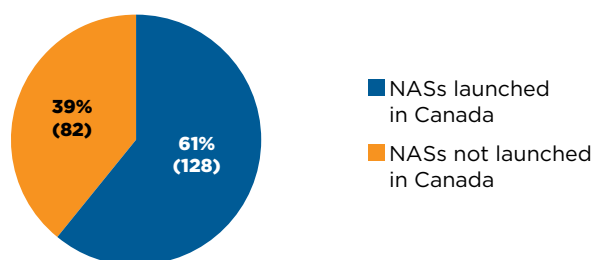
* France, Germany, Italy, Sweden, Switzerland, United Kingdom and the United States.

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.

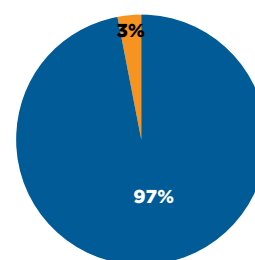
A4 Drug-level analysis of Canadian launches

Most of the 210 NASs launched in foreign markets from 2009 to 2014 were also launched in Canada by the end of 2015 (61%). Those that were launched in Canada accounted for almost all of the Canadian and PMPRB7 NAS sales (97%).

SHARE AND NUMBER OF NASs



SHARE OF SALES IN CANADA AND THE PMPRB7*



Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For the Canadian market, Health Canada's Drug Product Database and the Notice of Compliance database were cross-referenced to ensure that all NASs authorized for sale in Canada were accurately identified.

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

Source: MIDAS™ Database, 2015, IMS AG. All rights reserved.

The drugs launched in the Canadian market included many of the top-selling NASs, with the 30 top-selling drugs accounting for nearly three quarters of the NAS sales. A close examination of these drugs suggests that only a few offer a substantial or moderate level of improvement over existing drugs, while the majority offer a slight or no improvement. These drugs generally received conditional listing recommendations in Canada following their health technology assessments, and were usually reimbursed by the majority of the Canadian public drug plans⁵.

While the NASs launched in Canada and the PMPRB7 from 2009 to 2014 covered a broad spectrum of therapeutic classes, their sales were concentrated

within only a few. Figure A4.1 reports the share of NASs launched in Canada by anatomical classification, as well as the respective share of sales in Canada and the PMPRB7. The results are presented for the top 10 therapeutic classes at level 2 of the Anatomical Classification of Pharmaceutical Products⁶.

Antivirals, which include the new direct-acting antiviral (DAA) treatments for hepatitis C, are at the top of the list, accounting for the largest share of NAS sales (33%) in Q4-2015. Antineoplastic agents, immunosuppressants and diabetes drugs also had a high share of sales, accounting for 13%, 12% and 11%, respectively.

5. This includes the 10 provincial drug plans and Health Canada's Non-Insured Health Benefits (NIHB) Program.

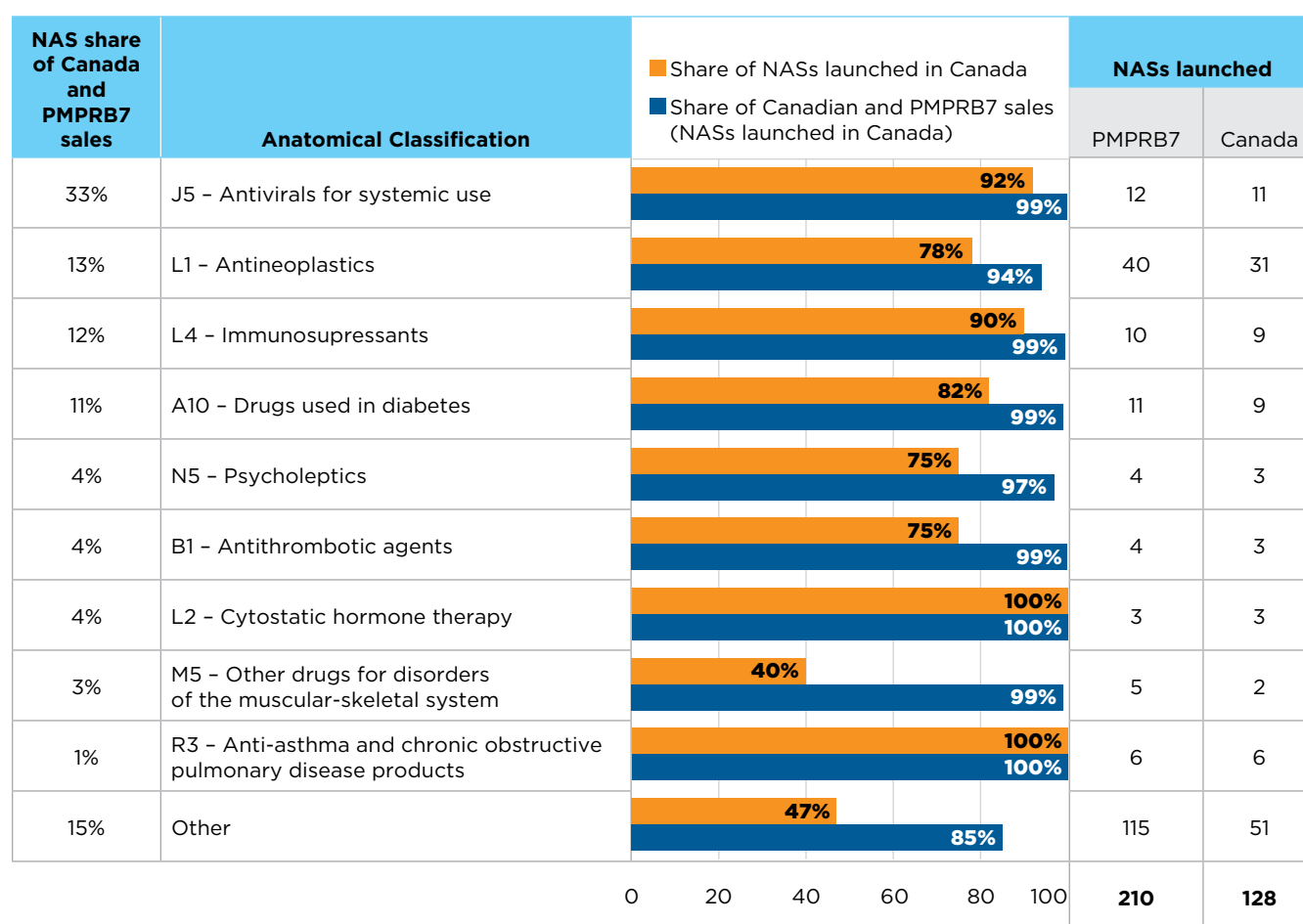
6. Developed jointly by the Pharmaceutical Business Intelligence and Research Group (PBIRG) and the European Pharmaceutical Market Research Association (EphMRA).

Most of the NASs in the top-selling therapeutic classes were available in Canada. For example, 11 of the 12 NASs (92%) in the antivirals class and 9 out of 10 NASs (90%) in the immunosuppressant class were launched in Canada. Other top-selling classes with high rates of availability in Canada (75% to 82%) included: antineoplastics, drugs used in diabetes, psycholeptics and antithrombotic agents. All of the NASs related to cytostatic hormone therapy and anti-asthma and chronic obstructive pulmonary disease products were available in Canada. The NASs available in Canada accounted for 94% or more of the total sales within their respective classes.

For the “other” therapeutic class category with lower sales levels, less than half of the NASs were available in Canada, but those that were available accounted for an average of 85% of the sales in their respective classes.

Table A4.1 focuses a lens on the 30 top-selling NASs launched in Canada and the PMPRB7 from 2009 to 2014. These drugs represented 74.5% of the total NAS sales in all countries analyzed and 85.7% of Canadian sales in Q4-2015.

