

Drivers of Prescription Drug Spending in Canada



Spending and Health Workforce

Who We Are

Established in 1994, CIHI is an independent, not-for-profit corporation that provides essential information on Canada's health system and the health of Canadians. Funded by federal, provincial and territorial governments, we are guided by a Board of Directors made up of health leaders across the country.

Our Vision

To help improve Canada's health system and the well-being of Canadians by being a leading source of unbiased, credible and comparable information that will enable health leaders to make better-informed decisions.

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Executive Summary

- Over the past two decades, pharmaceuticals have been one of the fastest-growing components of health system spending in Canada. However, since 2005, drug spending has grown more slowly than hospital spending, physician spending and total health care spending.
- Internationally, between 1997 and 2007, growth in per capita drug spending in Canada was second only to growth in the United States, among comparator countries.
- In Canada, between 1998 and 2007, spending on prescription drugs used outside of hospitals grew from \$8.0 billion to \$19.0 billion, an average annual rate of growth of 10.1%.
- Increased volume of use and changes in the mix of treatments being used were the largest contributors to the growth rate, accounting for average annual growth of 6.2% and 2.0%, respectively. Both volume and mix effects were due in part to changes in treatment guidelines, increased disease prevalence and the uptake of new drugs.
- Population growth and aging had more modest effects on drug spending during the study period, each accounting for average annual growth of 1.0%.
- Price changes did not have a significant impact on drug spending, and drug prices actually decreased when adjusted for general inflation.
- Cholesterol-lowering drugs, cancer drugs and immunosuppressants accounted for roughly one-third of overall growth in drug spending between 2004–2005 and 2009–2010. The growth for cancer drugs and immunosuppressants was due in part to the uptake of newer biologic drugs.
- Trends in drug development suggest that cancer drugs and immunosuppressants may continue to drive drug spending in the years to come.
- Some cost savings will be available in the upcoming three to five years due to the increased availability of generic drugs. In 2009, drugs whose patents were set to expire between 2010 and 2014 accounted for nearly \$8.7 billion in wholesale purchases. This was equal to more than one-third (38.2%) of all wholesale spending on prescription drugs in Canada.
- In the past two years, many public drug programs have reduced the amount that they are willing to pay for generic drugs. Generic drug prices are now regulated to be at most 25% to 56% of the price of brand name products.

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• Steve Morgan, Associate Director, Centre for Health Services and Policy Research, University of British Columbia

Please note that the analyses and conclusions in this document do not necessarily reflect those of the individuals or organizations mentioned above.

About CIHI

The Canadian Institute for Health Information (CIHI) collects and analyzes information on health and health care in Canada and makes it publicly available. Canada's federal, provincial and territorial governments created CIHI as a not-for-profit, independent organization dedicated to forging a common approach to Canadian health information. CIHI's goal: to provide timely, accurate and comparable information. CIHI's data and reports inform health policies, support the effective delivery of health services and raise awareness among Canadians of the factors that contribute to good health.

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Introduction

In 2010–2011, the Canadian Institute for Health Information (CIHI) undertook a project to analyze the cost drivers of health expenditure in Canada. This project looked at macroeconomic factors that influence health care expenditure, as well as cost drivers for physician expenditure, hospital expenditure, drug expenditure and other components of health expenditure. CIHI's National Health Expenditure Database (NHEX) and its associated annual publication, *National Health Expenditure Trends*, document health expenditure in Canada. NHEX's framework of definitions guided the data analysis in the cost drivers project.

The standard conceptual framework for the cost drivers project focused on six elements that can be measured using Canadian data:

- Population growth;
- Population aging;
- General inflation;
- Price effects;
- Volume effects; and
- Mix of drugs.

This report focuses on drug expenditure, the second-largest category of health spending in Canada. Drugs have become one of the most important components of the health care system, both in clinical and in financial terms. This report summarizes data on drug expenditures overall, by source of finance and by selected drug classes, with a focus on the factors that contributed to observed spending levels and trends. The first section of this report provides an overview of drug spending trends in Canada over the past decade. It compares these trends with those observed in other major sectors of health care spending in Canada and with drug spending trends observed in other countries. The second part examines the impact of cost drivers on these trends, based on the framework outlined above. This section also contains information regarding changes in drug discovery and pharmaceutical policy that influence the availability, use and price of drugs in Canada. It should be noted that this report examines drug spending using multiple data sources, and as such two concepts of drug spending are used: retail spending and wholesale spending. Retail spending refers to purchases from community pharmacies, including dispensing fees and pharmacy markups. This excludes spending on drugs dispensed in hospitals. Wholesale spending refers to purchases made by community pharmacies and hospitals at wholesale or manufacturer prices and does not include dispensing fees or pharmacy markups. For further details on the data sources, see appendices A and B.

Pharmaceutical Spending in Canada

Canadians spent an estimated \$31.1 billion on pharmaceuticals in 2010.¹ This equals \$910 per Canadian, an amount per capita that is more than three times what was spent in 1990.¹ Prescribed drugs accounted for the majority of overall drug spending and, at a forecast \$26.1 billion, were expected to account for 83.8% of total drug spending in 2010.¹

Over the past two decades, pharmaceuticals have been one of the fastest-growing components of health system spending in Canada. Spending on pharmaceuticals in Canada grew particularly rapidly during the 1990s, when many blockbuster drug classes were established and/or expanded in terms of use and cost. Pharmaceuticals accounted for 11.4% of health care spending in 1990 (Figure 1). Because spending on drugs outpaced spending on other components of health care during the 1990s, pharmaceuticals' share of total health care spending in Canada increased by 4 percentage points (to 15.4% in 2000). Drug expenditures surpassed physician expenditures in 1997 and have since been second to only hospital expenditures in terms of their share of total health care spending in Canada.



Note

f: forecast.

Source

National Health Expenditure Database, 2011, Canadian Institute for Health Information.

Although pharmaceutical spending continued to outpace spending in other major categories between 2000 and 2010, growth during this decade can be characterized by two stages (Figure 2). Pharmaceutical expenditure growth from 2000 to 2005 was rapid relative to that of other components of health care spending and was similar to the trends observed in the 1990s; average annual growth in per capita drug spending was 8.1% from 1990 to 2000 and 8.9% from 2000 to 2005. In contrast, pharmaceutical spending growth from 2005 to 2010 slowed to an average rate of 6.1% per year. Drug spending in these latter five years grew more slowly than hospital spending, physician spending and total health care spending. As will be discussed further below, this change in the rate of growth of pharmaceutical spending (in absolute terms and relative to other health care spending) was driven by trends in product development and government policy that are unique to the pharmaceutical component of health care.



Note

f: forecast.

Source

National Health Expenditure Database, 2011, Canadian Institute for Health Information.

