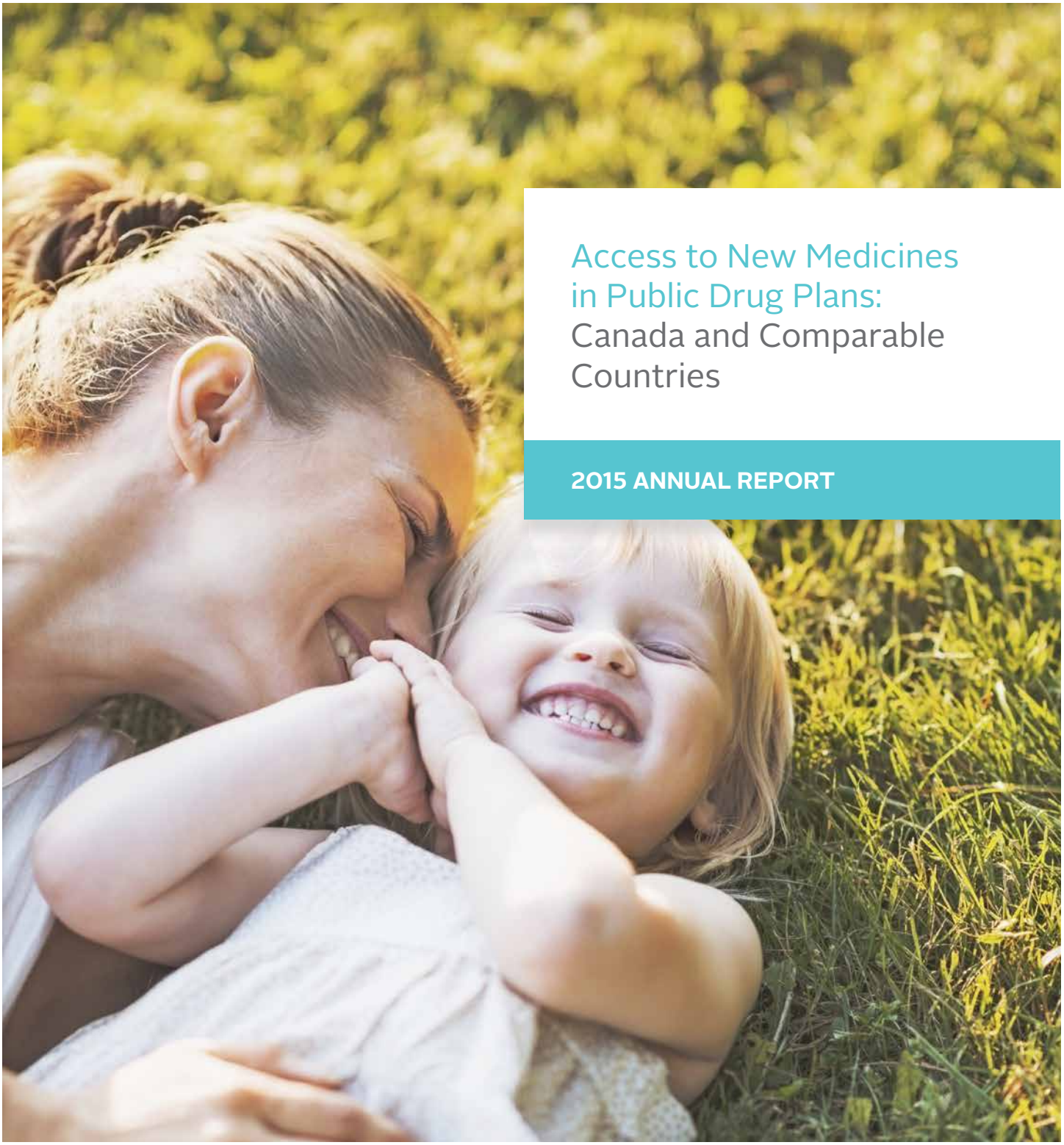
Canada's Research-Based Pharmaceutical Companies
Making Canada Better



Access to New Medicines in Public Drug Plans: Canada and Comparable Countries

2015 ANNUAL REPORT

Prepared with the assistance of:

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A UNIT OF IMS

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Foreword

To the reader,

Canada's Research-Based Pharmaceutical Companies (Rx&D) is pleased to publish the 2015 edition of our annual report comparing coverage for new medicines under public drug plans in Canada and other countries. Since 2006 Rx&D has been examining access to new medicines in a global context in order to gauge the performance of this aspect of Canada's health system. The findings of our report provide important information that has practical implications for the health of Canadians.

According to the World Health Organization (WHO), access to medicines and vaccines are a key component to a quality health system. There is no doubt that innovation in medicines and vaccines has made a significant contribution to improving health outcomes in Canada and around the world. It is therefore important for Canadians to know the state of access to new medicines in our country relative to comparable countries. The goal of this study is to measure access against international benchmarks in order to drive improvements in access here at home.

Rx&D is committed to engaging policy issues from an evidence-based perspective. As the national association representing the voice of Canada's innovative pharmaceutical industry Rx&D wishes to be an active participant in the health policy community and an equal partner at the table for policy decisions affecting access to new medicines and vaccines in Canada. Rx&D represents more than 50 companies investing over $1-billion in R&D annually, fuelling Canada's knowledge-based economy, while contributing over $3-billion overall to Canada's economy.

The research conducted for this report contributes to our larger vision of Canadians living healthier and longer lives through access to innovative medicines and vaccines. Rx&D advocates for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians.

Sincerely,

Russell Williams
President Rx&D

Summary

Innovative medicines make an important contribution to achieving good health. It is therefore important that Canadians are well-informed about the state of access to new medicines in Canada. For this reason, Rx&D annually examines how well Canada's public drug plans are performing on access to new medicines compared to public drug plans in other countries.[1]

In 2014 Rx&D partnered with IMS Health to develop a sophisticated and transparent methodology using data compiled by IMS Health. The analysis examines access to new medicines in the context of the health care systems across a group of countries that are most comparable to Canada in terms of economic development. Specifically, this report compares coverage for new medicines under public drug plans in the wealthiest Organization for Economic Co-operation and Development (OECD) countries (for which complete data were available) according to the drug approvals, commercial launch rates, public reimbursement rates, scope of reimbursement and wait times for reimbursement in each country. In total 18 countries were included.

The analysis compares public drug plan coverage against the particular basket of new medicines approved for sale within each country.

All new molecular entities or new combinations granted national marketing authorization by each country's national regulator between January 1, 2009 and December 31, 2013 were included. Products were considered new if they had not been previously approved or available in that specific country. The new medicines were selected for each country using the applicable, publicly available health regulatory agency approval lists. For example, in Canada, medicines with marketing authorization were identified from the Health Canada Notice of Compliance (NOC) database. In Europe, this list was determined from the pan-country EMA medicines database. While some products in Europe could be granted market authorization directly from a country's own health authority instead of the EMA, they were not included given the infrequent nature of these occurrences.

Reimbursement status was current as of June 2014. In general, most countries make public drug plan reimbursement decisions at the national level. Canada and the US are outliers in that reimbursement decisions are made separately and independently at the federal, provincial, or state level, creating a challenge in assigning a nationally representative measure of access to new medicines. As such, a unique approach was developed for both Canada and the US that weighted the observed drug reimbursement findings in each plan by taking into account the proportion of the population that was eligible for coverage under the public drug plan and aggregating across the country as a whole. In the US, public reimbursement was determined based on Medicare Part B and Part D. Under the US Medicare model private insurers provide coverage within a publicly funded scheme. For this report, coverage for new medicines was measured across the four largest private insurers that combined cover 86% of Medicare lives. For both Canada and the US, reimbursement was measured at three levels: 1) the product was listed in at

1 Data are not currently available to allow for an international comparison of access that would include private sector drug plans.

least one of the Canadian provinces or US plans examined, 2) the product was available for 50% of the eligible national public drug plan population covered in each respective country, and 3) the product was available for 80% of the eligible national public drug plan population covered in each respective country.