FIGURE A4.1 NASs by top 10 anatomical classifications*, Canada and PMPRB7†, Q4-2015



Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For the Canadian market, Health Canada's Drug Product Database and the Notice of Compliance database were cross-referenced to ensure that all NASs authorized for sale in Canada were accurately identified. Sales are based on manufacturer list prices.

* IMS AG Anatomical Therapeutic Classification level 2.

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

Source: MIDAS™ Database, 2009 to 2015, IMS AG. All rights reserved.

TABLE A4.1 The 30 top-selling NASs, Canada and PMPRB^{7*}, Q4-2015

			PMPRB level of therapeutic improvement				Common Drug Review			pan-Canadian Oncology Drug Review										
			Breakthrough	Substantial improvement	Moderate improvement†	Slight or no improvement	List	List with criteria/condition	Do not list	Do not list at submitted price	Funding	Funding conditional on cost-effectiveness being improved		Do not fund	pCPA status†	No. of public plans where NAS is listed§	Share of Canadian and PMPRB7 NAS sales, Q4-2015	Share of Canadian NAS sales, Q4-2015	Foreign-to-Canadian ratio of NAS consumption rate	
Rank	NAS (product name)	Year of first launch																		
1	Ledipasvir, sofosbuvir (Harvoni)	2014													10	16.1%	22.3%	1.0		
2	Sofosbuvir (Sovaldi)	2013													10	5.5%	6.5%	1.1		
3	Liraglutide (Victoza) B	2009													4	3.4%	3.0%	1.0		
4	Fingolimod (Gilenya)	2010													10	3.0%	2.6%	1.3		
5	Ustekinumab (Stelara) B	2009													10	2.9%	4.8%	0.5		
6	Elvitegravir, cobicistat (Stribild)	2012													9	2.8%	1.7%	2.1		
7	Denosumab (Prolia) B,O	2010													11	2.8%	3.5%	0.6		
8	Apixaban (Eliquis)	2011													11	2.8%	3.2%	0.8		
9	Dolutegravir (Triumeq)	2013													7	2.7%	2.6%	1.1		
10	Canagliflozin (Invokana)	2013													9	2.3%	2.5%	0.4		
11	Lurasidone (Latuda)	2011													10	2.1%	0.6%	1.0		
12	Paliperidone palmitate (Invega Sustenna)	2009													11	2.0%	3.7%	0.4		
13	Abiraterone acetate (Zytiga) C	2011													10	2.0%	2.6%	0.8		
14	Nivolumab (Opdivo) B,C,O	2014		**											0	2.0%	0.0%	-		
15	Ombitasvir, paritaprevir, dasabuvir (Holkira Pak)	2014													11	1.9%	1.5%	-		
16	Rilpivirine (Complera)	2011													9	1.8%	1.2%	2.1		
17	Golimumab (Simponi) B	2009													10	1.8%	3.5%	0.6		
18	Daclatasvir (Daklinza)	2014													0	1.7%	0.1%	-		
19	Enzalutamide (Xtandi) C	2012													10	1.6%	0.9%	1.9		
20	Ibrutinib (Imbruvica) C,O	2013													5	1.5%	1.3%	1.9		
21	Dexlansoprazole (Dexilant)	2009						Not reviewed							2	1.5%	1.8%	0.2		
22	Linagliptin (Trajenta)	2011													11	1.5%	1.7%	0.6		
23	Pertuzumab (Perjeta) B,C	2012													10	1.4%	2.0%	1.5		
24	Aflibercept (Eylea) B	2011													6	1.3%	5.2%	0.5		
25	Teriflunomide (Aubagio)	2012													9	1.3%	1.7%	0.6		
26	Saxagliptin (Onglyza)	2009													11	1.2%	2.5%	0.4		
27	Ipilimumab (Yervoy) B,C,O	2011													10	1.1%	1.3%	1.1		
28	Dapagliflozin (Forxiga)	2012													1	0.9%	0.9%	1.0		
29	Apremilast (Otezla) O	2014		**											1	0.9%	0.3%	3.4		
30	Linacotide (Constella)	2012													0	0.8%	0.2%	3.1		

Harvoni and Sovaldi, new DAA drugs offering a curative treatment for hepatitis C, were the two top-selling NASs launched during the study period. Together, these two drugs accounted for 21.6% of all NAS sales and 6.4% of all brand-name drug sales in Canada and the PMPRB7. In Canada, these drugs accounted for 28.8% of all NAS sales and 4.9% of all brand-name drug sales.

Of the top 30 NASs, six were oncology drugs and eight were biologics, accounting for 9.6% and 16.6%, respectively, of the total NAS sales in the countries analyzed.

The table also indicates the level of therapeutic improvement of each drug, as determined by the PMPRB as part of its current price review process. Of the 30 top-selling NASs, four were deemed to offer a *substantial improvement* over drugs already on the market, while seven offered a *moderate improvement* level. Two drugs were not reported in the 2015 PMPRB Annual Report, and the rest of the 17 drugs, which accounted for 47.0% of the NAS sales, were deemed to offer *slight or no improvement* over existing drugs7.

Recommendations from the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR) are also reported in Table A4.1. Note that there are more recommendations than drugs reviewed, given that some drugs are considered for more than one indication. The majority of the drugs reviewed by the CDR (17 out of 23) received a recommendation of *list with criteria/condition*. A few drugs received the recommendations of *list* (1), *do not list* (4), and *do not list at the submitted price* (3). The six oncology drugs reviewed by pCODR received a recommendation for funding on the condition that their cost effectiveness was improved to an acceptable level. One of these drugs also received a *funding* recommendation for one of its indications, while another drug also received a *does not recommend funding* for one of its indications.

The table also indicates the number of public formularies in which each NAS is listed8. The results suggest that the majority of top-selling NASs (22 of the 30 NASs) are generally reimbursed by most (6 or more) of the Canadian public drug plans.

An analysis of the consumption rates for the top-selling NASs suggests that Canada's use of these drugs, relative to its population, is comparable to

the use in foreign markets. Table A4.1 reports the foreign-to-Canadian rate of drug consumption per capita at drug level for Q4-2015.

Consumption rates are determined based on the quantity of units of drugs sold in a country and are reported on a per capita basis. The results are presented as a ratio, with the consumption rate in Canada set equal to one, and the rates in other countries determined relative to this measure. A ratio above one indicates correspondingly higher consumption rates in foreign markets and may flag drugs that have growth potential in Canada. A ratio below one indicates correspondingly lower consumption rates in foreign markets and may signal greater market penetration in Canada. This may be due to the timing of launch (e.g., Stelara was first launched in Canada), as well as the demographic and disease profiles of the population, and the use of other drugs.

The average foreign-to-Canadian ratio for the top 30 drugs is 0.9, suggesting that the consumption of NASs in foreign markets was, on average, 10% lower than in Canada.

The results of this table can be interpreted as follows: Harvoni had the highest sales share in Q4-2015, accounting for 16.1% of the total NAS sales in all countries analyzed and 22.3% of NAS sales in Canada. It was granted a *slight or no improvement* level by the PMPRB therapeutic review over its comparators (Sovaldi and Galexos) and was recommended to *be listed with clinical criteria and/or conditions* by the CDR. The pan-Canadian Pharmaceutical Alliance (pCPA) completed the price negotiation for this product, which is being reimbursed by almost all (10 out of 11) Canadian public drug plans. The foreign-to-Canadian consumption ratio is 1.0, suggesting that consumption rates in Canada are on par with those in the PMPRB7.

In terms of the launch sequence, the United States was typically the country of first introduction for the 30 top-selling NASs (Table A4.2). Twenty-three of the top 30 drugs were first launched in the United States, while Sweden was a distant second with six of the top-sellers first launched. Canada was the first country to launch one of the top-selling drugs, Stelara, and launched the novel hepatitis C drug Harvoni within the same month as the United States. Canada was the second country of launch for approximately one third of the 30 top-selling drugs.