Internationally, Canada's drug spending has increased at a relatively high rate in recent years. After adjusting for economy-wide inflation, per capita drug spending in Canada increased at an average annual rate of 5.2% between 1997 and 2007, second only to the United States (6.1%) among comparator countries (Figure 3). Much lower spending growth was observed in Japan (2.3%), the United Kingdom (2.3%), Italy (1.4%) and New Zealand (0.8%). Per capita drug spending was \$805 in Canada in 2007, again second to the United States, at \$1,060. Among comparator countries, the lowest levels of per capita spending were observed in the United Kingdom (\$442) and New Zealand (\$304).ⁱ



Source

Organisation for Economic Co-operation and Development and IRDES, OECD Health Data 2010 (Paris, France: OECD and IRDES, October 2010).

In Canada, drugs are unique among major categories of health spending in that they are not fully addressed in the *Canada Health Act*; thus a large portion of drug expenditure is financed by the private sector. In 2010, the public share of drug spending was expected to account for 39.0% of total drug spending and 46.4% of prescription drug spending. Public-sector drug spending is forecast to have been \$12.1 billion in 2010. Average annual growth in public prescribed drug spending during the decade was 8.6%, slightly higher than the overall prescribed drug spending growth rate of 8.3%.

It should be noted that in addition to the \$12.1 billion in the NHEX drugs category, the public sector also finances drugs dispensed in hospitals and drugs funded through provincial cancer agencies and other special programs that are not considered part of regular provincial drug programs. Using wholesale data for 2009, hospital drug expenditure was estimated to be \$2.4 billion, \$800 million of which was for cancer drugs.

i. To compare international drug spending levels, national currency units were converted to Canadian dollars using purchasing power parities. Purchasing power parities account for differences in the cost of living between countries and thereby allow international price comparisons in terms of consumer sacrifice.²

Pharmaceutical Cost Drivers

Economic indices can be used to determine which factors have contributed to expenditure trends in the pharmaceutical sector. For a more detailed discussion of these indices, see Appendix A. This section provides a discussion of the various factors, referred to as "cost drivers," that influenced spending on prescription drugs in Canada over the past decade. The cost drivers were adapted from the standard conceptual framework for the project and include the following:

- **Population growth** is the effect of changes in the size of the population on total drug spending. Other things being equal, an increase in population size will increase total spending.
- **Population aging** is the effect of changes in the age distribution of the population on spending. An aging population will result in increased spending if the use and cost of drugs increase with age for the average individual within the population.
- **General inflation** is the effect of changes in general price levels, as measured by the gross domestic product (GDP) deflator, on spending in a particular sector. It reflects the changing purchasing power of a dollar from one period to another.
- **Price effects** are factors that change the average cost of purchasing a particular strength and form of a given drug. These can be the result of changes to the price of either a brand name or generic version of a given drug or shifts in use (of either new or existing users) from brand name to generic versions of drugs (or vice versa). Price effects are meant to capture the effect of drug price changes that differ from trends in general inflation; they are therefore measured net of inflation. For example, if the spending increase due to price changes was 3% and general inflation was 2%, then 2% of the spending increase would be attributed to general inflation and 1% would be attributed to price effects.
- Volume effects are factors that relate to the number and size of prescriptions purchased to treat various conditions.
- **Mix effects** are factors that change the average cost of treating a given condition due to changes in the drugs selected for such treatment. This can include changes in selected drug classes within therapeutic classes (for example, angiotensin-converting enzyme [ACE] inhibitor use among antihypertensive users) and drugs within drug classes (for example, ramipril use among ACE inhibitor users). A person starting on or switching to a higher-cost drug in a class would increase the mix effect.

Cost Drivers of Prescription Drug Spending: Decade in Review

In Canada, between 1998 and 2007, retail spending on prescription drugs used outside of hospitals grew from \$8.0 billion to \$19.0 billion, an average annual growth rate of 10.1%. This growth rate was calculated using IMS Brogan's Second Generation Canadian CompuScript Audit. Although similar in magnitude, this differs from the 9.8% average annual growth in prescribed drug spending reported in CIHI's NHEX over the same period. For more information on differences between these and other data sources used in this report, see Appendix B.

Factors that influence each measured effect are discussed in detail in the sections that follow. It is important to note that the trends observed in the following analysis are heavily influenced by trends in the larger provinces, as they make up the largest proportion of retail spending. For example, Quebec and Ontario accounted for roughly two-thirds of drug spending in Canada in both 1998 and 2007. Trends in these two provinces therefore had a strong influence on national trends. That said, although there was some variation in observed growth rates in drug spending and in the impact of individual cost drivers, volume and mix effects were the major drivers of drug spending in all provinces.

Population growth: Growth in the population contributed to an average annual growth in retail pharmaceutical spending of 1.0% (Figure 4), leaving an annual growth rate of 9.1% to be explained by population aging and the effects of the volume, price and mix of drugs used.



Sources

Second Generation Canadian CompuScript Audit and Anonymized Longitudinal Patient Datasets, IMS Brogan; S. Morgan et al., *The Canadian Rx Atlas, 2nd Edition* (Vancouver, B.C.: Centre for Health Services and Policy Research, University of British Columbia, 2008).

Population aging: This accounted for an average annual growth in retail drug spending of 1.0%. Although retail spending per capita increases dramatically with age (for example, \$1,778 for people age 65 and older compared with \$132 for people age 19 and younger), the population ages more slowly than individuals; therefore, the impact of population aging over time is more modest than what might be expected.

General inflation: Inflation accounted for an average annual growth in retail spending of 2.6%.

Price effects: Price changes for existing products and the effect of new generic entries roughly offset each other, accounting for an average annual decrease of 0.1% in drug spending. Net of general inflation (which was assumed to be responsible for 2.6% in spending growth), price effects accounted for a 2.7% decrease in drug spending. The prices of patented drugs, which made up two-thirds of retail spending, are regulated in Canada and cannot grow in excess of the consumer price index (CPI) for extended periods. Some provinces also control the prices of generic products, which accounted for an additional quarter of spending. Given the regulatory environment, it is not surprising that prices grew at rates well below inflation. It is important to note that the effect of new drugs, which are often introduced at higher prices than those of existing products, is not captured in the price effect but rather in the volume and mix effects.

Volume effects: These accounted for average annual growth in drug spending of 6.2%, the highest of all cost drivers. Significant volume effects were seen in some of the larger therapeutic classes, such as antihypertensive, cholesterol-lowering and gastrointestinal drugs (see further details in appendices C, D and E). Factors that contributed to increased volumes in these categories included an increased prevalence and treatment of disease, as well as changes in treatment guidelines.

Mix effects: Change in the mix of drugs used was the second-largest contributor to growth in retail spending (the effects of price changes and general inflation were considered a combined effect), accounting for average annual growth of 2.0%. Although a less significant driver than volume effects, mix effects contributed significantly to increased spending in some therapeutic classes. The influence of newer biologic medications led to a significant mix effect driving spending on both cancer drugs and immunosuppressants (see further details in appendices F and G).