The findings of this report represent the most robust assessment currently available about how governments support access to new medicines in Canada in comparison with a group of Canada's peer countries, and builds on other global research on the subject of access to medicines.[2]

2 For an example see EFPIA (2015). PATIENTS W.A.I.T. INDICATOR. European Federation of Pharmaceutical Industries and Associations (EFPIA). URL — efpia.eu/documents/33/64/Market-Access-Delays

Highlights

Overall

- In Canada, 64% of available new medicines were reimbursed in at least one province, ranking Canada 7th out of 18 countries by this broad measure of reimbursement. However, only 43% of new medicines were available across provinces comprising at least 50% of the eligible national public drug plan population. When only considering products that were reimbursable across provinces accounting for at least 80% of the eligible national public drug plan population, Canada ranked 17th, with only 23% of new medicines receiving public reimbursement across the country.
- Canadian public drug plans placed reimbursement conditions on 90% of new medicines when measured across provinces comprising 80% of the eligible national public drug plan population, ranking Canada 14th out of 17 countries (Ireland was excluded from this analysis).
- In Canada, the wait from national marketing approval to public drug plan reimbursement was 462 days across provinces comprising 80% of the eligible national public drug plan population, ranking Canada 16th of 18 countries.

Biologics

- In Canada, 20% of new biologic medicines were reimbursed in public drug plans across provinces comprising at least 80% of the eligible national public drug plan population, putting Canada in 17th place of 18 countries.

Cancer

- In Canada, 29% of cancer medicines were covered in public drug plans across provinces comprising at least 80% of the eligible national public drug plan population, ranking Canada in 16th place of 18 countries.

First-In-Class

- In Canada, 18% of first-in-class medicines were covered in public drug plans across provinces comprising at least 80% of the eligible national public drug plan population, ranking Canada in 17th place of 18 countries.

Consolidated Results

- The relative international performance of Canada's public drug plans is illustrated below. Countries that fall into the upper left hand quadrant showed higher rates of public reimbursements for new medicines and shorter time to public reimbursement. Countries in the bottom right quadrant showed lower rates of reimbursement, and longer time to reimbursement. Relative to the average bubble size, countries with a smaller/larger bubble size had more/less restricted reimbursement than the average across countries.

*Reimbursement quality data for Ireland was not available
1 Listed in one province/ Medicare plan;
2 Covered for 50% of the eligible public drug plan population;
3 Covered for 80% of the eligible public drug plan population

Bubble size pertains to the percent of new medicines reimbursed without restrictions (i.e. fully reimbursed), indexed to the average across countries

1.0 About the Report

This report is the latest evolution of the work by Rx&D to objectively compare access to new medicines across the public drug plans of Canada and its peer countries. The report builds on previous editions, implementing a new global perspective, and refining the methodology to ensure countries are compared fairly and evenly in the context of highly unique health care systems. The analysis begins with a review of the process, mechanisms, and scope of public drug plan reimbursement across countries. From there, several key analyses were conducted to compare access to new medicines in publicly funded drug plans, including:

- **New Medicines:** Identifying the new medicines approved for sale in each country between January 1, 2009 and December 31, 2013.
- **Proportion Launched:** The proportion of newly approved medicines that were subsequently made available and sold.
- **Proportion Reimbursed:** The proportion of newly approved medicines that were reimbursed under public drug plans.
- **Restrictions and Criteria:** Comparing the quality of reimbursement by looking at product-specific prescribing restrictions and criteria for use imposed on reimbursed products.
- **Time to Launch and Time to Reimbursement:** Calculating the time elapsed from marketing approval to launch and from approval to reimbursement across countries.
- **Sub-Analyses:** Determining if differences in access exist in the sub-segments of cancer, biologics, first-in-class medicines, or other therapeutic areas.

1.1 Countries of Focus

The study focused on 18 of the top 25 OECD countries ranked by highest GDP per capita, as listed below (Table 1).[3] This subset of OECD countries was selected because the countries are most similar to Canada in terms of social and economic factors and comparable and complete data were available to measure reimbursement for new medicines within their public drug plans.

Table 1: OECD countries analyzed

Canada	CA	France	FR	New Zealand	NZ
Australia	AU	Germany	DE	Norway	NO
Austria	AT	Ireland	IE	Sweden	SE
Belgium	BE	Italy	IT	Switzerland	CH
Denmark	DK	Japan	JP	United Kingdom	UK
Finland	FI	Netherlands	NL	United States	US

3 OECD. StatExtracts. Accessed November 2014. stats.oecd.org

1.2 Data Sources

IMS Health propriety databases, including MIDAS™ and Pricing Insights™, were used as the primary source of product and country specific data regarding product launch and reimbursement. These actively managed datasets bring together health care facts and figures from over 70 countries, allowing for multi-country analyses in a systematic and uniform approach. Data was also collected from public sources, including national health regulatory agencies, and non-governmental organizations. More details on the data sources are provided in the Appendix of this report. Additionally, this report drew on input from IMS Health subject matter experts across the world to review the data and methodology, as well as provide additional insights and context to the findings. Reimbursement status continuously evolves. Data used in this report is current to June 2014.

1.3 Product Selection

All new molecular entities or new combinations granted national marketing authorization between January 1, 2009 and December 31, 2013 were included in the analysis. Products were considered new if they had not been previously approved or available in that specific country. Unique product lists were generated for each country. Throughout the report, all new molecular entities and new combinations selected for analysis will be referred to as 'new medicines'. For details regarding exclusion criteria, see Appendix 5.2.1.

The new medicines were selected for each country using the applicable, publicly available health regulatory agency approval lists. In Europe, this list was determined from the pan-country EMA[4] medicines database. While some products in Europe could be granted market authorization directly from a country's own health authority, they were not included given the infrequent nature of these occurrences. In Canada, medicines with marketing authorization were identified from the Health Canada Notice of Compliance (NOC) database.[5]

4 European Medicines Agency, European public assessment reports, Accessed September 2014. ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124

5 Health Canada Notice of Compliance (NOC) database. Accessed September 2014. webprod5.hc-sc.gc.ca/noc-ac/index-eng.jsp

1.4 Launch and Public Reimbursement Analysis

A new product was considered "launched" if it had been introduced into the market. The date of market introduction was considered the "launch date". Launch status and date of launch were identified for each of the selected products by country using the IMS Health MIDAS™ database.

Reimbursement measured whether or not the new product was granted public reimbursement, and/or included in a government-mandated reimbursed medicines list. The corresponding date on which the reimbursement was granted was defined as the "reimbursement date". Reimbursement status was determined using information from the IMS Health Pricing Insights™ database, as of June 2014. Reimbursement status was also supplemented with local country reimbursement sources where necessary and/or applicable. This analysis only tracks the status of medicines on public reimbursement systems.

Eligibility for public reimbursement can vary by country, with most countries in Europe providing coverage to the entire population, while countries like Canada and the US mainly provide coverage to select populations.

This study focuses only on public coverage of medicines as a proportion of the population eligible under public plans, notwithstanding supplementary private drug coverage or cash paying customers.

In general, most countries make public reimbursement decisions at the national level. Canada and the US are outliers in that the individual provinces, states and/or plan administrators make independent regional reimbursement decisions, creating a challenge in understanding national access to medicines. As such, a unique approach was developed for both Canada and the US, taking into account the proportion of the eligible national public drug plan population that was granted access to each new medicine.

In the US, public reimbursement was determined based on Medicare Part B and Part D. Coverage was determined across the four largest private insurers that combined, cover 86% of Medicare lives. Similar to Canada, product reimbursement was determined at 3 levels: 1) the product was listed in at least one of the four aforementioned plans, 2) the product was available for 50% of the population covered under any of the four plans considered, and 3) the product was available for 80% of the population covered under any of the four plans considered. Additional details can be found in the appendix of this report.

It is important to note that some countries have special access programs for exceptional circumstances that are not part of an official formulary. These special access programs were not included in the analysis as they are not widely available, are typically on an individual case-by-case basis, and have limited public transparency for empirical evaluation.