7. These include two NASs that are listed as Category 3 drugs. This is an older designation used by the PMPRB to denote a drug that provides moderate, little or no therapeutic advantage over comparable existing drugs.

8. The formulary information reported does not distinguish between full listing and listing with criteria.

TABLE A4.2 Launch sequence for the 30 top-selling NASs, Canada and PMPRB7*, Q4-2015

Rank	NAS (product name)	Year of first launch	Launch order (lag in months)								Year of Canadian launch	Canadian lag (months)	Foreign median lag (months)
			1 st	2 nd	3 rd	4 th	5 th	6 th	7 th	8 th			
1	Ledipasvir, sofosbuvir (Harvoni)	2014	US	CAN (0)	SWE (1)	GER (2)	UK (2)	FRA (2)	SWI (3)	ITA (7)	2014	0	2
2	Sofosbuvir (Sovaldi)	2013	US	UK (0)	SWE (1)	FRA (1)	CAN (1)	GER (2)	SWI (4)	ITA (12)	2014	1	2
3	Liraglutide (Victoza)	2009	SWE	GER (1)	UK (1)	SWI (7)	US (8)	FRA (10)	CAN (11)	ITA (14)	2010	11	8
4	Fingolimod (Gilenya)	2010	US	ITA (1)	SWI (5)	SWE (6)	CAN (7)	GER (7)	UK (7)	FRA (15)	2011	7	7
5	Ustekinumab (Stelara)	2009	CAN	GER (1)	UK (1)	SWE (3)	US (8)	ITA (13)	FRA (15)	SWI (25)	2009	0	8
6	Elvitegravir, cobicistat (Stribild)	2012	US	CAN (3)	SWE (8)	GER (9)	UK (9)	SWI (14)	FRA (17)	ITA (19)	2012	3	12
7	Denosumab (Prolia)	2010	SWE	UK (1)	US (1)	GER (2)	CAN (3)	SWI (4)	ITA (17)	FRA (20)	2010	3	3
8	Apixaban (Eliquis)	2011	SWE	GER (1)	UK (4)	SWI (5)	CAN (9)	ITA (12)	FRA (14)	US (20)	2012	9	9
9	Dolutegravir (Triumeq)	2013	US	CAN (3)	SWE (5)	UK (5)	GER (6)	SWI (9)	ITA (14)	FRA (15)	2013	3	8
10	Canagliflozin (Invokana)	2013	US	SWE (7)	UK (9)	SWI (10)	GER (11)	CAN (13)	ITA (18)		2014	13	10
11	Lurasidone (Latuda)	2011	US	CAN (20)	SWI (32)	UK (42)	GER (46)				2012	20	42
12	Paliperidone palmitate (Invega Sustenna)	2009	US	CAN (12)	SWE (19)	UK (20)	SWI (20)	GER (21)	ITA (31)	FRA (41)	2010	12	21
13	Abiraterone acetate (Zytiga)	2011	US	CAN (3)	SWE (4)	UK (4)	GER (5)	SWI (5)	ITA (6)	FRA (13)	2011	3	5
14	Nivolumab (Opdivo)	2014	US	ITA (5)	UK (5)	SWE (6)	GER (7)	FRA (8)	CAN (11)	SWI (12)	2015	11	7
15	Ombitasvir, paritaprevir, dasabuvir (Holkira Pak)	2014	US	CAN (1)	SWE (1)	UK (1)	FRA (2)	GER (2)	SWI (2)	ITA (5)	2015	1	2
16	Rilpivirine (Complera)	2011	US	CAN (4)	SWE (5)	UK (6)	GER (7)	FRA (15)	ITA (20)	SWI (22)	2011	4	11
17	Golimumab (Simponi)	2009	US	CAN (2)	SWE (6)	GER (7)	ITA (18)	SWI (18)	UK (18)	FRA (41)	2009	2	18
18	Daclatasvir (Daklinza)	2014	SWE	GER (1)	UK (1)	ITA (2)	SWI (11)	US (11)	CAN (13)		2015	13	2
19	Enzalutamide (Xtandi)	2012	US	CAN (9)	SWE (9)	UK (9)	GER (12)	SWI (15)	FRA (17)	ITA (18)	2013	9	14
20	Ibrutinib (Imbruvica)	2013	US	SWE (11)	UK (11)	CAN (12)	GER (12)	FRA (12)	SWI (15)	ITA (21)	2014	12	12
21	Dexlansoprazole (Dexilant)	2009	US	CAN (18)	GER (62)	SWI (65)					2010	18	64
22	Linagliptin (Trajenta)	2011	US	SWE (3)	CAN (4)	GER (5)	UK (5)	ITA (12)	SWI (12)		2011	4	5
23	Pertuzumab (Perjeta)	2012	US	SWI (2)	ITA (4)	SWE (9)	UK (9)	GER (10)	CAN (11)	FRA (16)	2013	11	9
24	Aflibercept (Eylea)	2011	US	SWE (11)	SWI (11)	GER (12)	UK (12)	ITA (17)	FRA (23)	CAN (24)	2013	24	12
25	Teriflunomide (Aubagio)	2012	US	SWE (11)	GER (13)	SWI (15)	CAN (16)	UK (17)	ITA (23)	FRA (26)	2014	16	16
26	Saxagliptin (Onglyza)	2009	US	SWE (2)	UK (2)	CAN (3)	GER (3)	SWI (7)	FRA (13)	ITA (13)	2009	3	5
27	Ipilimumab (Yervoy)	2011	US	FRA (3)	SWE (3)	GER (4)	UK (4)	SWI (6)	CAN (7)	ITA (23)	2011	7	4
28	Dapagliflozin (Forxiga)	2012	SWE	GER (11)	UK (11)	US (24)	SWI (34)	CAN (36)	ITA (39)		2015	36	24
29	Apremilast (Otezla)	2014	US	CAN (9)	SWE (9)	GER (10)	UK (10)	SWI (15)			2015	9	10
30	Linacotide (Constella)	2012	SWE	US (1)	UK (4)	GER (6)	SWI (9)	ITA (16)	CAN (18)		2014	18	6

Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales.

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

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.

**TABLE A4.3 Multilateral foreign-to-Canadian price ratios for Canadian new drug launches
Top 30 NASs by sales in Canada and the PMPRB*, Q4-2015**

