

More than 20 million Canadians rely on new medicines and vaccines to help them stay healthy and productive both at work and at home. Employers also benefit from competitive drug plans that allow their employees and families to be healthy and productive. These plans are a major part of the compensation package for employees.

IMS Brogan Private Drug Plan Drug Cost Forecast Commissioned by Rx&D

Introduction

Employers are faced with cost pressures and other challenges such as an aging workforce and a rapidly changing economy and business environment. Concerns have been expressed that specialty and biologic drugs make up a growing proportion of their drug plan costs and that private drug plan expenditures on new medicines may threaten the sustainability of private sector drug plans. As well, some employees are becoming increasingly concerned about their drug coverage to treat chronic conditions and about having access to the appropriate treatment.

This Forecast adds a new dimension to the debate. It shows with clear and empirical evidence that growth in overall private drug plan drug costs will be sustainable and there is room for innovative new therapies to support a healthy and productive workplace.

Project Description

To test the validity of these assumptions and predictions and contribute to the dialogue over sustainability, Rx&D commissioned IMS Brogan, the Canadian business unit of IMS Health, a global leader in healthcare market insights, to conduct a five year forecast of private drug plan drug costs for 2013-2017. The result is a comprehensive report and forecast that is unprecedented in its level of transparency, rigour and detail and includes a sensitivity analyses for stakeholders to discuss and interpret.

The Forecast predicts growth in private drug plan drug costs at the overall market level and may not reflect the experience of individual plans.

It pays particular attention to historical and future baseline costs at a therapeutic level and analyzes key relevant cost drivers affecting future growth. These factors encompass market entry of new medicines currently in the pipeline including specialty medicines/biologics, the impact of generic entry and pricing reforms as well as the changing demographics in the workplace.

These elements of the methodology are crucial to a rigorous forecast and cannot be viewed in isolation when predicting future growth as seen in some models which concentrate almost exclusively on the drug development pipeline. For example, while it has been increasingly discussed in the market that the utilization of specialty medicines¹ will account for an increasing proportion of drug costs in the future, this must be taken into consideration with other market drivers to conclude the relative incremental impact on overall drug costs. This is partly because the impact of new products coming to market is not truly an additive cost, as displacement of existing therapies occurs and ongoing generic penetration offset the cost of new innovations.

Methodology

This IMS Brogan Private Drug Plan Drug Cost Forecast is both rigorous and transparent with a quantitative and qualitative focus on the pharmaceutical phase III pipeline and the distribution of molecule types (small molecule, specialty and cancer) using as a comparator what the market has experienced historically. The model is also innovative because it is interactive which allows users to change assumptions to provide for various scenarios.

The projections are based upon the drug costs of pay direct claims and represent approximately 70% of the private market. The source is the IMS Brogan Private Drug Plan databases which include pay direct claims data representing the majority of drug cost to private plans. Drug cost includes ingredient cost plus wholesale and pharmacy mark-ups (excludes professional & compounding fees²). Prices are held constant to latest price/volume (Q4 2012).