CANADA'S UNIQUE SITUATION

For Canada, the reimbursement decision is made independently by each province, and as such, the same product reimbursed in one province may not be reimbursed in another, adding to the complexity of a global comparison. Arguments can be made on how to appropriately measure publicly funded access to new medicines given these constraints. In order to fully understand the reimbursement levels for Canada, this analysis uses three benchmarks to cover a spectrum of views:

1. ***Products with at least one public drug plan approval:*** Tracks all products that were listed for coverage in at least one provincial drug plan.

2. ***Products reimbursed for 50% of the eligible national public drug plan population:*** Tracks all products that were covered for at least 50% of the total national population that was eligible for publicly funded drug plan benefits, and was calculated using a weighted average by province.

3. ***Products reimbursed for 80% of the eligible national public drug plan population:*** Tracks all products that were covered for at least 80% of the total national population that was eligible for publicly funded drug plan benefits, and was calculated using a weighted average by province. This level of reimbursement represents coverage for most Canadians, and in the context of this global analysis, best represents the reimbursement coverage in comparator OECD countries.

1.5 Sub-Analyses

Additional analyses were conducted to understand if there were any differences in how countries provide access to specific types of products.

Biologics: This group was selected as they are typically high cost, yet innovative, medicines. All products that were produced from biological sources or systems were included, such as antibodies, hormones, and enzymes.

Cancer: Many nations put a priority on life-threatening diseases, such as cancer. Cancer products were identified using the US National Cancer Institute medicines list[6] and validated by IMS Health expertise.

First-In-Class: These medicines were chosen because they reflect the priority countries place on adopting new incremental and breakthrough innovations. This list was generated using the US FDA designation for first-in-class medicines[7].

By ATC: All products were grouped under their ATC level 1 code, and analyzed to understand if there were any differences across countries based on therapeutic areas.

6 The United States National Cancer Institute, cancer.gov/cancertopics/treatment/drugs

7 Eder J, *et al.* The discovery of first-in-class medicines: origins and evolutions. *Nature Reviews Drug Discovery*. 2014 Aug:13(8):577-87.

1.6 Quality of Reimbursement

Moving beyond a binary analysis of reimbursement, this metric provides insight into how broadly reimbursed products are made available to the eligible national public drug plan population, and how extensively countries impose restrictions on access. This analysis disregards any system-wide eligibility restrictions or co-pays, and instead focuses on restrictions uniquely assigned to individual products. Each product was categorized into one of three levels in increasing order of restriction:

1. **Full reimbursement:** The new product received the highest level of reimbursement available for that country.
2. **Partial reimbursement:** Only part of the product's eligible cost is covered.
3. **Restricted reimbursement:** Access to the reimbursed product was restricted to a subset of the eligible national public drug plan population, or required special authorization or prerequisite conditions to be met.

Products with more than one level of coverage were categorized according to their most restrictive condition. Partial reimbursement was not applicable in Canada as no province employs variable co-pays at the product specific level.

1.7 Time to Launch and Time to Reimbursement

In addition to measuring the extent of reimbursement across countries, it is also important to examine the speed at which new medicines are made available. These metrics look at the time required to access new medicines, starting from the date of health regulatory approval in each country.

- **Time to launch:** The time, measured in calendar days, from the date of market authorization to the date of introduction on to the market. This is an indicator of the relative time each company required to make their product generally available to the public.
- **Time to reimbursement:** The time, in days, from the date of market authorization to the date of public reimbursement. This is an indicator of the time required for public payers to review and include new medicines in their formularies.

The date of marketing authorization was available at the exact day, month, and year, whereas dates of launch and reimbursement were available only at month and year. As such, in order to calculate the time to launch and time to reimbursement in calendar days, the date of launch and reimbursement was set at the 15th of the month, to equally balance for all products launched or reimbursed before and after this date. Where the calculation yielded a negative value, the days to launch or reimbursement were set to zero.

In Canada, the time to reimbursement was calculated as the average time from NOC (notice of compliance) to reimbursement for all products in each province. The average time to reimbursement for each province was then weighted by the relative size of the eligible national public drug plan population in each province to determine a final weighted average time to reimbursement.

2.0 Health Systems: Structure and Design

Each country has its own political priorities, economic constraints, and cultural expectations when it comes to health care. These factors and others lead to significant diversity in how health care is administered and delivered. For this report the structure of each health system was analyzed to develop a contextual understanding of the drug coverage model in each country.

2.1 Components of a Health System

The World Health Organization (WHO) defines a health system as the sum of all organizations, institutions and resources whose overall objective is to improve health.[8] These systems operate with the aim to improve people's lives in everyday tangible ways, including a broad spectrum of activities from disease prevention to treatment and management. A good health system is one that "delivers quality services to all people, when and where they need them".[9] The WHO has listed several key components of an effective health system: health system financing, health workforce, health information and resources, national health policies and essential medicines and health technologies.[10]

- **Health systems financing** can range from general taxation to fee for service models. These financing methods ensure that funds and resources are allocated equally, are sustainable, and can reduce barriers to access to health care in a system where the goal is to achieve universal coverage.

- **A highly skilled and knowledgeable health workforce** is an essential component in providing quality care in complex medical settings.

- **Health information and resources** are the foundation for efficient and effective management of a health system by providing access to information. Health information allows for informed and appropriate health decision making, health sector reviews, planning, resource allocation and program monitoring and evaluation.

- **National health policies** set the strategic direction of a country and can directly highlight key priorities for a nation. Policies can also help to correct undesirable trends and regulate the behavior of actors in the health care field. Overall, national health policies help to establish transparency and accountability in the health system.

- **Access to affordable medicines, vaccines, and health technologies** are a key component to a quality health system. These represent the arsenal that medical professionals have as a means to combat diseases and treat illness.

2.2 Health care System Financing and Reimbursement Policies

Structural differences between health care systems can impact how the burden of cost is distributed across governments, employers, and individuals, and thus may confuse comparisons of access to new medicines across public drug plans. For example, many countries publicly fund prescription drug costs on a universal basis for their entire populations. With some variation

8 World Health Organization Website. Accessed 24 November 2014. who.int/healthsystems/publications/hss_key/en

9 World Health Organization Website. Accessed 24 November 2014. who.int/topics/health_systems/en

10 *Ibid*

between them, other countries such as the Netherlands, Switzerland and Germany utilize universal mandatory private health insurance supported by public subsidization for individuals. In the Netherlands and Switzerland health systems, basic health insurance is mandatory for all residents, who are free to choose from a set of private plan providers, and there is substantial public subsidization of the costs for individuals. The United States has a public system in place that covers seniors, low income households, and disabled persons (Medicare and Medicaid), with private drug plans covering the remaining population. Furthermore, in the US, this public coverage, while paid publicly, is administered by private insurance carriers. As of 2010, the US system also requires that all individuals not covered by an employer sponsored health plan, Medicaid, Medicare or other public insurance programs to secure a government-approved private health insurance policy that includes prescription medicines.

In Canada, each provincial and territorial government offers a drug benefit plan for eligible groups, as does the federal government for the eligible populations under its specific jurisdiction. Most provincial/territorial drug insurance systems are separate public-private sector models, others are income-eligibility and deductible-based universal public programs with supplemental private coverage (e.g. British Columbia, Saskatchewan), while others are closer to social insurance models (e.g. Quebec, New Brunswick). Most jurisdictions have specific programs for population groups that may require more enhanced coverage for high drug costs, including seniors, recipients of social assistance, and individuals with diseases or conditions that are associated with high drug costs.

For the purposes of facilitating comparisons in this report, the universal mandatory private health insurance systems and the social insurance health systems were deemed to have universal public drug plans, because the public element (subsidization) could not be treated separately from the private element given available data. For the US health system, Medicare was used as the comparative public drug plan for the purpose of this comparative analysis.

The process by which countries make public drug plan reimbursement decisions for new medicines is another critical element to understanding differences in international access to medicines. This approach typically starts with a marketing authorization body which approves the sale of new medicines, followed by a body that conducts a health technology assessment (HTA) and finally a body that makes reimbursement decisions. Generally, most nations have a centralized marketing authorization, HTA body and reimbursement process, and these groups are usually separate organizations. In Canada, medicines are approved for sale through the national regulatory agency (Health Canada). Subsequently, new medicines undergo a national HTA through the Canadian Agency for Medicines and Technologies in Health (CADTH). The recommendations from this agency are non-binding with provincial and federal drug plans independently making the final decision on reimbursement for their covered population. Quebec is the exception, conducting its own provincial-level HTA, and at present making reimbursement decisions independently of CADTH and the other provinces.