			Canadian price = 1										Number of countries
			Lower foreign prices		Higher foreign prices								
Rank	NAS (product name, form, strength, volume)	Canadian price (\$)	0.0	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0		
1	Ledipasvir (Harvoni, film-ctd tabs, 90 mg + 400 mg)	782.99			▲◆	×						7	
2	Sofosbuvir (Sovaldi, film-ctd tabs, 400 mg)	639.27			▲◆		×					7	
3	Liraglutide (Victoza, P-F pens, 6 mg/mL, 3 mL)	80.03		▲	■	◆				×		7	
4	Fingolimod (Gilenya, capsules, 500 Y)	86.25		▲	■	◆			×			7	
5	Ustekinumab (Stelara, P-F syrng SC, 90 mg/mL, 1 mL)	4,573.96		▲	■	◆						6	
6	Elvitegravir (Stribild, film-ctd tabs, combi str)	43.56		▲	■	◆		×				7	
7	Denosumab (Prolia, P-F syrng SC, 60 mg/mL, 1 mL)	353.42		▲	■	◆			×			7	
8	Apixaban (Eliquis, film-ctd tabs, 5 mg)	1.63		▲	■	◆						7	
9	Dolutegravir (Triumeq, film-ctd tabs, 600 mg + 50 mg + 300 mg)	40.82		▲	■	◆		×				6	
10	Canagliflozin (Invokana, film-ctd tabs, 300 mg)	2.68	▲		■	◆						6	
11	Lurasidone (Latuda, film-ctd tabs, 40 mg)	4.14				▲						2	
12	Paliperidone palmitate (Invega Sustenna, P-F syr IM RT, 100 mg/mL, NA)	530.82										0	
13	Abiraterone acetate (Zytiga, tablets, 250 mg)	29.25			▲	■			×			7	
14	Nivolumab (Opdivo, infus.via/bot., 10 mg/mL, 10 mL)	1,893.00			▲◆	×						7	
15	Ombitasvir, paritaprevir, dasabuvir (Holkira Pak, film-ctd tabs, combi str)	11,579.24										0	
16	Rilpivirine (Complera, film-ctd tabs, 200 mg + 25 mg + 245 mg)	39.66		▲	■	◆		×				7	
17	Golimumab (Simponi, prefil autoinj, 100 mg/mL, 0.5 mL)	1,512.25		▲	■	◆			×			7	
18	Daclatasvir (Daklinza, film-ctd tabs, 60 mg)	433.44			■	◆		×				6	
19	Enzalutamide (Xtandi, capsules, 40 mg)	28.45			▲	■	◆		×			7	
20	Ibrutinib (Imbruvica, capsules, 140 mg)	90.49		▲	■	×						7	
21	Dexlansoprazole (Dexilant, capsules, 60 mg)	0.80				▲						2	
22	Linagliptin (Trajenta, film-ctd tabs, 5 mg)	2.50		▲	■		◆					5	
23	Pertuzumab (Perjeta, Inf. via bottle, 30 mg/mL, 14 mL)	3,132.85			▲	◆	×					7	
24	Aflibercept (Eylea, vial, 40 mg/mL, NA)	1,395.12										0	
25	Teriflunomide (Aubagio, film-ctd tabs, 14 mg)	53.36		▲	■	◆						7	
26	Saxagliptin (Onglyza, film-ctd tabs, 5 mg)	2.60		▲	■	◆						7	
27	Ipilimumab (Yervoy, infus.via/bot., 5 mg/mL, 40 mL)	22,421.81		▲	◆	×						7	
28	Dapagliflozin (Forxiga, film-ctd tabs, 10 mg)	2.66	▲		■	◆						6	
29	Apremilast (Otezla, film-ctd tabs, 30 mg)	19.37		▲	■	◆		×				5	
30	Linacotide (Constella, capsules, 145 Y)	3.36										0	

Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales.

Prices reported are manufacturer list prices.

For presentation purposes, the scale reporting the foreign-to-Canadian price ratio was limited to 4.0; observations higher than this value are not depicted here.

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

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.

◆	Average
■	Median
▲	Minimum
×	Maximum



A close look at the price of the top-selling new drugs substantiates the findings from Section A3, namely that at introduction, Canadian drugs prices are in line with the median foreign levels, with a few notable exceptions. Table A4.3 reports the multi-lateral foreign-to-Canadian price differentials for the 30 top-selling NASs at form and strength level. The United States had the maximum price for all of the 30 top-selling NASs, while France had the lowest price for 11 of these drugs.

A few top-selling new drugs have lower foreign median prices than in Canada. These include Onglyza and Trajenta, for which the median foreign prices in Q4-2015 were 0.74 and 0.83, respectively, of the Canadian level. Appendix II provides bilateral price ratios for the 30 top-selling NASs.

Appendix III focuses a lens on the NASs launched in international markets in 2014 and authorized for sale in Canada as of Q4-2015.

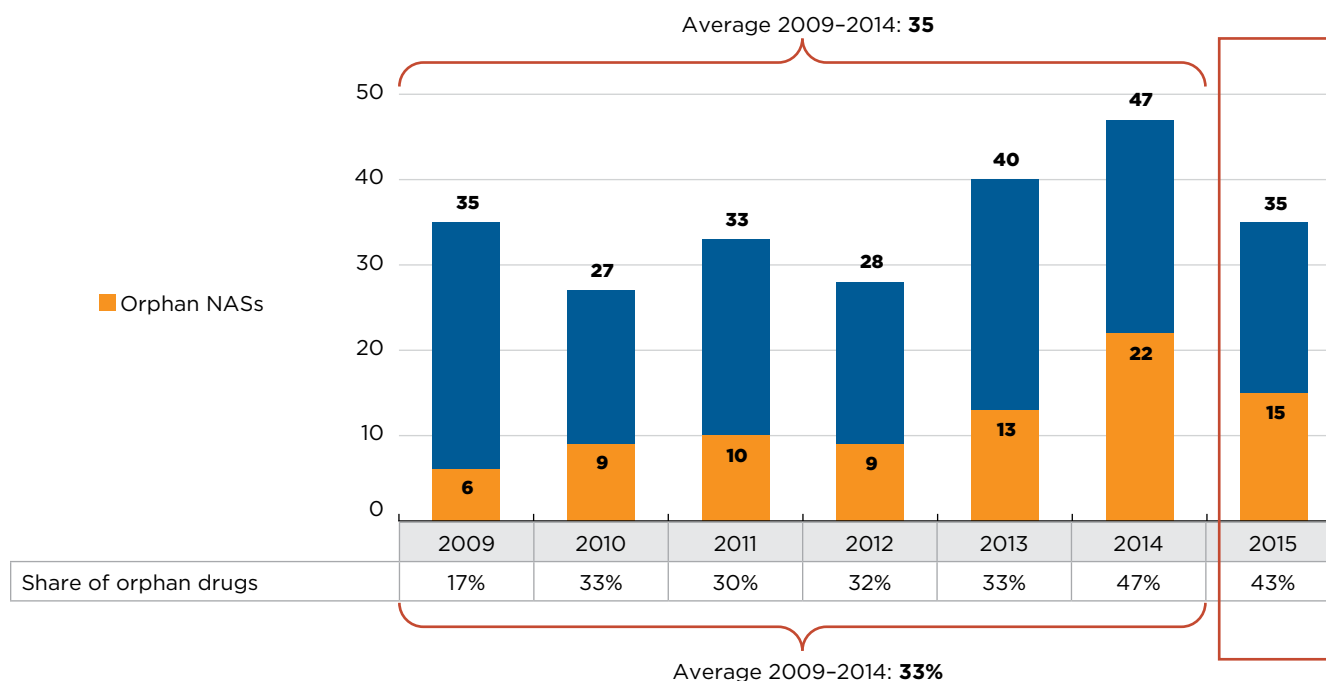
B MEDS ENTRY WATCH, 2015

Thirty-five NASs were launched in the foreign markets analyzed in 2015, consistent with the average in recent years. The United States was the country of first launch for most of these drugs (28). Many of the 2015 NASs were specialty drugs, including biologics (14), orphan drugs (15) and/or oncology products (14). More than half (20) of the NASs were available in Canada by the end of 2016. An analysis of these products suggests that the unit prices of most NASs are in the hundreds of dollars, with the most expensive orphan drugs costing thousands of dollars.

In terms of the number of new drugs launched, 2015 was a typical year; with 35 launches it was consistent with the average over the previous years, but lower than in 2014 (47) – Figure B.1. The share of orphan

drugs in 2015 (43%) was higher than the average from 2009 to 2014 (33%), but just below the 2014 share of 47%.

FIGURE B1 Number of NASs by year of launch
Canada and the PMPRB*, 2009 to 2015



Note: New active substances (NASs) launched between 2009 and 2015. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales.

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

Source: MIDAS™ Database, 2009 to 2015, IMS AG. All rights reserved.