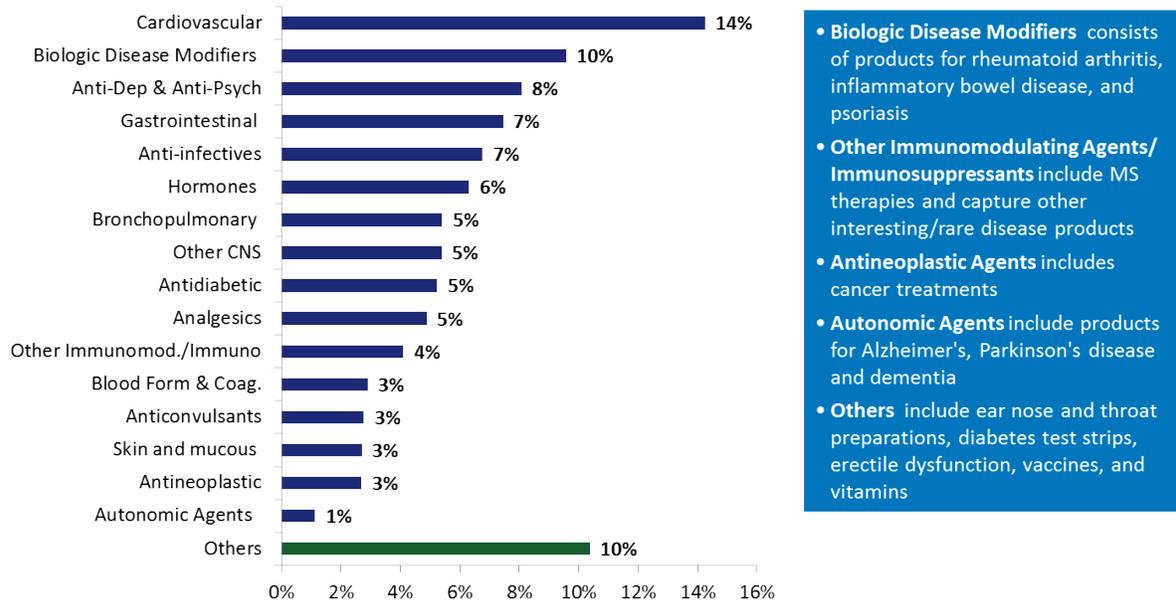
A baseline analysis: Actual historical volume trends were pulled from the IMS Brogan Private Drug Plan databases. They were broken down into 16 therapeutic classes representing 90% of private market drug costs, along with one additional category of “other” representing the remaining therapeutic classes that account for 10% of expenditure (Table 1). The historical growth rates in each class were trended forward to predict future utilization of each class, creating the baseline analysis which depicts a status quo scenario assuming no changes in the market beyond the historical trends.

¹ Specialty - are generally biologic chemicals and injectables. For the purpose of this analysis, specialty products are defined to have costs exceeding \$10,000 per claimant. Specialty products are generally in niche or new therapy areas including Anti-TNFs, Multiple Sclerosis, Alzheimer's, Lupus and HEP products.

² Except in the province of Quebec, where these fees cannot be disaggregated from the total claim amount.

Table 1

Share of Private Drug Plan Drug Costs by Therapeutic Class 2012



Cost drivers: In addition to the baseline analysis, four key events were applied to the baseline analyses which are most likely to impact future growth:

- I. Generic Entry/loss of exclusivity of branded products
- II. New Drug Entry
- III. Ageing of Drug Plan Beneficiaries
- IV. Cost Containment/drug plan management strategies.

For the purposes of this analysis in the current environment, previously implemented cost containment measures were inherently included in the baseline but future cost containment strategies were not part of the analysis. This was done to demonstrate a conservative estimate of future drug costs based on the assumption that current drug plan designs would remain *status quo* (i.e. no expansion of managed plans, increasing restrictions, etc.). Similarly, the potential cost savings introduced by subsequent entry biologics (SEBs) were not incorporated as limited information is available at this time to suggest the potential pricing impact of SEBs; thereby, further generating a conservative estimate of cost growth.

IMS Brogan Private Drug Plan Drug Cost Forecast looks at overall drug costs and is fundamentally different from other private market forecasts which look at drug *plan* costs.

Generally, projections of drug plan costs concentrate on data from a single employer and may take into consideration such items as plan advisor commissions, administration fees and trend factors, in addition to supply chain costs such as dispensing fees and markups. This forecast, by contrast, captures the growth anticipated across the overall private drug plan market in Canada that is attributed to drug costs (ingredient cost plus wholesale and pharmacy mark-ups.)

Key Findings

Table 2 displayed the forecasted growth in private drug expenditures in Canada. **By 2017, in a high scenario, private drug costs are estimated to grow at a Compounded Annual Growth Rate (CAGR) of 2.8 % and will reach \$7.734 billion³. In a low scenario, the CAGR is predicted to be 1.6% with 2017 costs reaching \$7.311 billion.**

Table 2

Drug Cost Forecast – Adjusted for Identified Events (\$ millions)

| Description | 2013f | 2014f | 2015f | 2016f | 2017f | CAGR 2012-2017 |
|-------------------------------------|---------|---------|---------|---------|---------|-------------------|
| Drug Cost – Impact of High Scenario | \$6,743 | \$7,022 | \$7,222 | \$7,513 | \$7,734 | 2.8% |
| Percent Growth | 0.02% | 4.13% | 2.85% | 4.04% | 2.93% | |
| Drug Cost – Impact of Low Scenario | \$6,732 | \$7,004 | \$7,202 | \$7,125 | \$7,311 | 1.6% |
| Percent Growth | -0.15% | 4.05% | 2.82% | -1.07% | 2.61% | |

Events Impacting Forecast

Event 1: Generic Entry

The largest impact on future drug costs will be loss of exclusivity of brand name medicines and generic pricing reforms. By 2017, the generic event is projected to impact the baseline analysis by -13.85% in the high growth scenario for a reduction of \$1.206 billion. The low growth scenario impact by 2017 is forecast at -18.33% or \$1.596 billion in savings.