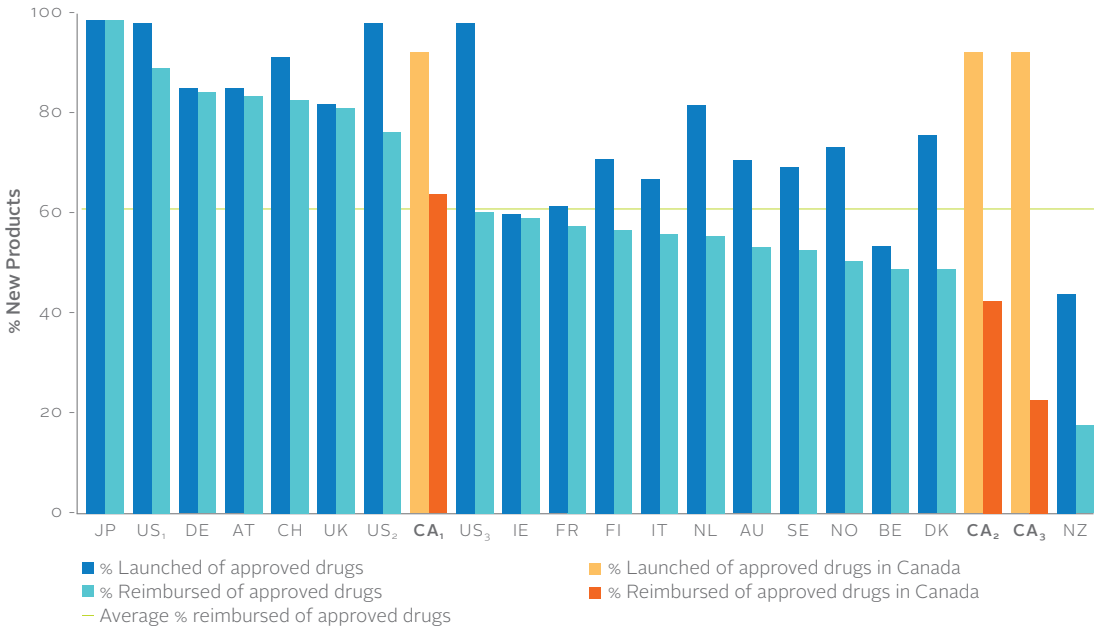
Co-payments may also be employed to manage public system affordability by shifting some of the cost-burden to the patient. Use of and scope for co-payments vary across countries and affects the comparability of drug coverage between drug plans. For example, Canada has income-based deductibles, co-payment systems, and out-of-pocket caps in place which vary by province.

3.0 Results: Comparing Access to New Medicines in Public Drug Plans

3.1 All New Medicines

While there was significant overlap of products across many countries, each country had a unique list, which served as the basis of evaluation for access to medicine in that country. The proportions of all new medicines launched and publicly reimbursed are shown in Figure 1. In Canada, 141 new medicines were granted marketing authorization between 2009 and 2013, out of which 130 (92%) were launched, ranking Canada 3rd for proportion of new medicines launched. Of the 141 new medicines that were approved in Canada, 90 (64%) were publicly reimbursed in at least one province. At this level of reimbursement, Canada ranks 7th overall. However, at 50% eligible national public drug plan population coverage, the proportion of new medicines reimbursed dropped to 43% (ranking 17th), and at 80% eligible national public drug plan population coverage, only 23% of new medicines were reimbursed, again putting Canada 17th out of 18 countries studied.

Figure 1: Percentage of new medicines launched and publicly reimbursed by country



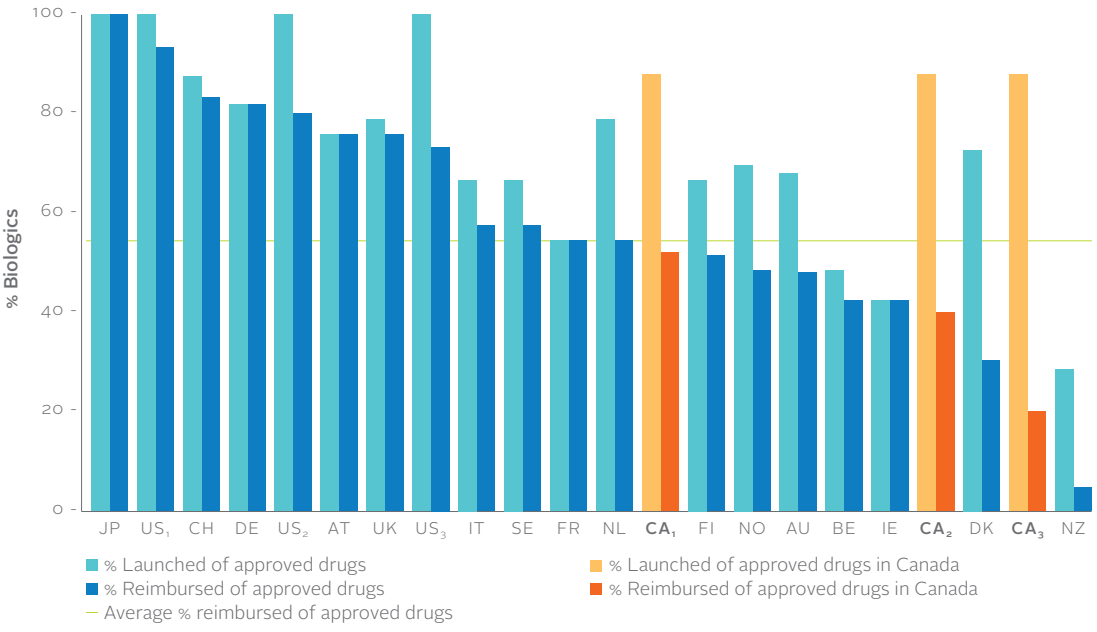
1 Listed in one province/ Medicare plan;
2 Covered for 50% of the eligible public drug plan population;
3 Covered for 80% of the eligible public drug plan population

3.2 Biologics

The proportions of biologics launched and publicly reimbursed are shown in Figure 2. In Canada, 88% of biologics were launched and 52% were reimbursed in one or more provinces, positioning Canada at 11th place.

However, reviewing the coverage in at least 50% and 80% of the eligible national public drug plan population, reimbursement dropped to 40% (16th rank) and 20% (17th rank), respectively.

Figure 2: Percentage of new biologic medicines launched and publicly reimbursed by country

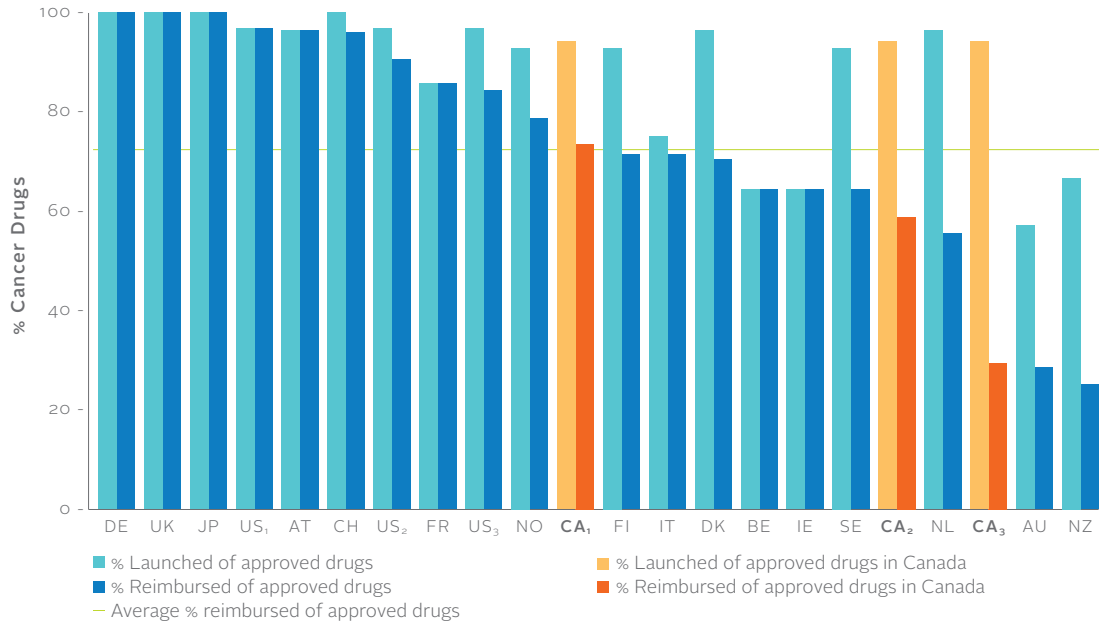


1 Listed in one province/ Medicare plan;
2 Covered for 50% of the eligible public drug plan population;
3 Covered for 80% of the eligible public drug plan population