Cost Drivers of Prescription Drug Spending: A Closer Look at Each Driver

Population Growth and Aging

Decade in Review

The effects of population growth were measured directly by dividing pharmaceutical spending by the size of the Canadian population. The average annual growth in drug spending attributable to population growth is therefore equal to the rate of population growth, which from 1998 to 2007 was 1.0%.

The effects of population aging were measured using age standardization: the profile of drug spending across age categories was held constant over time, while the population share in each category changed to reflect the changes in population age.

The aging of the Canadian population from 1998 to 2007 caused pharmaceutical spending to grow by approximately 1.0% per year. This relatively modest effect is due to the fact that, although the age gradient in prescription drug spending is steep (Figure 5), the population does not age as rapidly as individuals do. Other factors, such as the increased number of drugs purchased, were more significant drivers of pharmaceutical spending in Canada.



Source

S. Morgan et al., *The Canadian Rx Atlas, 2nd Edition* (Vancouver, B.C.: Centre for Health Services and Policy Research, University of British Columbia, 2008).

The aging effect was relatively small for all major categories of drug spending, though it did affect some therapeutic categories more than others. For example, population aging had 50% more impact on spending on cholesterol-lowering drugs (1.5% per year) than it did on overall pharmaceutical spending (1.0%). Aging had a greater impact on this category because the use of cholesterol-lowering drugs is uncommon in people younger than 45; therefore, the age gradient for this drug class is far steeper than for drugs overall.

Future Outlook

Population projections for Canada point to further population growth and aging in the coming years. Population aging will be of particular importance in the next 20 to 30 years as the baby boomer generation reaches age 65 and older. As this age group is known to have the highest per capita levels of drug spending (as well as of other categories of health spending), the effect of population aging on drug expenditure is likely to persist for the foreseeable future. People age 65 and older currently account for roughly 15% of the population and are forecast to account for approximately 25% of the population by 2036.³ That said, results from the past 10 years suggest that the impact of an aging population on drug spending is modest relative to other factors. A study examining future impacts of aging on drug spending predicted that population aging will contribute average annual growth in drug spending of less than 1.0% up to 2036.⁴

Drug Prices and General Inflation

Decade in Review

Two groups of drug products must be considered when examining Canadian drug prices: patented products and non-patented products (that is, generic products and brand name products whose patents have expired). Canadian prices of patented products are regulated by the Patented Medicine Prices Review Board (PMPRB). In general, PMPRB regulations ensure that increases in patented drug prices do not exceed growth in the CPI. Historically, however, price increases have been lower than annual growth in the CPI, and on average they did not grow by more than 1.0% in any year during the study period.⁵ In 2009, the PMPRB reported that patented products accounted for 62.4% of spending in Canada, which was a decrease in their share of total spending. Due to the fact that such a significant portion of drug spending in Canada is for products that are subject to price controls, there is limited upward pressure on drug prices in Canada. This is unique in health care, where other sectors have experienced significant price inflation during the past decade.⁶

The second group of drugs to consider is non-patented drugs, the majority of which are generic drugs. From 2004–2005 to 2009–2010, the total wholesale value (including purchases by drug stores and hospitals) of generic drugs sold in Canada grew at a rate (15.0%) that was three times faster than the growth rate for total wholesale purchases of brand name drugs (4.6%). As a result, the share of Canadian wholesale purchases of prescription drugs accounted for by brand name drugs fell from 82.1% in 2004–2005 to 74.1% in 2009–2010 (Figure 6).



Source

Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan.

Unlike new patented drugs that are chemically or biologically distinct from their competitors, generic drugs in most cases are considered equivalent to their competitors. Generics therefore generally compete by being cheaper than their brand name counterparts. Generic prices decreased as a percentage of brand name prices, from 65.1% in 2004–2005 to 59.9% in 2009–2010. Some provinces regulate the prices of generic drugs to be a percentage of the equivalent brand name product in order to be reimbursed by the public drug program. This practice has become commonplace and will be discussed in more detail later in this report.

The combined effect of prices and general inflation resulted in an average annual decrease in drug spending of 0.1% from 1998 to 2007. This suggests that, without considering general inflation, price increases are more or less offset by savings from generic competition and other price decreases. During this period, economy-wide inflation increased by 2.6% per year as measured by the GDP deflator (used as the measure of inflation in this analysis) and 2.2% as measured by the CPI.^{III} This suggests that although there was a small nominal decrease in drug prices, in real terms (net of inflation) the decrease was more substantial.

ii. GDP deflator and CPI data is available from Statistics Canada.

As with other effects, the price effect varied by major category of drug spending. The introduction of generic versions of widely used products provided relatively large savings in terms of spending in some categories. The introduction of generic atorvastatin contributed to a -4.5% price effect (net of inflation) in cholesterol-lowering drugs, and the introduction of generic versions of several proton pump inhibitors (PPIs), including omeprazole and pantoprazole, contributed to a -4.4% price effect (net of inflation) in gastrointestinal drugs.

Future Outlook

The generic share of the Canadian prescription drug market is expected to increase in the coming years as patents of many blockbuster drugs expire. The financial significance of patent expiries in the coming years was estimated by using the 2009 wholesale purchases (by drug stores and hospitals) of drugs whose patents are about to expire (Figure 7).



Sources

Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan; Patent Register, Health Canada.

In 2009, drugs whose patents were set to expire between 2010 and 2014 accounted for nearly \$8.7 billion in wholesale purchases. This equalled more than one-third (38.2%) of all wholesale purchases of prescription drugs in Canada during that year. This suggests that there is potential for significant savings from new generic competition that will occur over the coming years. It should be noted, however, that although many people switch to lower-cost generic products following the expiration of a patent, other factors can offset potential savings. These factors include patients continuing to take the brand name product following patent expiry, increased use of other patented products within the same drug class and patients starting on a generic who were not previously taking the brand name product. It should also be noted that in the case of some biologics, there may be more limited potential for generic price competition because there remains some uncertainty regarding the regulatory requirements, manufacturing processes and pricing for bio-generics or bio-similar drugs.

In addition to a high number of generic products about to come to market, there has also been, as previously mentioned, a recent trend for public drug programs to regulate generic prices as a percentage of the equivalent brand name product. Several provinces implemented policies in 2010 and 2011, either setting a maximum price or lowering the existing maximum for generic products listed on their formularies (that is, products that will be reimbursed by the program for eligible beneficiaries). These policies capped generic prices at between 25% and 56% of brand name products in most provinces. As generic prices are further reduced and these policies spread across public drug programs, it will be important to monitor their impact on drug spending.

Volume and Mix of Therapies

Decade in Review

Between 1998 and 2007, Canadians of all ages purchased more prescription drugs than ever before. These volume effects caused drug spending to increase by 6.2% per year during the period. This was the largest contribution of all of the drivers of drug spending trends in Canada over the period. Changes in the mix of drugs selected from within drug classes also caused spending on drugs to increase, at a rate of 2.0% per year from 1998 to 2007.