Table 2.1

Generic Impact Scenario

| Description | 2013f | 2014f | 2015f | 2016f | 2017f |
|--|---------|---------|---------|-----------|-----------|
| High Scenario (Suggested Scenario) | | | | | |
| Impact of Generic Savings – High Scenario | -4.41% | -6.92% | -9.66% | -11.61% | -13.85% |
| Savings from Generic Impact (\$millions) – High Scenario | (\$309) | (\$515) | (\$760) | (\$963) | (\$1,206) |
| Low Scenario | | | | | |
| Impact of Generic Savings – Low Scenario | -4.41% | -6.92% | -9.66% | -15.96% | -18.33% |
| Savings from Generic Impact (\$millions) – Low Scenario | (\$309) | (\$515) | (\$760) | (\$1,324) | (\$1,596) |

³ Of note, costs in this report represent 70% of the private drug plan market and have not been extrapolated to 100%.

Overall, the generic factor largely offsets the incremental impact of new drug entries, the ageing population and increases in utilization. Table 3 below summarizes the annual generic pricing ratios used in estimating the impact of the generic event on the baseline drug cost forecast.

| Table 3 National Generic Pricing Ratios in “High” and “Low” Scenarios | Scenarios | 2013f | 2014f | 2015f | 2016f | 2017f |
|--|-----------|-------|-------|-------|-------|-------|
| | High | 26.3% | 25.2% | 25.0% | 25.0% | 25.0% |
| Low | 26.3% | 25.7% | 25.5% | 20.0% | 20.0% | |

In addition, the generic impact is based on a sampling of 57 brand name medicines which are expected to lose exclusivity over the 2013-2017 period. In 2012 alone, these 57 medicines accounted for nearly \$1 billion (\$947 million) in private market costs.

Event 2: New Medicine Entry

Much of the discussion regarding the sustainability of private drug plans revolves around the entry of new specialty medicines and the number of drugs in the pipeline. The cost of new medicines entering the market is projected to contribute an **incremental impact** on the baseline analysis in 2017 of 2.25% or \$196 million in the low scenario and up to 2.51%, or \$219 million, in the high scenario. Over the entire forecast period, this amounts to an incremental impact of 7.9% in the low scenario and 8.8% in the high scenario. These findings were derived from an historical analysis of the impact of new medicine entries from 2008-2012 by product mix (small molecules, cancer therapies and specialty products) and supplemented by an analysis of the mix distribution in the current phase III pipeline as seen in Table 4.

| Table 4 Distribution of NMEs by Molecule Type in “High” and “Low” Scenarios | Scenarios | Small | Cancer | Specialty |
|--|-----------|-------|--------|-----------|
| | High | 48% | 31% | 21% |
| Low | 61% | 20% | 18% | |

Note: The products in the pipeline should not be interpreted as the launches that will occur during the forecast period.

Rationale for Scenarios

Low Scenario- Assumes the New Molecular Entities (NMEs)⁴ launching in the forecast period follow the same distribution of small molecule, cancer and specialty products as the historical period. It also assumes that on average the same number of molecules will be launched in the forecast period as we have seen historically (Table 5).

High Scenario - Assumes the NMEs launched in the forecast period will have a greater proportion of cancer and specialty products than in the historical period and is based on distribution of molecules from the current phase III pipeline analysis. The high scenario assumes that 22 new products will be launched annually in the private drug plan market from 2013 to 2017 which represents a 12% increase over the historical period. This assumption is based on the highest number of NMEs launched in a single year during the historical period, illustrated in table 5 below.