3.3 Cancer Medicines

The proportions of cancer medicines launched and publicly reimbursed are shown in Figure 3. In Canada, 34 (24%) of all new medicines were cancer medicines, and 94% of these were launched. Of the 34 cancer medicines that were approved, 25 (74%) were reimbursed in at least one province. At this level of coverage Canada ranked 9th overall. However, at 50% and 80% eligible national public drug plan population coverage, reimbursement rates dropped to 59% (ranked 15th) and 29% (ranked 16th) respectively.

Figure 3: Percentage of new cancer medicines launched and publicly reimbursed by country

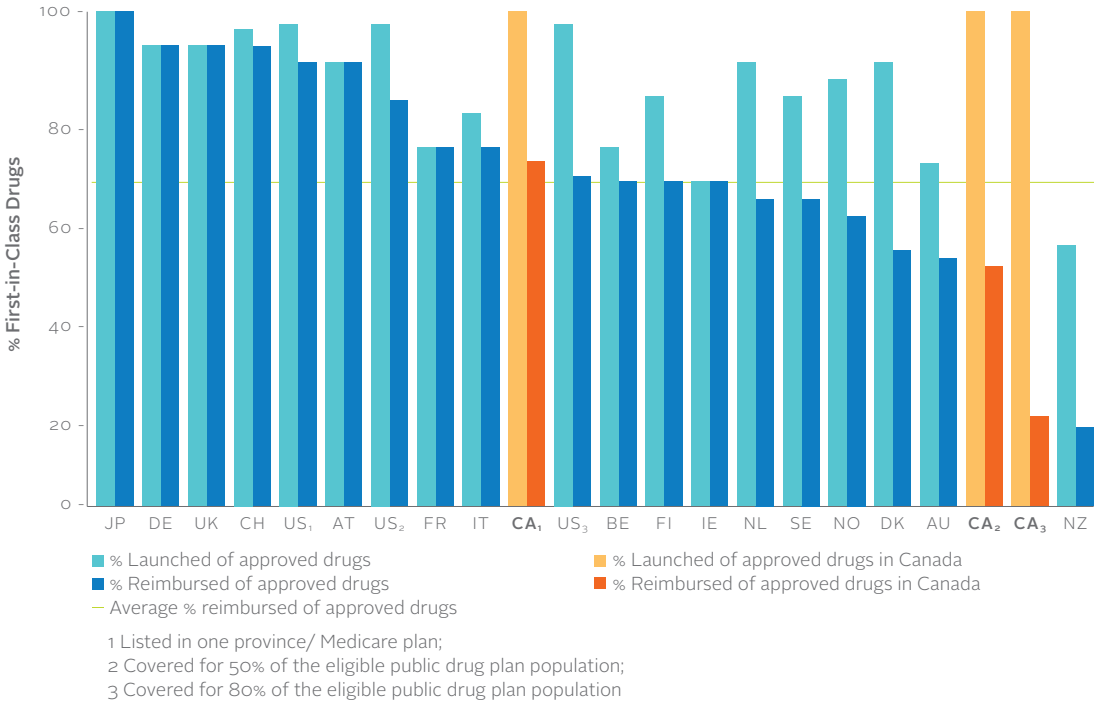


1 Listed in one province/ Medicare plan;
2 Covered for 50% of the eligible public drug plan population;
3 Covered for 80% of the eligible public drug plan population

3.4 First–In-Class

The proportions of first-in-class medicines launched and publicly reimbursed are shown in Figure 4. In Canada, out of the 33 first-in-class medicines granted marketing authorization, 100% were launched and 70% were reimbursed in at least one province, ranking Canada 9th overall. At the 50% and 80% of eligible national public drug plan population coverage levels, reimbursement rates dropped to 48% (ranked 17th) and 18% (ranked 17th), respectively.

Figure 4: Percentage of first-in-class medicines launched and publicly reimbursed by country



1 Listed in one province/ Medicare plan;
2 Covered for 50% of the eligible public drug plan population;
3 Covered for 80% of the eligible public drug plan population

3.5 Therapeutic Comparison by ATC

The relative mix of therapeutic areas was also examined by country to understand if differences in market access exist by therapeutic class. The average mix of classes by ATC Level 1 is shown in Figure 5. Overall, the average reimbursement rates were relatively similar across ATC classes (Table 2). Across all studied countries, the majority of new medicines launched and reimbursed were in ATC-L: antineoplastic and immunomodulating agents, ATC-C: medicines for the cardiovascular system, ATC-N: nervous system, and ATC-A: alimentary tract and metabolism classes. The remaining products were spread across the other classes relatively evenly. As shown in Table 2, at the 80% of eligible national public drug plan population coverage level, Canada ranked between 15th and 18th of 18 countries across all ATC classes studied.