Volume effects can result from changes in the proportion of the population that is taking prescription drugs, changes in the average number of drugs people are taking or changes in the dose or duration of existing drug treatments. If these changes are positive (for example, more people taking drugs or people taking a larger number of drugs), the volume effect will be positive, while if these changes are negative (for example, people taking lower doses or shorter durations of their therapies), the volume effect will be negative.

Mix effects can result from patients switching drugs—either within a drug class (for example, existing PPI users switching from omeprazole to rabeprazole) or between drug classes within a therapeutic category (for example, gastrointestinal drug users switching from histamine-2 receptor antagonists [H2RAs] to PPIs)—or from new users using a relatively high proportion of a particular drug or drug class; all of these change the distribution of drugs used within a therapeutic class. If these changes result in a larger proportion of higher-cost drugs being used within the class, the mix effect will be positive, while if these changes result in a higher proportion of lower-cost drugs being used, the mix effect will be negative. It should be noted that switches between brand name and generic products are not captured here, unless the patient switched from a brand name version of one chemical to a generic version of another one, or vice versa. The effect of patients switching to generic versions of the same chemical is captured in the price effect.

The effect of the uptake of new drugs that enter the market is shared between volume and mix effects. This is because new drugs may change not only the distribution of drugs used within a class but also the overall utilization of that class.

The drug classes that drive pharmaceutical spending in Canada have changed over the past decade, reflecting shifts in drug development. While drug classes for relatively common conditions—such as hypertension, high cholesterol, ulcers and heart burn, and depression—expanded rapidly in the 1990s and early 2000s, their growth rates in spending began to slow down toward the end of the past decade.⁷ A closer look at the last half of the past decade revealed an increase in the growth rate of spending on drugs to treat less common conditions, such as cancer and autoimmune diseases (Table 1).

Immunosuppressants (such as etanercept, used to treat rheumatoid arthritis) exhibited the highest average annual growth rate in spending (25.1%) between 2004–2005 and 2009–2010, although they accounted for a relatively small share of total drug spending. Cancer drugs, which were the third-largest class in terms of wholesale spending in 2009–2010, also exhibited one of the highest average annual growth rates (13.4%). The introduction of newer biologic medications, which are often more expensive than existing drugs (where they exist), was a significant factor in the growth seen in both of these classes.

Table 1: Top 10 Therapeutic Categories by Contribution to Overall Wholesale Purchases (Drug Stores and Hospitals) Growth, Average Annual Growth (Percentage), 2004–2005 to 2009–2010

Drug Class	Contribution to Growth	AAG
Immunosuppressants	12.2%	25.1%
Cholesterol-Lowering Drugs	10.5%	7.8%
Cancer Drugs	9.3%	13.4%
Respiratory Drugs	5.4%	8.4%
Diabetes Drugs	4.5%	9.9%
Analgesics	4.3%	6.3%
HIV Drugs	4.1%	11.4%
Anti-Epileptics	3.5%	13.0%
Antidepressants	3.0%	4.2%
Antihypertensives	2.7%	1.6%

Note AAG: average annual growth.

Source

Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan.

Although volume and mix of use were among the primary drivers of spending on all major drug classes, there were variations in how each driver affected spending across categories. For example, while volume effects were the primary driver of spending on cholesterol-lowering drugs and antihypertensives (appendices C and D), mix effects were the primary driver of spending on immunosuppressants and cancer drugs (appendices F and G).

In the case of cholesterol-lowering drugs, treatment guidelines have lowered their target cholesterol levels; this in turn increased the number of patients recommended for treatment with medication.^{8–11} There have also been increases in the prevalence of obesity, diabetes and high blood pressure, which are all risk factors for heart disease.¹¹ Changes in treatment guidelines and the increased prevalence and treatment of high blood pressure were also likely the primary drivers of spending on antihypertensives.^{11–14}

The influence of newer biologic medications has led to a significant mix effect driving spending on both cancer drugs and immunosuppressants. In cancer drugs, much of the growth was due to increased expenditure on newer biologics known as monoclonal antibodies (MABs). These included trastuzumab, bevacizumab and rituximab. Spending on immunosuppressants was driven in large part by significant growth in spending on tumour necrosis factor alpha inhibitors (anti-TNF agents) such as etanercept and infliximab, which are used to treat multiple conditions, including rheumatoid arthritis and Crohn's disease.

Future Outlook

Past and future trends in drug spending in Canada are shaped by patterns of drug development, which are global in nature. For example, as new drugs are discovered and become available to treat previously unmet health care needs, the use of and spending on these class-defining drugs within related therapeutic categories will likely increase. Such dynamics are captured in the volume effect.

As drugs enter the market to compete with those in already-established chemical and therapeutic categories (also known as "me-too" drugs), they generally compete for market share through promotional activities rather than through price discounts. Late-entrant competitors in existing drug classes have historically been priced at higher costs per patient treated, relative to their older competitors.¹⁵ Whether or not the increased cost per patient treated comes with commensurate increases in the quality of health outcomes, the resulting changes in spending are captured in the mix effect.

Finally, when the 20-year patents that protect new products from competition expire, generic competition can enter the market. As mentioned previously, generics typically compete on price; they therefore tend to reduce the average price paid for essentially the same drug. This dynamic is captured in the price effects results reported above.

The potential impact of these volume and mix effects are determined in large part by the timing and pattern of drug discovery. The interaction between scientific and economic competition produces a cycle of market expansion (volume effects) and product differentiation (mix and volume effects) and, eventually, price competition (price effects) within therapeutic categories. Historical data concerning drug approvals illustrates patterns consistent with the view that the pharmaceutical industry experienced a significant wave of innovation in the 1990s. The five-year averages of new chemicals and drug classes approved for sale in Canada from 1949 to 2010 show that the number of new drug approvals peaked in Canada in the 1990s (Figure 8). In contrast to the total number of new drugs, the number of category-defining drug discoveries has been relatively stable (arguably even on a downward trend since the 1970s). Thus, a large portion of the spike of new drug approvals in the 1990s was accounted for by approvals for follow-on or me-too drugs in established drug classes. The same peak was also observed in data on drug approvals made by the U.S. Food and Drug Administration.¹⁶



Sources

National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information; Drug Product Database, Health Canada.

The rise and fall of follow-on drug competition in the late 1990s likely reflects changes in the nature of drug discoveries. Many drug classes that were developed in the 1970s and 1980s were based on common scientific paradigms: theories regarding receptors and enzymes. By the nature of both the scientific opportunities and economic incentives, the most successful drug classes were blockbuster drug classes to treat relatively common conditions. Many entrants followed pioneering discoveries of the time by developing similar-but-distinct chemical compounds to engage the same therapeutic target. This likely explains the rise in follow-on drug development in the 1990s.