**TABLE B1 NASs launched in Canada and the PMPRB7* in 2015 and corresponding share of sales, Q4-2015**

NAS (product name)	Anatomical Classification	Country of first launch	Month of first launch	Canadian availability [†]	Share of Canadian and PMPRB7 sales, Q4-2015							
					CAN	FRA	GER	ITA	SWE	SWI	UK	US
Edoxaban (Lixiana)	B1-Antithrombotic agents	US	Jan	Nov-16 [‡]			32.2%			3.6%	0.2%	63.9%
Secukinumab (Cosentyx) ^B	D5-Nonsteroidal products for inflammatory skin disorders	SWE	Jan	Apr-15	3.8%		11.1%		0.5%	1.1%	0.8%	82.7%
Susoctocog alfa (Obizur) ^{B,O}	B2-Blood coagulation system, other products	US	Jan	Nov-16								
Suvorexant (Belsomra)	N5-Psycholeptics	US	Jan									100%
Palbociclib (Ibrance) ^C	L1-Antineoplastics	US	Feb	Apr-16								100%
Vaccine, human papillomavirus type-6,11,16,18,31,33,45,52,58 (Gardasil 9) ^B	J7-Vaccines	US	Feb	Mar-15	1.3%							98.7%
Cangrelor (Kengreal)	B1-Antithrombotic agents	SWE	Mar				1.7%		2.8%		0.4%	95.1%
Panobinostat (Farydak) ^{O,C}	L1-Antineoplastics	US	Mar				25.9%		0.3%		0.7%	73.2%
Avibactam (Avycaz)	J1-Systemic antibacterials	US	Apr									100%
Isavuconazonium (Cresemba) ^O	J2-Systemic agents for fungal infections	US	Apr				<0.1%					100%
Lenvatinib (Lenvima) ^{O,C}	L1-Antineoplastics	FRA	Apr	Mar-16	<0.1%	89.4%			2.4%	5.9%	1.8%	0.5%
Safinamide (Xadago)	N4-Anti-parkinson drugs	GER	May				99.8%			0.2%		
Alirocumab (Praluent) ^B	C10-Lipid-regulating/anti-atheroma preparations	US	July	Apr-16			8.3%		<0.1%		0.1%	91.5%
Brexipiprazole (Rexulti)	N5-Psycholeptics	US	July									100%
Dinutuximab (Unituxin) ^{B,O,C}	L1-Antineoplastics	US	July									100%
Evolocumab (Repatha) ^{B,O}	C10-Lipid-regulating/anti-atheroma preparations	SWE	July	Sep-15	0.8%		16.4%		0.4%		0.3%	82.1%
Lumacaftor (Orkambi) ^O	R7-Other respiratory system products	US	July	Jan-16			3.3%					96.7%
Sacubitril (Entresto)	C9-Agents acting on the renin-angiotensin system	US	July	Nov-15	0.6%					1.3%	<0.1%	98.1%
Cobimetinib (Cotellic) ^{O,C}	L1-Antineoplastics	SWI	Sept	Apr-16			37.4%			33.2%		29.4%
Asfotase alfa (Strensiq) ^{B,O}	A16-Other alimentary tract and metabolism products	GER	Oct	Oct-15			82.6%				6.7%	10.8%
Eluxadoline (Viberzi)	A3-Functional gastro-intestinal disorder drugs	US	Oct									100%
Flibanserin (Addyi)	G2-Other gynaecologicals	US	Oct									100%
Idarucizumab (Praxbind) ^B	V3-All other therapeutic products	US	Oct	May-16					1.0%			99.0%
Sonidegib (Odomzo) ^{B,C}	L1-Antineoplastics	US	Oct									100%
Tipiracil (Lonsurf) ^C	L1-Antineoplastics	US	Oct									100%
Daratumumab (Darzalex) ^{B,O,C}	L1-Antineoplastics	US	Nov	Jul-16								100%
Elotuzumab (Empliciti) ^{B,O,C}	L1-Antineoplastics	US	Nov	Jun-16 [‡]								100%
Ixazomib (Ninlaro) ^{O,C}	L1-Antineoplastics	US	Nov	Sep-16								100%
Mepolizumab (Nucala) ^{B,O}	R3-Anti-asthma and chronic obstructive pulmonary disease	US	Nov	Mar-16								100%
Necitumumab (Portrazza) ^{B,C}	L1-Antineoplastics	US	Nov									100%
Osimertinib (Tagrisso) ^{O,C}	L1-Antineoplastics	US	Nov	Jul-16								100%
Rolapitant (Varubi)	A4-Antiemetics and antinauseants	US	Nov									100%
Talimogene laherparepvec (Imlygic) ^{B,C}	L1-Antineoplastics	US	Nov									100%
Tenofovir alafenamide (Genvoya)	J5-Antivirals for systemic use	US	Nov	Feb-16					0.1%		<0.1%	99.9%
Alectinib (Alecensaro) ^{O,C}	L1-Antineoplastics	US	Dec	Oct-16								100%

Note: A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For the Canadian market, Health Canada's Drug Product Database and the Notice of Compliance database were cross-referenced to ensure that all NASs authorized for sale in Canada were accurately identified. Sales are based on manufacturer list prices.

NASs are identified as biologic (B), cancer (C) and/or orphan (O) drugs when appropriate.

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

[†] Available in Canada as of December 31, 2016.

[‡] Notice of Compliance issued, but not yet marketed.

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.

TABLE B2 Q4-2015 prices (CAD\$) for NASs launched in 2015 in Canada and PMPRB7*

NAS (product, form, strength, volume)	CAN	FRA	GER	ITA	SWE	SWI	UK	US
Edoxaban (Lixiana, film-ctd tabs, 60 mg)			3.22			3.74	3.72	11.58
Secukinumab (Cosentyx, prefil autoinj, 150 mg/mL, 1 mL) ^B	816.58		1,122.25		868.59	1,104.10	1,079.76	2,355.78
Susoctocog alfa (Obizur, FPB vial dry, 500 IU) ^{B,O}			No sales Q4-2015					
Suvorexant (Belsomra, film-ctd tabs, 10 mg)								11.08
Palbociclib (Ibrance, capsules, 125 mg) ^C								597.39
Vaccine, human papillomavirus type-6,11,16,18,31,33,45,52,58 (Gardasil 9, comb. str.) ^B	157.83							207.06
Cangrelor (Kengrexal, vial dry, 50 mg)			511.33		498.53		443.04	945.42
Panobinostat (Farydak, capsules, 20 mg) ^{O,C}			1,446.08		949.39		1,375.20	1,466.49
Avibactam (Avycaz, inf dry bottle, 500 mg + 2 g)								359.71
Isavuconazonium (Cresamba, capsules, 186 mg) ^O								85.92
Lenvatinib (Lenvima, capsules, 10 mg) ^{O,C}			104.70		82.31	93.30	84.89	
Safinamide (Xadago, film-ctd tabs, 50 mg)			7.81			8.03		
Alirocumab (Praluent, prefil autoinj, 75 mg/mL, 1 mL) ^B			422.50				297.72	694.31
Brexiprazole (Rexulti, tablets, 2 mg)								36.64
Dinutuximab (Unituxin, infus.via/bot., 3.5 mg/mL, 5 mL) ^{B,O,C}								9,903.46
Evolocumab (Repatha, prefil autoinj, 140 mg/mL, 1 mL) ^{B,O}	278.62		422.23		306.28		301.39	671.04
Lumacaftor (Orkambi, film-ctd tabs, 125 mg + 200 mg) ^O			161.99					196.56
Sacubitril (Entresto, film-ctd tabs, 48.6 mg + 51.4 mg)	3.75						2.93	
Cobimetinib (Cotellic, film-ctd tabs, 20 mg) ^{O,C}			134.47			118.12		123.42
Asfotase alfa (Strensiq, vial SC, 40 mg/mL, 0.7 mL) ^{B,O}			3,431.43					
Eluxadoline (Viberzi, coated tablets, 100 mg)								12.33
Flibanserin (Addyi, film-ctd tabs, 100 mg)								33.74
Idarucizumab (Praxbind, vial IV, 50 mg/mL, 50 mL) ^B								2,211.89
Sonidegib (Odomzo, capsules, 200 mg) ^{B,C}								437.70
Tipiracil (Lonsurf, film-ctd tabs, 8.19 mg + 15 mg) ^C								177.62
Daratumumab (Darzalex, infus.via/bot., 20 mg/mL, 20 mL) ^{B,O,C}								2,228.76
Elotuzumab (Empliciti, inf dry bottle, 300 mg) ^{B,O,C}								2,225.87
Ixazomib (Ninlaro, capsules, 4 mg) ^{O,C}								3,196.67
Mepolizumab (Nucala, vial dry, 100 mg) ^{B,O}								3,214.67
Necitumumab (Portrazza, infus.via/bot., 16 mg/mL, 50 mL) ^{B,C}								5,231.23
Osimertinib (Tagrisso, film-ctd tabs, 80 mg) ^{O,C}								546.32
Rolapitant (Varubi, film-ctd tabs, 90 mg)								278.20
Talimogene laherparepvec (Imlygic, vial, 1M/mL, 1 mL) ^{B,C}								3,036.21
Tenofovir alafenamide (Genvoya, film-ctd tabs, combi str)					46.59		51.96	105.44
Alectinib (Alecensaro, capsules, 150 mg) ^{O,C}								66.98