Figure 5: Breakdown of products at the ATC level granted marketing authorization

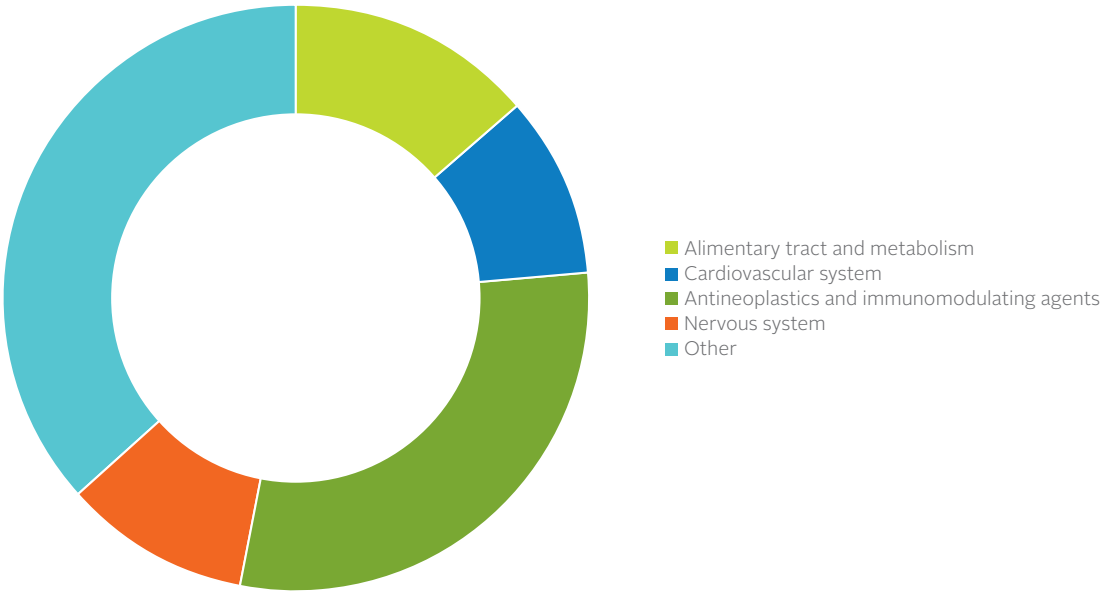


Table 2: Public Reimbursement rates by ATC class

ATC A		ATC C		ATC L		ATC N		Other	
JP	100%	JP	94%	DE	100%	JP	96%	JP	100%
AT	88%	US_1	82%	UK	100%	US_1	94%	US_1	87%
UK	82%	CH	82%	JP	100%	US_2	89%	DE	82%
US_1	82%	US_2	71%	AT	98%	DE	83%	CH	80%
CH	80%	DE	69%	US_1	97%	UK	83%	AT	77%
US_2	68%	CA_1	64%	US_2	95%	US_3	83%	UK	77%
AU	65%	AT	62%	CH	94%	AT	75%	IE	68%
DK	65%	IE	54%	US_3	89%	FR	75%	CA_1	62%
DE	65%	AU	47%	FR	80%	CH	73%	AU	62%
NL	59%	NL	33%	NO	78%	IE	67%	US_2	59%
CA_1	56%	NZ	33%	CA_1	76%	DK	58%	NL	59%
FI	47%	BE	31%	IT	73%	FI	58%	FI	55%
IE	47%	FI	31%	FI	71%	IT	58%	FR	55%
SE	47%	UK	31%	SE	71%	NL	58%	IT	55%
IT	41%	FR	23%	BE	63%	CA_1	58%	SE	52%
NO	41%	IT	23%	CA_2	61%	SE	50%	US_3	49%
BE	35%	NO	23%	DK	61%	AU	47%	BE	48%
US_3	32%	CA_2	18%	NL	56%	BE	42%	DK	41%
FR	24%	CA_3	18%	IE	54%	NO	42%	NO	39%
CA_2	22%	US_3	18%	AU	38%	CA_2	37%	CA_2	38%
CA_3	22%	SE	15%	CA_3	24%	CA_3	21%	NZ	23%
NZ	7%	DK	8%	NZ	11%	NZ	14%	CA_3	18%
Average	**55%**	**Average**	**42%**	**Average**	**72%**	**Average**	**61%**	**Average**	**59%**
Median	**53%**	**Median**	**32%**	**Median**	**72%**	**Median**	**58%**	**Median**	**57%**

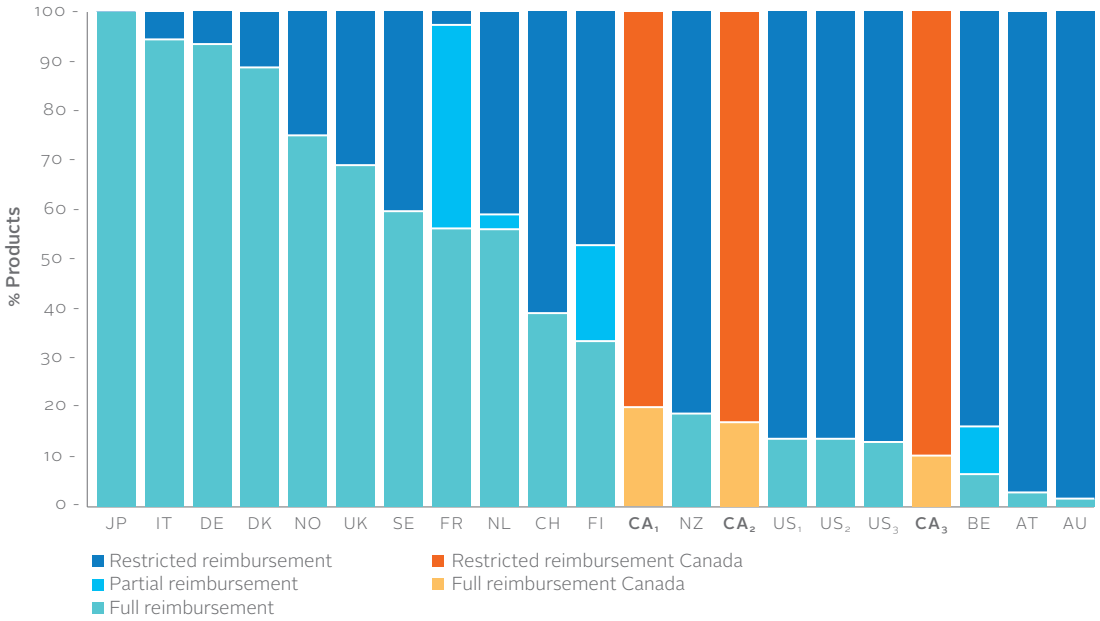
ATC A, Alimentary Tract and Metabolism; ATC C, Cardiovascular System; ATC L, Antineoplastic and Immunomodulating Agents; ATC N, Nervous System.
See appendix for full list of ATC categories.

3.6 Quality of Reimbursement

In order to understand and compare the extent to which countries impose reimbursement restrictions on new medicines, the quality of reimbursement was compared for each product by examining any product-specific prescribing or reimbursement restrictions imposed by the payer. The results are presented in Figure 6. For most countries, the results were compiled from national payer restrictions and criteria. In the US and Canada, in the absence of national payers, restrictions were examined at the carrier or provincial payer level, respectively. Results in the UK were taken from guidance issued by the National Institute for Health and Care Excellence (NICE). While not a national payer, NICE guidance is generally accepted and followed by local payers in England and Wales.[11] Additionally, cancer products that were reviewed and granted access through the Cancer Medicines Fund were also captured in this analysis. Data was not available for Ireland, and it was therefore not included in this analysis.

Canada was found to be among the most restrictive countries, with 80% of new medicines covered in at least one province having reimbursement criteria restricting broad access. This puts Canada 12th out of the 17 countries considered in this analysis. When considering only products with 50% and 80% eligible national public drug plan population coverage, the restrictions increased to 83% (13th rank) and 90% (14th rank), respectively, indicating that as products become more widely available across provinces, the likelihood of restrictions on that availability increases[12].

Figure 6: Quality of public reimbursement for covered products across countries



1 Listed in one province/ Medicare plan;
2 Covered for 50% of the eligible public drug plan population;
3 Covered for 80% of the eligible public drug plan population

Note: Data was not available for Ireland; it was therefore not included in this analysis

11 The Scottish Medicines Consortium (SMC) which issues reimbursement guidance for Scotland was not included in this analysis. Given the relatively small population represented by the SMC, the authors would not expect the results to be materially different.

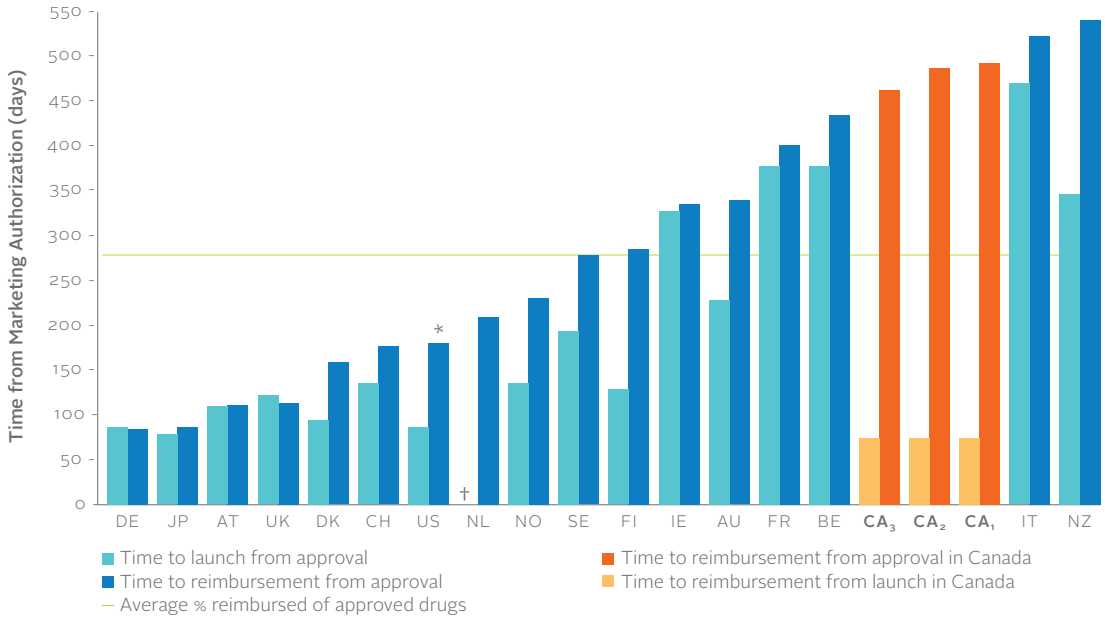
12 The majority of restrictions captured for this analysis were at the national payer level. It should be noted that further access restrictions may also be imposed at the regional level which would be beyond the visibility of the study methods.