The pharmaceutical industry is currently between the paradigms of small-molecule receptortheory drug development and that based on molecular medicine. Molecular targeting in particular has produced a wave of new drug development in the antineoplastic and immunomodulating agent categories (for example, MABs, as previously mentioned). Although those therapeutic categories have historically accounted for less than 10% of all previously approved drugs on the market, they accounted for 20% of drugs approved in the past decade and nearly 30% of drugs under clinical development today (Table 2).¹⁶

2000, by Bload metapetitic Oategory							
Broad Therapeutic Category	Percentage of New Drugs, 2001–2009	Percentage of Drugs in Phase III Trials					
Antineoplastic and Immunomodulating Agents	20.4	28.4					
Anti-Infectives for Systemic Use	20.4	9.6					
Nervous System	13.1	12.5					
Alimentary Tract and Metabolism	9.9	10.4					
Blood and Blood-Forming Organs	6.3	3.7					
Cardiovascular System	6.3	8.4					
Genitourinary System and Sex Hormones	5.2	3.9					
Systemic Hormonal Preparations	3.7	2.5					
Sensory Organs	3.7	4.5					
Dermatologicals	2.6	2.2					
Respiratory System	2.6	4.1					
Other	5.8	9.8					
Total	100.0	100.0					

Table 2: Newly Marketed Drugs in Canada, 2001 to 2009, and Drugs in Phase III Clinical Trials, 2009, by Broad Therapeutic Category

Sources

Newly Marketed Substances in Canada: Patented Medicine Prices Review Board; Drugs in Phase III Clinical Trials: New Medicines in Development Database (<u>www.innovation.org</u>).

Many of the drugs under development today are for much smaller markets than the blockbuster drugs of the past. The smaller markets for drugs that are brought to market under emerging scientific paradigms may not lead to as many follow-on competitors as drug discoveries of the past; however, development of drugs for smaller populations of patients with more dire health needs does present new policy challenges. Policy-makers and health professionals are already confronting major clinical, economic and ethical challenges caused by the growing rate of approval of new drugs to treat more serious conditions. One of the biggest challenges is that such drugs are often priced at historically unheard-of levels: prices not in the hundreds or thousands of dollars per patient treated but in the hundreds of thousands of dollars per patient treated but in the hundreds of thousands of dollars per patient therapies, and their higher prices are not necessarily unwarranted. However, the fact remains that increased prices mean that public drug programs must allocate more resources to fund these drugs, making choices about which drugs to cover more difficult.

Summary

This report examined drug cost drivers between 1998 and 2007, when retail spending on prescription drugs in Canada grew from \$8.0 billion to \$19.0 billion, an average annual growth rate of 10.1%. Increased volume of use and changes in the mix of treatments being used were the largest contributors, accounting for average annual growth of 6.2% and 2.0%, respectively. Both volume and mix effects were due in part to changes in treatment guidelines, increased disease prevalence and the uptake of new drugs.

Population growth and aging had a more modest impact on drug spending during the study period, each accounting for average annual growth of 1.0%, while price changes did not have a significant role. Although, on average, older Canadians spend significantly more than their younger counterparts, the population does not age as rapidly as individuals do; as such, the impact of aging is smaller than some might expect.

Cholesterol-lowering drugs, cancer drugs and immunosuppressants accounted for roughly onethird of overall growth in drug spending; the growth of cancer drugs and immunosuppressants was due in part to the uptake of newer biologic drugs. Trends in drug development suggest that these classes may continue to drive drug spending in the years to come. Although these therapeutic categories historically accounted for less than 10% of all approved drugs on the market, they account for 20% of drugs approved in the past decade and nearly 30% of drugs under clinical development today.¹⁶

Some cost savings may also be available in future due to the increased availability of generic drugs. In 2009, drugs whose patents were set to expire between 2010 and 2014 accounted for nearly \$8.7 billion in wholesale purchases. This was equal to more than one-third (38.2%) of all wholesale spending on prescription drugs in Canada. However, availability of these cost savings appears to drop off significantly in subsequent years.

In addition to a high number of generic products about to come to market, there has also been a trend in the past year for public drug programs to regulate generic prices as a percentage of the equivalent brand name product (these prices are often applied by private drug programs as well). Although generic price controls may offer significant savings in the short term, growth in spending will persist if increased utilization continues to be the most significant driver of drug spending.

Appendix A: Methodological Notes

Cost Driver Calculations

Cost drivers were calculated for two separate time periods. The main cost driver analysis focused on the period from 1998 to 2007, and used IMS Brogan's Second Generation Canadian CompuScript Audit. Based on this data, in Canada, retail spending on prescription drugs used outside of hospitals grew at an average annual rate of 10.1% between 1998 and 2007. Although similar in magnitude, this growth rate differs from the 9.8% average annual growth in prescribed drug spending reported in CIHI's NHEX over the same period. Differences between data sources contribute to the differences in the measured growth rates. For example, NHEX data includes only costs to Canadian customers, whereas CompuScript data includes all retail pharmacy sales, including those to non-Canadian customers. As well, NHEX data contains spending on drugs dispensed outside of retail pharmacies (for example, in ambulatory clinics), whereas this spending is not included in the CompuScript data. For more information on differences between these and other data sources used in this report, see Appendix B.

An analysis of the drivers of spending on cancer drugs and immunosuppressants was conducted for the period 2004–2005 to 2009–2010. This analysis used IMS Brogan's Canadian Drug Store and Hospital Purchases Audit. Due to data availability, years were defined as being from October to September. For example, 2009–2010 includes the 12 months from October 2009 to September 2010.

Spending was first divided by population to remove the impact of population growth. The population growth effect was calculated as the average annual rate of change in population during the study period.

Per capita spending (spending divided by population) was then divided by the GDP deflator in the last year of the study period (using the first year as a base year) to account for general inflation. General inflation was calculated as the average annual rate of change in the GDP deflator during the study period (that is, 2.6% for the analysis conducted for the period between 1998 and 2007, and 2.2% for the analysis conducted for the period between 2004–2005 and 2009–2010).

Real per capita spending was then age-standardized for each drug and aggregated. The population aging effect was calculated as the difference in average annual growth in spending and growth in age-standardized spending (holding the age distribution of the population constant throughout the study period). It should be noted that the population aging effect was not calculated for the analysis using purchase data (shown in appendices F and G), as patient-level data was not available.