Note: This table reports manufacturer list prices. For some recently launched NASs, price information may not yet be available in MIDAS™.

NASs are identified as biologic (B), cancer (C) and/or orphan (O) drugs when appropriate.

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

† Authorized for sale in Canada as of December 31, 2016.

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.



Table B1 lists the NASs launched in Canada and the PMPRB7 in 2015. The table also reports the country of first launch for each NAS, and indicates whether it was available in Canada. The share of sales for Q4-2015 is reported for countries with available sales. Note that this information reflects the early uptake and availability of these products in emerging markets.

Table B2 reports the prices available as of Q4-2015 for the NASs launched in Canada and the PMPRB7 in 2015. The prices are reported for the highest selling form and strength of each drug at the time of the analysis. Note that for some recently launched NASs, price information may not yet be available in MIDAS™.

The second edition of the *Meds Entry Watch* will provide a more detailed analysis of the NASs launched in 2015, including drug-level information related to the PMPRB level of therapeutic improvement and recommendations from the Common Drug Review and the pan-Canadian Oncology Drug Review, as well as the status of public reimbursement and pan-Canadian Pharmaceutical Alliance price negotiations. The international launch sequence, lag time and an international price comparison will be reported for NASs launched in 2015, which can be assessed against the benchmark retrospective analysis for the 2009–2014 period provided in Section A of this report.



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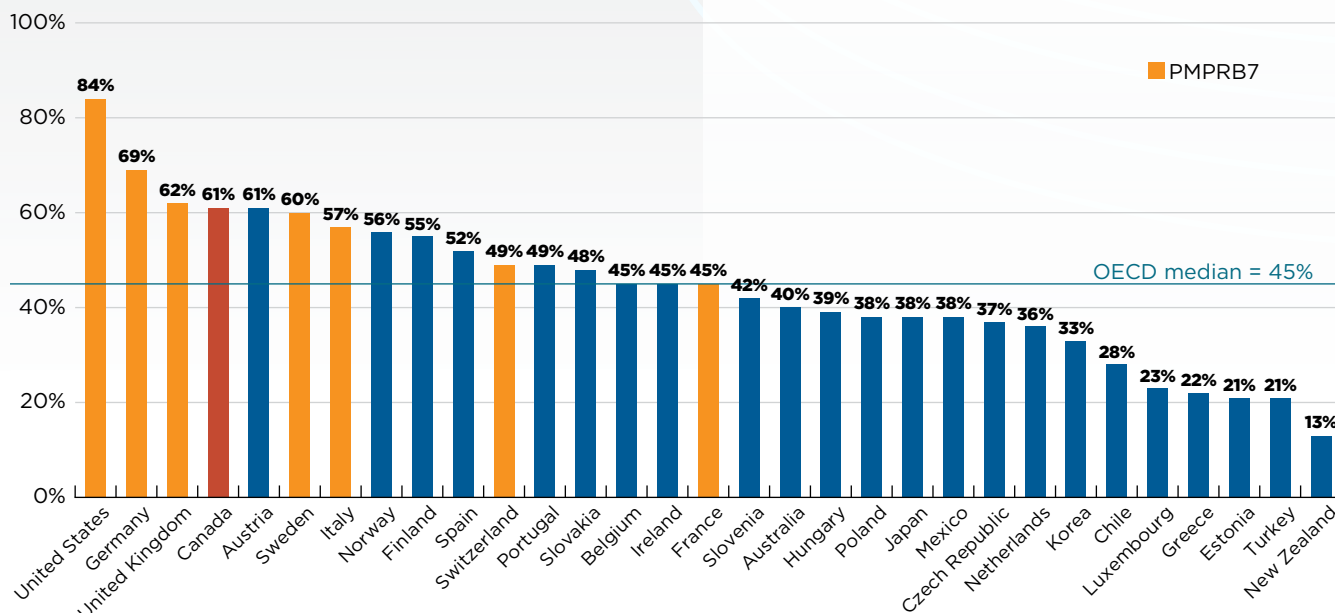
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APPENDICES

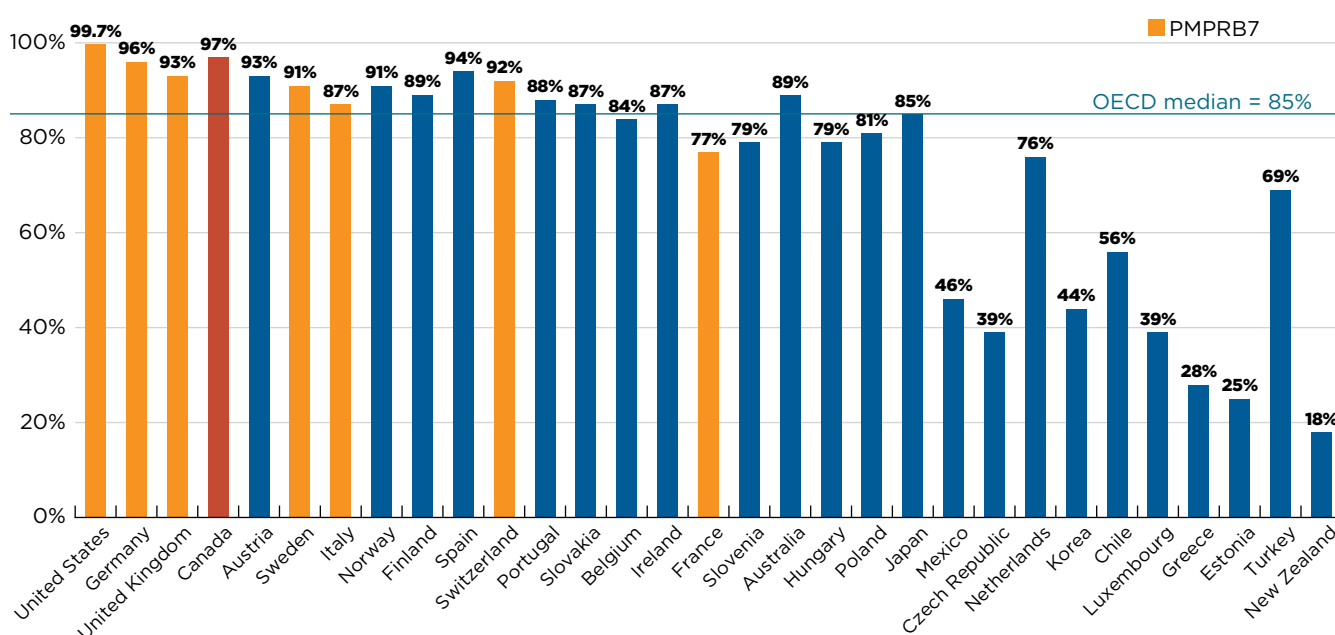
Appendix I: NASs launched in OECD countries, 2009-2014

FIGURE I.1 Share of NASs launched by OECD country, Q4-2015



Note: New active substances (NASs) launched between 2009 and 2014 in Canada and the PMPRB7. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For the Canadian market, Health Canada's Drug Product Database and the Notice of Compliance database were cross-referenced to ensure that all NASs authorized for sale in Canada were accurately identified. Prices reported are manufacturer list prices. Source: MIDAS™ Database, October-December 2015, IMS AG. All rights reserved.