3.7 Time to Launch and Reimbursement

The last major metric we examined in our analysis was the time required to launch and reimburse new products by country. This measure gives an indication as to the extent to which patients are delayed access to new medicines by country. The results of this analysis are illustrated in Figure 7. Time to reimbursement data were not available for the United States; however, CMS (Centers for Medicare and Medicaid Services) requires that, for products on Medicare part D, the P&T committee reviews a new FDA approved drug product within 90 days and will make a decision within 180 days of its release onto the market.[13] Therefore, the time frame of 180 days has been incorporated into the results. However, in the real-world setting, IMS Health expertise suggests that the time to reimbursement may fall closer to 90 days.

Canada was the quickest country to launch, at 74 days. However, the time needed to obtain public reimbursement was among the slowest, ranking 16th of 18 countries overall. Time to listing (in at least one province) was 493 days, 217 days longer than the average (276 days) and 238 days longer than the median (255 days) of all countries. There was little difference in the time to reimbursement between the three benchmarks of coverage (at least one province, 50% and 80% eligible national public drug plan population coverage), with 493 days, 487 days, and 462 days on average, respectively.

Figure 7: Average time to launch and time to reimbursement from marketing authorization in days by country



1 Listed in one province;
2 Covered for 50% of the eligible public drug plan population;
3 Covered for 80% of the eligible public drug plan population

* Time to public listing data was not available in the US; the results represent the maximum time allowed for a listing decision to be made for Medicare Part D products
† Time to launch was not available in the Netherlands

13 *CMS Prescription Drug Benefit Manual*, Chapter 6, cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html

3.8 Results Summary

The relative international performance of Canada's public drug plans is illustrated below. Countries that fall into the upper left hand quadrant showed higher rates of public reimbursements for new medicines and shorter time to public reimbursement. Countries in the bottom right quadrant showed lower rates of reimbursement, and longer time to reimbursement. Relative to the average bubble size, countries with a smaller/larger bubble size had more/less restricted reimbursement than the average across countries.

Figure 8: Overall comparison of countries based on three metrics: percentage reimbursed of new medicines approved, quality of reimbursement, and time to reimbursement from marketing authorization.

*Reimbursement quality data for Ireland was not available
1 Listed in one province/ Medicare plan;
2 Covered for 50% of the eligible public drug plan population;
3 Covered for 80% of the eligible public drug plan population

Bubble size pertains to the percent of new medicines reimbursed without restrictions (i.e. fully reimbursed), indexed to the average across countries

4.0 Conclusion

This report represents a comprehensive assessment of access to new medicines within the public drug plans of 18 comparable OECD countries. The proportion of new medicines that are publicly reimbursed as well as the level of reimbursement and time to reimbursement was assessed and compared with a focus on how Canada compares to its global peers.

Using a population coverage definition comparable with global counterparts (reimbursement for > 80% of the eligible national public drug plan population), Canada ranked 17th out of 18, with only 23% of new medicines being reimbursed across the country. Canada also ranked 16th of 18 countries for the length of time before reimbursement was granted in public drug plans, taking on average 462 days from new drug approval to reimbursement. In addition, a large proportion (90%) of the new medicines reimbursed in Canada came with restrictions limiting patient access in publicly funded drug plans ranking Canada 14th of 17 countries.

It is important to get an evidence-based understanding of how we compare to global counterparts in providing access to new medicines. The findings of this report provide a comparative framework which can be used as a basis for informing future policy decision-making. It may also serve as a starting point to look deeper into countries that are highly successful at providing timely access to new medicines for their populations to understand how this can be achieved, and what lessons could be applied to the Canadian context.

5.0 Appendix

5.1 Report Limitations

This report compared public reimbursement across 18 OECD countries to highlight differences in access to medicines. It should be noted that while this comparison gives an understanding of public access to medicines, overall access may be represented more fully by considering both public and private reimbursement systems, depending on the health care system structure.

Comparisons were made given a specific time period and only new medicines that were granted market authorization between 2009 and 2013 were considered. The date that market authorization was granted depends greatly on both the manufacturer's decision and timing to submit their application, as well as the length of time that is required for a country to make their decision. As such, the mix of products analyzed varied by country. This report does not make conclusions on the time the same group of products took to achieve public reimbursement, rather the real-world access experienced in each country.

The determination of launch and reimbursement status was made using data current to June 2014, providing a snapshot in time. Due to limitations in the availability of the private insurer listing information in the US, reimbursement data in the US was current to January 2014, 6 months fewer than the other countries. The reimbursement and access landscape can change on a daily basis. Updating the results in the future may provide insight into how access is evolving in different countries.

Finally, due to the uniqueness of each country's scheme, the methodologies and sources for determining reimbursement status, level, and date were not identical across all countries. The methodology used was developed to provide a balanced and fair view across all countries, however, the results should be interpreted with an understanding of the particular environment in each country.

5.2 Methodological Considerations

5.2.1 Product Exclusions

New medicines were defined as being new molecular entities or new combinations of existing molecules. Products where the molecule had been launched previously in another indication prior to 2009 were excluded from the analysis. When the same molecule was launched as two separate products, only the first product was included in the analysis as the following product was no longer within the definition of a new molecular entity. When two products of the same molecule but different indications were granted market authorization on the same day, both indications were included in the analysis.

5.2.2 Reimbursement Data Coverage

Reimbursement status, level, and dates were not available through IMS Health data for Denmark, Australia, New Zealand and US. As such, this information was determined from publicly available health agency sources.

Products where the reimbursement decision was still pending were considered to be not reimbursed.

Canada

Listing information, including listing date and listing status on provincial formularies was extracted from the IMS Brogan, iMAM database. Since cancer products in some provinces are reimbursed outside of the provincial drug formulary (e.g. Cancer agencies), the listing information for cancer medicines was obtained from both the Canadian Agency for Medicines and Technologies in Health (CADTH) and the pan Canadian Oncology Drug Review (pCODR). Product reimbursement status was assessed for each of the 10 provinces, British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Newfoundland and Labrador, and Prince Edward Island. Reimbursement data for federal and territorial government drug programs were not considered in the analysis, as they represent a relatively small proportion of the overall Canadian population. Additionally, reimbursement data for oncology intravenous (IV) products in Quebec was not available and therefore these products were excluded from the analysis for Quebec.

Denmark

For some hospital-only products where reimbursement status could not be reliably determined from public sources, reimbursement status was determined from available sales data in the IMS Health MIDASTM database. Hospital-only products were considered reimbursed if considerable sales were recorded in the hospital setting with no sales in the retail setting.

United Kingdom

Reimbursement levels were taken from NICE guidance, assuming that the 211 clinical commissioning groups (CCG) who comprise the payers, typically follow NICE guidelines. Medicines covered under the national Cancer Medicines Fund were also considered to be reimbursed with restrictions, given the prior authorization required for patients to access the program. Decisions for Scotland from SMC were not included in this study. Reimbursement date was determined using IMS Health data, and indicated the date on which the product became available for coverage, rather than the date on which NICE issued guidance or the Cancer Medicines Fund made a coverage decision.

United States

Public reimbursement was determined based on Medicare Part B and Part D plan coverage. Part B medicines were considered reimbursed for all levels of coverage (covered in one plan, covered for 50% of the eligible national public drug plan population, and covered for 80% of the eligible national public drug plan population) if they had a maximum reimbursement price listed by the Centre for Medicare and Medicaid Services.

Part D coverage was determined across the four largest managed Medicare plans that combined cover 86% of Medicare lives: Aetna, Humana, United Health Care, and Cigna Corporation. The level of reimbursement was weighted according to the population covered by each plan.