The measurements of price, volume and mix effects are net of the changes in population size and age and general inflation, which means that they are calculated as contributions to changes in age-standardized, real per capita drug spending. They are based on Fisher's ideal index formula (which is the geometric mean of the Laspeyres and Paasche indices) for indices of the implicit price, quantity and mix of therapy used by the Canadian population. To measure price effects, prices were calculated as total spending on a given chemical, strength and form combination in a given year, divided by the number of units dispensed of that combination in that same year. Price effects were measured as changes in age-standardized, real per capita expenditure by drug class due to price changes, holding the size of each therapeutic class (for further details on the assignment of drug classifications, see Appendix H) and the relative share of each drug in its respective therapeutic class expenditure constant over time. Because prices were defined at the chemical strength and form levels and not the specific product level, switching between brand name and generic products will result in a price effect, as will true changes in the price of either brand name or generic products. As previously mentioned, it is important to note that the effect of new drugs, which often enter the market at prices higher than those of existing products, is not captured in the price effect, but rather in the volume and mix effects.

To calculate mix effects, average prices for each therapeutic category were calculated as the total number of units dispensed for a given chemical, strength and form combination in a given year, multiplied by the price of that combination (as defined above) in the base year (as prices are held constant when measuring mix effects), then divided by the total number of units dispensed for that therapeutic category in that year. Mix effects reflect changes in agestandardized per capita expenditure by therapeutic category due to changes in the (weighted) average price of all claims within that category. Because all other factors are held constant, mix effects occur due to shifts in the relative shares of drugs (that is, distinct combinations of chemical, strength and form) within each therapeutic class, holding drug prices, agestandardized expenditure per drug and the size of each therapeutic category constant. A drug's share in its therapeutic class is calculated as the number of units of that drug dispensed divided by the total number of units dispensed for its therapeutic class. If the drugs accounting for increasing proportions of total volume in their class (including drugs introduced to the market during the study period) had, on average, higher prices (as measured above) than those accounting for decreasing proportions, then the mix effect for that category was positive. Therapeutic class-specific effects were then aggregated to give the overall mix effect.

Volume effects were measured as changes in age-standardized, real per capita expenditure by drug class, holding prices and the share of each drug in its respective therapeutic class (as measured above) constant over time. Again, therapeutic class–specific effects were then aggregated to give the overall volume effect. As was the case with mix effects, the effects could be caused by both new and existing products.

Value of Patent Expiries

The value of patent expiries was obtained by assigning patent expiry dates from Health Canada's Patent Register to each product in IMS Brogan's Drug Store and Hospital Purchases Audit. Products without patents in the Patent Register were assumed to not have a valid patent. In many cases, multiple patents were associated with a given product. In these cases, the estimated date of patent expiry for each product was assumed to be the date of the earliest expiring patent in Health Canada's Patent Register for that drug. This method was validated by comparing the year of generic drug approval with these estimates of patent expiration dates for products with patents that had already expired; these dates coincided frequently. In some cases, however, products can be protected from generic competition by additional patents that expire after the first relevant patent does. A company may also license a generic company to produce a generic product before the relevant patent has expired.

New Chemicals and Drug Classes

New chemicals and new drug classes were identified using Health Canada's Drug Product Database and CIHI's National Prescription Drug Utilization Information System (NPDUIS) Database. A chemical was considered new in the first year in which it was marketed in Canada. A drug class was considered new in the first year in which a chemical from that class was marketed in Canada. For more information on how chemicals and drug classes were defined, see Appendix H. To reduce the impact of year-to-year variation, five-year averages are reported. The number of new chemicals/drug classes reported in each year is equal to the average number of chemicals/drug classes that were newly marketed in that year and the four preceding years.

Limitations

No single data source exists that provides information on all drugs dispensed in Canada and on the patients to whom they were dispensed. For this reason, this study makes use of multiple drug sources. Some sources are more complete in terms of drug spending but contain less detailed information, while others contain more detail but are narrower in terms of coverage. It is recognized that there are differences in source data (for example, wholesale spending will not be equal to retail spending); however, it is felt that the observed trends are similar between sources. Multiple data sources were required to examine a wide range of important issues, such as the impact of aging and trends in cancer drugs; many cancer drugs are primarily dispensed in hospitals and information on them is therefore not available in data collected from retail pharmacies.

IMS Brogan data contains projections based on a sample of data suppliers; it is therefore subject to a sampling error. However, this error is very small when using pan-Canadian data.

No information regarding diagnoses or the conditions for which prescriptions were written was available for this study. For this reason, drug classes were assigned according to the primary indication and may not reflect what the drug was actually used for. For example, many drugs classified in this study as antihypertensives are also used to treat heart failure.

Appendix B: Data Sources

Table B1: Data Sources								
Source		Cost Inclusions		Spending Detail Available				
Custodian	Data Source	Admin. Costs	Fees and Markups	Source of Finance	Drug Class	Age/Sex	Community/ Hospital	
СІНІ	NHEX	Yes	Yes	Yes	No	No	Community Only	
	NPDUIS	No	Yes	Public Only	Yes	Yes	Community Only	
IMS Brogan	DS&H	No	No	No	Yes	No	Yes	
	CS/ALPD	No	Yes	No	Yes	Yes	Community Only	

Data used in this study comes from data holdings maintained by CIHI and IMS Brogan.

Notes

NHEX: National Health Expenditure Database.

NPDUIS: National Prescription Drug Utilization Information System.

CS/ALPD: Second Generation Canadian CompuScript Audit and Anonymized Longitudinal Patient Datasets.

CIHI's NHEX contains a historical series of macro-level health expenditure statistics by province and territory. The "drugs" category in NHEX is intended to measure final consumption, outside an institutional setting, of drugs purchased by consumers or third-party payers on their behalf, generally from retail outlets. Drug expenditure data in NHEX is an estimate that represents the final costs to Canadian consumers, including dispensing fees, markups and appropriate taxes. For more information on the drugs component of NHEX, please refer to CIHI's *Drug Expenditure in Canada* report series.

The NPDUIS Database, also maintained by CIHI, contains drug claims accepted by public drug programs, either for reimbursement or toward a deductible. Costs include dispensing fees and markups. As of December 2010, the NPDUIS Database included data submitted by provincial drug programs in Alberta, Saskatchewan, Manitoba, New Brunswick, Nova Scotia and Prince Edward Island. Not all public drug programs submit data in all provinces.

The Canadian Drug Store and Hospital Purchases Audit (DS&H), maintained by IMS Brogan, contains sales volumes of dollars and units of pharmaceutical products purchased by retail pharmacies and hospitals. Dollars represent wholesale or manufacturer prices and do not include dispensing fees or retail markups. Data is collected from a sample of pharmacies and then projected to be representative of purchases in all retail pharmacies and hospitals across Canada.

DS&H: Canadian Drug Store and Hospital Purchases Audit.