FIGURE I.2 Share of NAS sales* by OECD country, Q4-2015



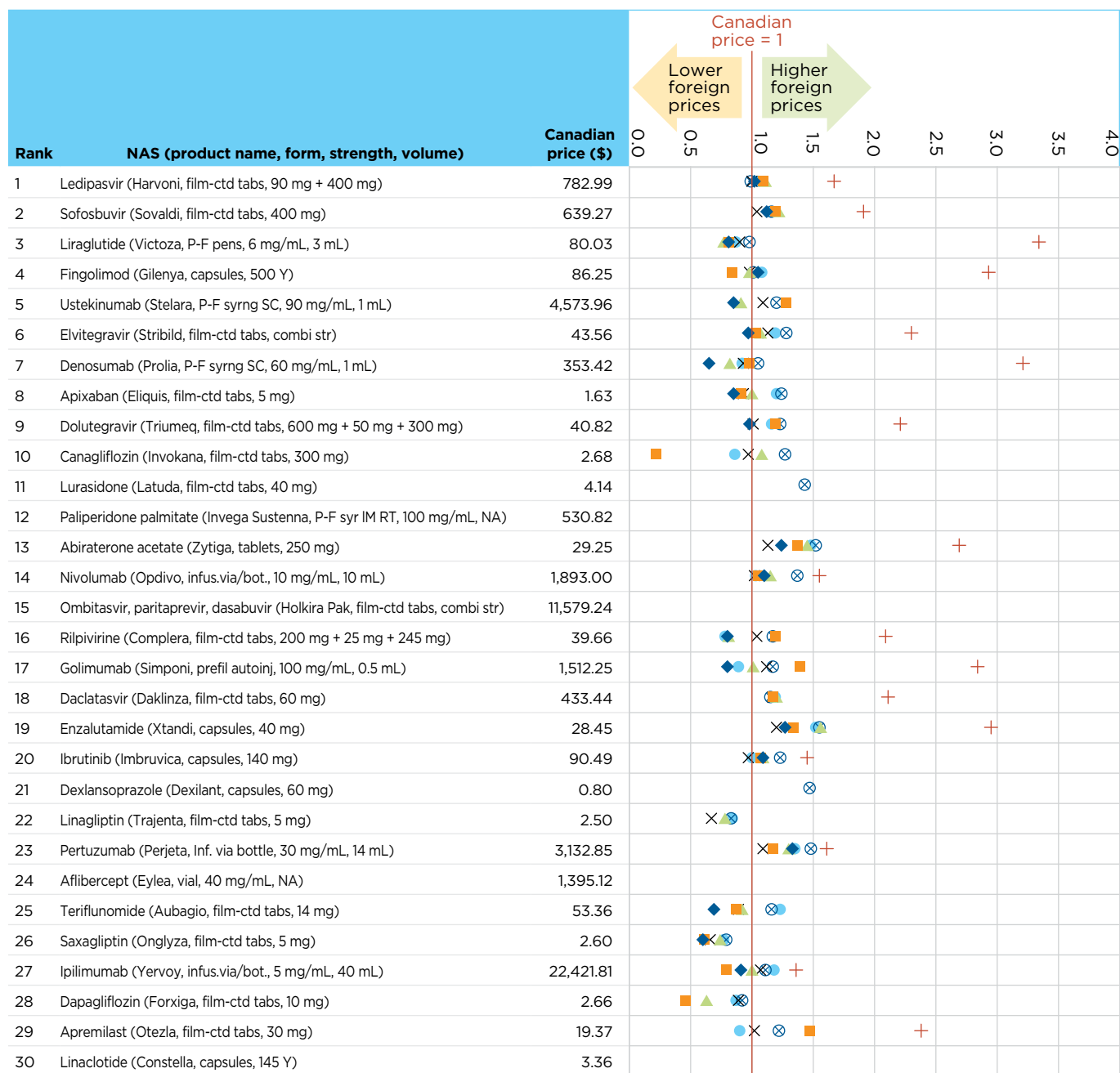
Note: New active substances (NASs) launched between 2009 and 2014 in Canada and the PMPRB7. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For the Canadian market, Health Canada's Drug Product Database and the Notice of Compliance database were cross-referenced to ensure that all NASs authorized for sale in Canada were accurately identified. Prices reported are manufacturer list prices.

* Sales of all OECD countries.

Source: MIDAS™ Database, October-December 2015, IMS AG. All rights reserved.

Appendix II: Bilateral price comparison of top-selling NASSs, 2009-2014

TABLE II.1 Bilateral foreign-to-Canadian price ratios for NASSs launched in Canada
Top 30 NASSs by Canadian and PMPRB* sales, Q4-2015



Note: New active substances (NASSs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For this analysis, launches in the Canadian market were solely based on available MIDAS™ sales.

For presentation purposes, the scale reporting the foreign-to-Canadian price ratio was limited to 4.0; observations higher than this value are not depicted here.

Prices reported are manufacturer list prices.

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

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.





Appendix III: 2014 NASs available in Canada as of Q4-2015

This appendix focuses on the 28 NASs launched in international markets in 2014 that were authorized for sale in Canada as of Q4-2015.

TABLE III.1 NASs launched in 2014 in Canada and the PMPRB*, and authorized for sale in Canada as of Q4-2015