Listing information by insurer is published annually, with the latest list available from January 2014. Any developments from January to June 2014 were not available for the study, reducing the time considered in the US compare to the other countries.

Medicaid, a public insurance provider in the US is implemented and managed at the State level, typically covers all FDA-approved out-patient medicines to label, and manages access through preferred drug lists. Some product types are excluded from reimbursement by federal government allowance. Reimbursement under Medicaid also requires that the manufacturer

agrees to enroll in the defined federal schemes. Due to the manufacturer involvement and management systems, reimbursement under Medicaid has not been included in this analysis.

Total new medicines launched and reimbursed by country

Since each country had a different basket of medicines based on health regulatory approvals, the number of medicines differed by country. The number of new medicines launched and granted reimbursement is shown in Table 3, below.

Table 3: Number of products launched and reimbursed by country

Country	# Medicines launched	# Medicines reimbursed
AT	108	106
AU	89	67
BE	68	62
CA_1	130	90
CA_2	130	60
CA_3	130	32
CH	116	105
DE	108	107
DK	96	62
FI	90	72
FR	78	73
IE	76	75
IT	85	71
JP	154	154
NL	103	70
NO	93	64
NZ	40	16
SE	88	67
UK	104	103
US_1	153	139
US_2	153	119
US_3	153	94

5.2.3 Hospital vs. Retail Reimbursement

For some products, the reimbursement status depended on the setting where the drug was administered: hospital vs. retail. In many countries, medicines administered in the hospital are automatically reimbursed, (inclusion for in-patient vs. out-patient varies by country). Some products that are primarily administered in a retail setting may sometimes be given in the hospital setting where they would be reimbursed, thus potentially distorting the overall reimbursement assessment for a mainly retail product. For the purposes of this analysis, products that were not reimbursed in a retail setting, but reimbursed in a hospital setting were counted only if they were primarily a hospital-based product.

5.2.4 Reimbursement Quality

Canada

The number of products with full benefit was calculated as a weighted average by eligible national public drug plan population across the included provinces. The number of products with restricted benefit was calculated by subtracting the weighted average number of products with full benefit from the total number of reimbursed products. Reimbursement level was calculated for each of the three coverage benchmarks examined (listed in at least one province, available for 50% of the eligible national public drug plan population, and available for 80% of the eligible national public drug plan population).

United States

Products requiring prior authorizations, step edits, or quantity limits were considered to be restricted. If none of these applied, then the product was considered to be fully reimbursed.

Denmark

Hospital-only products where reimbursement status was determined using IMS Health MIDAS™ sales data were considered fully reimbursed.

United Kingdom

Reimbursement quality was determined from guidance issued by NICE. Products were considered to have restricted reimbursement when the NICE guidance gave a positive recommendation with patient access restrictions beyond the product label. Products where no NICE guidance was issued, or where NICE gave a positive recommendation with no further restrictions beyond the label were considered "fully reimbursed".

5.2.5 Launch and Reimbursement Dates

Launch and reimbursement dates were determined from IMS Health Pricing Insights™ database as outlined in section 1.7 with the following exclusions:

- The launch date in all countries was defined as the date of introduction of a new product to the market captured in the IMS Health production system; launch date could be defined as either the date from which sales start to accrue or the date of launch by the manufacturer. Launch date for the Netherlands was defined as the date when the pharmacy organization officially issued the relevant code for a new product. Due to the disparity between these definitions, launch date for the Netherlands was excluded from the analysis.

- Some products for which the reimbursement date wasn't available were also excluded from the analysis.

- In Denmark, hospital-only products where reimbursement status was determined using IMS Health MIDASTM sales data were not included in the time to reimbursement analysis.

Time to launch was inclusive of the time taken for the manufacturer to decide to launch their product.

5.3 Data Sources

5.3.1 Marketing Authorization

EU: European Medicines Agency, European public assessment reports, ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124

Switzerland: The Swiss Agency for Therapeutic products, swissmedic.ch/ueber/00134/00441/00445/00566/index.html?lang=en

Australia: Australian Government Department of Health, Therapeutic Goods Administration (TGA), search-au.funnelback.com/s/search.html?collection=tga-artg

Japan: Pharmaceuticals and Medical Devices Agency (PMDA) Japan, pmda.go.jp/english/service/list_s.html

New Zealand: New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE), medsafe.govt.nz/index.asp

United States: US Food and Drug Administration (FDA), accessdata.fda.gov/scripts/cder/ob/default.cfm

Canada: Health Canada, hc-sc.gc.ca

5.3.2 Launch Status and Launch Date

All countries: IMS Health MIDAS Quantum™ is a unique global market measurement platform used by pharmaceutical professionals to assess international markets, product portfolio performance, understand disease treatment and benchmark promotional mix and expenditure.

DETAILS

Over 94% of the global prescription universe; retail and hospital channels.

Incorporates Sales, promotional and medical data.

- Accurately details estimated product volumes, trends and market share by product and therapy class
- Multiple market country comparisons
- Customized presentation
- Breadth & depth of information: 500,000 products, 5,000,000 packs, 18,000 manufacturers, and 8,000 ingredients
- Historical data: 12 years Sales (retail/hospital) volume and prices, and kilogram sales, 6 years Primary care prescribing and promotional activity

5.3.3 Reimbursement Status, Level, and Date

Canada: IMS Brogan iMAM database: iMAM® is a comprehensive online resource for market access information needs. It displays up-to-date information on the current and historical formulary listing status of drug products across Canada; IMS Brogan PharmaStat® database: PharmaStat® provides convenient insight into the actual payment activities of public and private plans. It provides an accurate picture of drug plan utilization to help with market sizing, formulary reimbursement tracking, market share estimation and performance benchmarking, allowing the user to detect and monitor trends as they occur.

Canada: Canadian Agency for Medicines and Technologies in Health (CADTH), pan Canadian Oncology Drug Review (pCODR), cadth.ca;

EU countries (excl. Denmark): IMS Pricing Insights database™: A database service from IMS Health focused on global pharmaceutical regulated list prices & reimbursement information, combined with analytical reporting and international standardization for ease of use in pharmaceutical price management.

Denmark: The Danish Medicines Agency, medicinpriser.dk; Danske Regioner, regioner.dk

Sweden: The Dental and Pharmaceutical Benefits Agency (TLV), tlv.se

Norway: The Norwegian Medicines Agency, legemiddelverket.no/Sider/default.aspx

Switzerland: The Swiss Agency for Therapeutic Products, swissmedic.ch/index.html?lang=en

Australia: Australian Government Department of Health, Pharmaceutical Benefits Scheme, pbs.gov.au/pbs

New Zealand: PHARMAC, Pharmaceutical Medicines Agency, pharmac.health.nz

United States: Aetna: 2014 Comprehensive Formulary Aetna Medicare Base, aetnamedicare.com; Humana: Humana Group Medicare National, apps.humana.com; United Health care: United Health care Medicare Complete, uhcmedicaresolutions.com; Cigna Corporation: Cigna Medicare Rx Secure, cigna.com; Centre for Medicare and Medicaid Services, cms.gov

6.0 About Rx&D

Canada's Research-Based Pharmaceutical Companies (Rx&D) is the national association representing the voice of Canada's innovative pharmaceutical industry. We serve our membership by advocating for policies that enable the discovery, development and delivery of innovative medicines and vaccines to improve the lives of all Canadians. We support our memberships' commitment to being a valued partner in the Canadian healthcare system. We represent more than 50 companies investing over $1-billion in R&D annually, fuelling Canada's knowledge-based economy, while contributing over $3-billion overall to Canada's economy. Guided by our Code of Ethical Practices, we work with governments, private payers, healthcare professionals and stakeholders in a highly ethical manner.

R&D Canada's Research-Based Pharmaceutical Companies
Making Canada Better

Vision Statement

Canadians living healthier and longer lives through access to innovative medicines and vaccines.

Mission Statement

As the national voice of research-based pharmaceutical companies, Rx&D advocates for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our member's commitment to being valued partners in the Canadian healthcare system.

Notes

Canada's Research-Based Pharmaceutical Companies

Making Canada Better