The final two IMS Brogan data holdings sourced in this study, the Second Generation Canadian CompuScript Audit and the Anonymized Longitudinal Patient Datasets (CS/ALPD), were used as a combined data source, as sourced in the *Canadian Rx Atlas*, published by the Centre for Health Services and Policy Research at the University of British Columbia. This combined data set contains total volumes of prescriptions, units and dollars for retail pharmacies in every province, including dispensing fees and markups. It also provides estimates of age-specific shares of prescriptions filled for every province and every type of drug. Data is collected from a sample of pharmacies and then projected to be representative of purchases in all retail pharmacies across Canada. Results from the *Canadian Rx Atlas* were re-analyzed in this study so that the methodology would be consistent with that used to measure cost drivers of other categories of health spending in CIHI's report *Health Care Cost Drivers: The Facts*.

Appendix C: Drivers of Retail Spending on Antihypertensives in Canada, 1998 to 2007

Drugs for the treatment of hypertension (high blood pressure) make up the largest therapeutic category of drugs in Canada. Spending on these drugs grew from \$1.3 billion in 1998 to \$2.7 billion in 2007, an average annual rate of 9.1%. As with overall spending on drugs, general inflation and population growth contributed to average annual increases in antihypertensive spending of 2.6% and 1.0%, respectively, between 1998 and 2007.



Sources

Second Generation Canadian CompuScript Audit and Anonymized Longitudinal Patient Datasets, IMS Brogan; S. Morgan et al., *The Canadian Rx Atlas, 2nd Edition* (Vancouver, B.C.: Centre for Health Services and Policy Research, University of British Columbia, 2008).

Population aging had a slightly larger impact on spending on antihypertensives (1.3% per year) than it did on overall pharmaceutical spending (1.0%) during this period. This is because the use of antihypertensives is more concentrated among older populations than is the use of drugs in general.

After population aging was accounted for, changes in the volume of hypertension treatments purchased in Canada increased spending on this class of drugs by 6.5% per year from 1998 to 2007. The increased volume of antihypertensives used is likely related to increased diagnosis and treatment of hypertension.¹¹ Such trends likely reflect a combination of actual changes in population morbidity and changes in clinical practice (including screening and diagnosis).^{11–14}

Changes in the mix of drugs selected from within the broad category of hypertension treatments caused spending on these drugs to increase at a rate of 0.6% per year from 1998 to 2007. This modest impact of drug mix stems from more rapid growth in the use of newer ACE inhibitors and angiotensin II receptor blockers (ARBs) compared with growth of older diuretics and beta blockers. The financial effects of such patterns were more than offset by the savings created by the increased availability and use of generic versions of antihypertensives. Such generic competition resulted in average price decreases (net of inflation) of 2.8% per year between 1998 and 2007.

Appendix D: Drivers of Retail Spending on Cholesterol-Lowering Drugs in Canada, 1998 to 2007

Drugs used to manage cardiovascular risks associated with high cholesterol (statins) have been one of the fastest-growing therapeutic categories of prescription drugs, making them the second-largest category in terms of retail spending in Canada during 2007. Between 1998 and 2007, retail spending on cholesterol-lowering drugs grew from \$0.5 billion to \$1.9 billion, an average annual rate of 14.8%. This was the fastest-growing major therapeutic category in terms of retail prescription drug sales in Canada over the period; this class also continued to be among the fastest-growing categories in terms of wholesale spending in Canada through to 2010.

General inflation and population growth contributed to average annual increases in spending on cholesterol-lowering drugs of 2.6% and 1.0%, respectively, between 1998 and 2007, leaving 11.1% per year growth in inflation-adjusted retail spending per capita to be explained by other factors.



Sources

Second Generation Canadian CompuScript Audit and Anonymized Longitudinal Patient Datasets, IMS Brogan; S. Morgan et al., *The Canadian Rx Atlas, 2nd Edition* (Vancouver, B.C.: Centre for Health Services and Policy Research, University of British Columbia, 2008).

From 1998 to 2007, population aging had 50% more impact on spending on cholesterollowering drugs (1.5% per year) than it did on overall pharmaceutical spending (1.0%). Aging had a greater impact on this category because use of cholesterol-lowering drugs is very rare among people younger than age 45; therefore, the age gradient for this drug class is far steeper than for drugs overall.

The volume of cholesterol treatments purchased in Canada was the dominant cost driver in this category, with use among age groups growing sufficiently quickly to cause spending on this drug class to increase by 12.9% per year from 1998 to 2007. This is likely because of increases in both the prevalence of hyperlipidemia and related risk factors as well as changes in prescribing practices and guidelines.^{8–11}

Changes in the mix of drugs selected from within this therapeutic category caused spending on these drugs to increase at a rate of 1.3% per year from 1998 to 2007. This was more than offset by savings generated by the availability of generic drugs within this category. Further savings are expected in years following 2007, because the first patent on the leading drug within the category expired in 2010.

Appendix E: Drivers of Retail Spending on Gastrointestinal Drugs in Canada, 1998 to 2007

Gastrointestinal drugs used to treat heartburn, ulcers and damage to the esophagus resulting from acid reflux (acid-reducing drugs) were the third-largest therapeutic category of prescription drugs in terms of retail spending in Canada in 2007. Between 1998 and 2007, retail spending on gastrointestinal drugs grew from \$0.5 billion to \$1.4 billion, an average annual rate of 10.9%. General inflation and population growth contributed to average annual increases in spending on gastrointestinal drugs of 2.6% and 1.0%, respectively, between 1998 and 2007, leaving 7.3% per year growth in inflation-adjusted spending per capita to be explained by other factors.



Sources

Second Generation Canadian CompuScript Audit and Anonymized Longitudinal Patient Datasets, IMS Brogan; S. Morgan et al., *The Canadian Rx Atlas, 2nd Edition* (Vancouver, B.C.: Centre for Health Services and Policy Research, University of British Columbia, 2008).

Because the use of gastrointestinal drugs increases steadily with age, the aging of the Canadian population from 1998 to 2007 caused spending on this therapeutic category to increase by approximately 1.1% per year. As with other leading drug classes, a far more important driver of spending trends was the increased use of gastrointestinal drugs by people within each age category. The increased volume of gastrointestinal drug use contributed to growth in spending on these drugs of 8.4% per year between 1998 and 2007.

The increased use of gastrointestinal drugs was driven by increases in the use of PPIs. The growth in PPI use also had an effect on the mix of drugs used within this category: because PPIs are more costly than older H2RAs, their growing share of this therapeutic category caused spending to increase by an average of 2.1% per year from 1998 to 2007. Because of the increased availability of generic H2RAs and PPIs, generic competition resulted in significant price reductions in this category. Prices fell by 4.4% per year (relative to inflation) over the period. Such patterns are expected to continue, as most of the leading drugs in this category are available in generic format now or will be in the near future.