NAS (product name)	Anatomical Classification	Country of first launch	Share of Canadian and PMPRB sales	Share of Canadian and PMPRB sales, Q4-2015							
				CAN	FRA	GER	ITA	SWE	SWI	UK	US
Ledipasvir, sofosbuvir (Harvoni)	J5-Antivirals for systemic use	US	16.1%	3.8%	2.4%	3.8%	8.7%	0.6%	0.5%	1.6%	78.7%
Nivolumab (Opdivo) ^{B,O}	L1-Antineoplastics	US	2.0%	<0.1%	8.6%	4.5%	0.3%	0.4%	<0.1%	0.3%	85.8%
Ombitasvir, paritaprevir, dasabuvir (Holkira Pak)	J5-Antivirals for systemic use	US	1.9%	2.2%	3.1%	9.4%	34.2%	0.4%	1.4%	1.7%	47.6%
Daclatasvir (Daklinza)	J5-Antivirals for systemic use	SWE	1.7%	0.1%		7.3%	29.5%	2.4%	1.4%	3.9%	55.4%
Apremilast (Otezla) ^O	L4-Immunosuppressants	US	0.9%	0.9%		3.8%		0.5%	0.7%	0.9%	93.1%
Vedolizumab (Entyvio) ^B	L4-Immunosuppressants	SWE	0.7%	1.1%	5.5%	11.0%		1.6%	1.5%	3.7%	75.6%
Pembrolizumab (Keytruda) ^{B,O}	L1-Antineoplastics	US	0.7%	0.5%	11.1%	11.0%	0.1%	0.2%	1.3%	2.4%	73.5%
Peginterferon beta-1a (Plegridy) ^B	L3-Immunostimulants	SWE	0.6%	<0.1%	<0.1%	18.3%	0.8%	0.4%	0.2%	0.9%	79.3%
Dulaglutide (Trulicity) ^B	A10-Drugs used in diabetes	US	0.5%			11.3%		0.2%	0.4%	0.3%	87.8%
Empagliflozin (Jardiance)	A10-Drugs used in diabetes	SWE	0.5%	0.9%		4.9%	1.1%	0.2%	0.6%	0.8%	91.4%
Nintedanib (Ofev) ^O	L1-Antineoplastics	US	0.5%	0.5%	1.3%	11.5%		0.2%	0.4%	4.8%	81.2%
Efinaconazole (Jublia)	D1-Antifungals, dermatological	US	0.4%	4.2%							95.8%
Ramucirumab (Cyramza) ^{B,O}	L1-Antineoplastics	US	0.3%	<0.1%		7.7%	0.5%	<0.1%	<0.1%	0.3%	91.5%
Umeclidinium bromide (Incruse Ellipta)	R3-Anti-asthma and chronic obstructive pulmonary disease products	US	0.2%	1.3%		4.7%	1.0%	0.1%	0.9%	5.6%	86.3%
Albiglutide (Eperzan) ^B	A10-Drugs used in diabetes	US	0.2%	†		<0.1%					100%
Idelalisib (Zydelig) ^O	L1-Antineoplastics	FRA	0.2%	0.3%	10.9%	17.2%	2.8%	0.9%	2.5%	8.0%	57.5%
Efmoroctocog alfa (Eloctate) ^{B,O}	B2-Blood coagulation system, other products	US	0.1%	†							100%
Ceritinib (Zykadia) ^O	L1-Antineoplastics	US	0.1%	1.9%	10.6%	8.6%		1.0%		0.7%	77.2%
Elosulfase alfa (Vimizim) ^{B,O}	A16-Other alimentary tract and metabolism products	US	0.1%		20.0%	6.6%		0.5%			72.9%
Blinatumomab (Blincyto) ^{B,O}	L1-Antineoplastics	US	0.1%	†		4.5%					95.5%
Naloxegol (Movantik)	A6-Drugs for constipation and bowel cleansers	SWE	0.1%	0.3%		1.3%		0.2%		0.1%	98.2%
Eftrenonacog alfa (Alprolix) ^{B,O}	B2-Blood coagulation system, other products	US	0.1%								100%
Ceftolozane (Zerbaxa)	J1-Systemic antibacterials	US	<0.1%	†		0.7%		<0.1%		0.6%	98.6%
Tedizolid (Sivextro)	J1-Systemic antibacterials	US	<0.1%	†				0.2%		0.7%	99.1%
Siltuximab (Sylvant) ^{B,O}	L1-Antineoplastics	US	<0.1%			6.9%		0.5%		2.4%	90.2%
Simoctocog alfa (Nuwiq) ^B	B2-Blood coagulation system, other products	SWE	<0.1%			15.4%	63.3%	3.2%		18.1%	
Ambrosia psilostachya (Ragwitek) ^B	V1-Allergens	US	<0.1%	21.8%							78.2%
Catridecacog (Tretten) ^B	B2-Blood coagulation system, other products	ITA	<0.1%				100%				
			28.0%								

Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For the Canadian market, Health Canada's Drug Product Database and the Notice of Compliance database were cross-referenced to ensure that all NASs authorized for sale in Canada were accurately identified.

Sales are based on manufacturer list prices.

NASs are identified as biologic (B) and/or orphan (O) drugs when appropriate.

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

† Notice of Compliance issued, but not yet marketed.

Source: MIDAS™ Database, October–December 2015, IMS AG. All rights reserved.

TABLE III.2 Prices (CAD\$) for NASs launched in 2014 in Canada and the PMPRB7*, and authorized for sale in Canada as of Q4-2015

NAS (product, form, strength, volume)	CAN	FRA	GER	ITA	SWE	SWI	UK	US
Ledipasvir (Harvoni, film-ctd tabs, 90 mg + 400 mg)	783.05	800.99	851.05	862.00	781.96	775.37	822.54	1,362.75
Nivolumab (Opdivo, infus.via/bot., 10 mg/mL, 10 mL)	1,893.00	2,080.41	1,995.07	2,174.24	1,936.36	2,595.67	1,943.75	2,932.26
Ombitasvir, paritaprevir, dasabuvir (Holkira Pak, film-ctd tabs, combi str)	11,563.49							
Daclatasvir (Daklinza, film-ctd tabs, 60 mg)	433.44		506.29	521.76	505.43	499.06	517.26	912.44
Apremilast (Otezla, film-ctd tabs, 30 mg)	19.37		28.54		19.73	23.71	17.41	46.13
Vedolizumab (Entyvio, inf dry bottle, NA intstr)	3,184.72							
Pembrolizumab (Keytruda, inf dry bottle, 50 mg)	2,245.09	2,607.72	2,490.41	2,900.70	2,526.05	2,852.28	2,330.40	2,633.66
Peginterferon beta-1a (Plegridy, Pf Autoinj Ret, NA, NA)	842.96							
Dulaglutide (Trulicity, P-F pens, 3 mg/mL, 0.5 mL)			45.29		42.24	46.02	34.27	169.46
Empagliflozin (Jardiance, film-ctd tabs, 10 mg)	2.68		2.09	1.86	2.02	2.34	2.32	14.95
Nintedanib (Ofev, capsules, 150 mg)	55.80	51.73	71.18		49.94	69.06	63.54	171.24
Efinacazole (Jublia, liquid.topical, 10%, 6 mL)	10.98							
Ramucirumab (Cyramza, vial IV, 10 mg/mL, 50 mL)	4,107.00							
Umeclidinium bromide (Incruse Ellipta, U-D pwd n-ref, 74.2Y/dose)	2.05				1.49	1.89	1.62	9.82
Albiglutide (Tanzeum, dry P-F pen Rt, 30 mg)								126.71
Idelalisib (Zydelig, film-ctd tabs, 150 mg)	69.52		109.57	97.40	88.46	110.84	92.00	162.85
Efmoroctocog alfa (Eloctate, inf dry bottle, 3K)								2.70
Ceritinib (Zykadia, capsules, 150 mg)	7.14	65.32	71.25		50.21		58.17	114.95
Elosulfase alfa (Vimizim, infus.via/bot., 1 mg/mL, 5 mL)		1,673.55	1,095.00		1,201.55			1,250.67
Blinatumomab (Blincyto, inf dry bottle, 35Y)								4,136.21
Naloxegol (Movantik, film-ctd tabs, 25 mg)	5.98		4.66		3.49		3.26	10.49
Eftrenonacog alfa (Alprolix, inf dry bottle, 3K)								4.53
Ceftolozane (Zerbaxa, inf dry bottle, 1.5 G + 500 mg)								108.81
Tedizolid (Sivextro, film-ctd tabs, 200 mg)					252.55		254.59	354.38
Siltuximab (Sylvant, inf dry bottle, 400 mg)		2,938.57					2,943.58	4,049.73
Simoctocog alfa (Nuwiq, vial dry, 2K)		2,556.63		1,899.21			2,693.69	
Ambrosia psilostachya (Ragwitek, subling tabs)	3.86							10.47
Catridecacog (Novothirteen, vial dry, 2.5K)				294.47				

Note: New active substances (NASs) launched between 2009 and 2014. A NAS was considered to be launched in a particular country once sales data was available in MIDAS™. For the Canadian market, Health Canada's Drug Product Database and the Notice of Compliance database were cross-referenced to ensure that all NASs authorized for sale in Canada were accurately identified.

Prices reported are manufacturer list prices.

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

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