Appendix F: Drivers of the Wholesale Value of Cancer Drug Purchases by Hospitals and Drug Stores in Canada, 2004–2005 to 2009–2010

According to Canadian Drug Store and Hospital Purchases Audit data from IMS Brogan, cancer drugs have been one of the fastest-growing components of pharmaceutical spending in the past six years. Wholesale purchases of cancer drugs by hospitals grew from \$444 million for the 12 months ending in September 2005 to \$848 million for the 12 months ending in September 2010, an average annual growth rate of 15.2%. Wholesale purchases of cancer drugs by community drug stores grew from \$271 million to \$444 million, for an average annual growth rate of 10.4% during the same period. General inflation and population growth contributed to average annual growth in spending on cancer drugs of 2.2% and 1.1%, respectively, during this period, leaving 11.9% (hospitals) and 7.1% (drug stores) per year growth in inflation-adjusted spending per capita to be explained by other factors.



Source

Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan.

Wholesale data does not allow for the calculation of the effects of population aging on cancer drug spending. Increases in the volume of hospital-based cancer therapy used by the population as a whole contributed to average annual growth in wholesale spending on this therapeutic category for hospitals of 3.9%. While growth in the volume of hospital purchases of cancer drugs was offset by a 4.3% average annual decrease in hospitals' wholesale prices of existing cancer drugs (including generic savings), changes in the mix of cancer drugs purchased by hospitals have had a major impact on spending in this category. Growing purchases of newer, high-cost cancer treatments resulted in average annual increases of 12.2% in the cost of wholesale cancer drug purchases by hospitals from 2004–2005 to 2009–2010. The available data does not reflect negotiated discounts received by hospitals from drug manufacturers, which may have offset some of this cost increase.



Source

Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan.

The drivers of community drug store cancer drug spending were similar to the drivers of hospital spending, though there were some differences. This was not surprising given that the mix of cancer drugs dispensed in hospitals differs substantially from that dispensed in community pharmacies. One of the major differences was that increases in the volume of therapy used by the population as a whole were not a major cost driver of community drug store purchases. The prices of wholesale cancer drugs purchased by community drug stores grew below the rate of inflation, resulting in a modest negative price effect. As with hospitals, growing purchases of newer, high-cost cancer treatments resulted in significant average annual increases in costs. For wholesale cancer drug purchases by community drug stores, changes in the mix of drugs purchased from 2004–2005 to 2009–2010, due in large part to these newer therapies, caused costs to increase by an average of 7.0% per year.

Appendix G: Drivers of the Wholesale Value of Immunosuppressant Drug Purchases by Drug Stores in Canada, 2004–2005 to 2009–2010

The wholesale value of Canadian purchases of immunosuppressant drugs grew more quickly over the past six years than purchases from any other major therapeutic category. This was driven largely by increases in purchases by community drug stores. Wholesale purchases of immunosuppressant drugs by hospitals grew from \$83 million for the 12 months ending in September 2005 to \$95 million for the 12 months ending in September 2010, for an average annual growth rate of 2.8%. In contrast, wholesale purchases of immunosuppressant drugs by community drug stores grew from \$297 million to \$1.070 billion, for an average annual growth rate of 29.2% during the same period. General inflation and population growth contributed to average annual growth in immunosuppressant spending of 2.2% and 1.1%, respectively, during this period.



Source

Canadian Drug Store and Hospital Purchases Audit, 2010, IMS Brogan.

Much of the increase in immunosuppressant drug purchases in the community setting was a result of increased purchases of anti-TNF drugs, which are relatively new drugs used to treat multiple conditions, including rheumatoid arthritis, psoriasis and Crohn's disease. The three most commonly used anti-TNF drugs were marketed in Canada between 2001 and 2004. All three had significant uptake, contributing to both the volume and mix effects.

The change in the mix of drugs used had the greatest impact on spending in this category, accounting for an average annual increase of 17.8% in community drug store wholesale purchases of immunosuppressant drugs. The growth in purchases of the newer, high-cost anti-TNF drugs compared with previous lower-cost treatments was a major contributor to the mix effect growth. These drugs can cost, on average, anywhere from roughly \$9,000 to more than \$30,000 per patient per year, depending on the dose and the reason for use.^{17–19}

Appendix H: Drug Classification Systems

Drugs can be analyzed using many different classification systems. This analysis is based on the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system.

- In the ATC classification system, drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.
- The ATC does not distinguish between strength, dosage, route or form of drug, except as implied by the ATC (for example, inhaled corticosteroid).
- Drugs are classified in groups at five different levels:
 - The drugs are divided into 14 anatomical main groups (first level), with pharmacological/therapeutic subgroups (second level).
 - The third and fourth levels are chemical/pharmacological/therapeutic subgroups.
 - The fifth level is the chemical substance.
 - The second, third and fourth levels are often used to identify pharmacological subgroups when that is considered more appropriate for analysis than therapeutic or chemical subgroups.

In the analysis of drug cost drivers, the WHO ATC classification system was used as reported in IMS Brogan's Second Generation Canadian CompuScript Audit and Canadian Drug Store and Hospital Purchases Audit. In this analysis

- IMS Brogan assigned drug products to a fourth-level ATC;
- "Drug class" refers to the pharmacological subgroup (ATC level 3); and
- "Therapeutic category" refers to groups of pharmacological subgroups with similar primary indications.

In the analysis of new chemicals and drug classes, the WHO ATC classification system was used as reported in Health Canada's Drug Product Database. In this analysis

- Health Canada typically assigned drug products to a fifth-level ATC, although in some cases it assigned an ATC at another level;
- "Chemical" refers to the chemical substance (ATC level 5). A single chemical may appear in multiple ATC level 5 codes if it is used in multiple ways to treat multiple medical conditions;
- "Drug class" refers to the chemical subgroup (ATC level 4) of the WHO ATC classification system. At this level, subgroups are, in theory, regarded as groups of different chemicals that act in the same way to treat similar medical conditions. Drug class was defined differently from above because more detail was required for this analysis; and
- "Broad therapeutic category" refers to the anatomical main group (ATC level 1) of the WHO ATC classification system. At this level, groups are, in theory, regarded as groups of different chemicals that act on the same organ or system.

Appendix I: IMS Brogan Disclaimer

IMS Brogan, a unit of IMS Health, has offices in Montréal, Toronto and Ottawa.

IMS Health provides market intelligence and health information to pharmaceutical and health care industries worldwide. For this report, CIHI used IMS Brogan's Canadian Drug Store and Hospital Purchases Audit (CDH), which measures the dollar value and unit volume of pharmaceutical products purchased by Canadian retail pharmacy outlets and hospitals. Data for the CDH was collected from a representative sample of 2,700 drug stores and 686 hospitals and long-term care facilities. The sample data was then projected to the universe of drug stores and hospitals, to reflect all purchases across Canada.

IMS Brogan relies on external suppliers for all of its data and therefore, while employing its best efforts to ensure the accuracy and completeness of its data and any analysis thereof, IMS Brogan makes no representation as to the reliability of such data or any application derivative thereof. In no event shall IMS Brogan be liable for any damages, including any consequential, incidental or special damages, resulting from any use or application of its data, whether foreseeable or not, even if IMS Brogan has been advised of the possibility of such damages.

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