Table 5
NMEs Launched in 2007-2012 with Claims Activities in PDP

| Year | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|----------------|------|------|------|------|------|------|
| Number of NMEs | 22 | 19 | 22 | 19 | 17 | 21 |

Event 3: Changing Demographics/Aging Population

In addition to the impact of new medicines coming to market, it is anticipated that an ageing population will also contribute to an incremental increase of 0.12% year over year on the baseline costs or \$10.7 million in the high scenario and no incremental impact in the low scenario (which assumed increasing utilization trends due to ageing were already captured in the baseline analysis). Over the forecast period, this represents a 0.62% or \$48 million impact to the baseline analysis in the high scenario.

⁴ A New Molecular Entity (NME) is defined as an active ingredient never marketed in any form

Context and Observations

1. **Excluded Factors:** Several factors were excluded from the IMS Brogan Private Drug Plan Drug Cost Forecast because the exact impact of these factors on drug costs could not be forecasted with a high degree of confidence. These factors are shown below with the expected trend direction of the impact. In some cases, the estimated effect on overall sales growth in the overall market assumed by IMS Brogan in their separate *Market Prognosis* model is shown. If sufficient data existed to allow the inclusion of these factors in the Forecast model, the combined effect would very likely be to reduce the predicted CAGR over the forecast period.

Table 6

Factors Excluded from the IMS Brogan Private Market Forecast

| Excluded Factors | Speculative Effect on PMF CAGR | Source |
|--|--------------------------------|-------------------------------------|
| *Future cost containment strategies | -0.30% | IMS Brogan, <i>Market Prognosis</i> |
| Market entry of bio-similars | -0.02% | IMS Brogan, <i>Market Prognosis</i> |
| PDP spill-over from new MPP reimbursement for PPIs in Quebec | -0.04% | IMS Brogan, <i>Market Prognosis</i> |
| GDP, employment | +/- (?) | - |
| New indications for existing drugs, incl. therapy displacement | +/- (?) | - |
| **Pricing trends | +/- (?) | - |

*Private payers have recently begun to implement cost-containment strategies. Access to private formularies over the forecast period is expected to become more restrictive. For example, in 2012 Great-West Life and Sun Life implemented mandatory generic substitution, and Great West Life implemented a case management system substituting lower-cost medicines in place of prescribed higher-cost specialty drugs. The exact impact on total drug costs cannot be forecasted with a high level of confidence. IMS Brogan's overall forecast in its *Market Prognosis* assumes a future cost containment impact of -0.30% CAGR.

****PMPRB data strongly suggests zero or below CPI for current products; at or below international median prices for new entries.**

2. **Marginal impact of new medicines:** The cost of New Medicine Entry is mostly offset by the displacement of previous therapies, so the net marginal impact on the overall market is mitigated.
3. **Proportional impact of high-cost specialty medicines:** Specialty medicines treat small patient populations and so the proportional impact of these products on the overall market is mitigated. As well, cancer New Molecular Entities (NME's) had a relatively minor impact on private drug costs, mainly because these costs are often paid by hospitals, cancer care agencies and provincial programs. In addition, cancer medicines accounted for only 3% of overall drug costs in 2012, about the same as for skin and membrane preparations including acne therapy.

4. **Private market costs are not comparable to public market costs:** The private market differs from the public market in several significant ways that preclude valid cost comparisons. For example:
- a. The private and public markets are characterized by **different insured populations** with distinctly different demographics and health status profiles. Private plans contain younger, healthier employed populations; public plans contain more mature and less healthy populations often living on fixed incomes.
 - b. The generosity of **drug insurance benefits differs drastically** between private and public plans. The most recent annual analysis published by Canadian Health Policy Institute (CHPI) using data from IMS Brogan and Health Canada showed that in a private-public comparison across the country, 81% of new drugs were insured by at least one private plan compared to only 47% by at least one public plan. Additionally, patients covered under private plans waited 127 days for insured access on average, compared to 467 days for patients covered under public plans.
 - c. **Average plan costs have a different meaning** for the private market and public market because of uniformity versus variability of plan design. Public plans vary only by jurisdiction, while private plans vary by insurance carrier and plan sponsor. Generous and competitive private plans are often a strong incentive to attract and retain qualified employees.
 - d. On average, maximum allowable dispensing fees and mark-ups in the private market are greater than in the public market.

Project Observations/Conclusions by Rx&D

The IMS Brogan Private Drug Plan Drug Cost Forecast is based on rigorous analysis as well as a detailed, transparent methodology and assumptions. The projections are based upon pay direct drug costs and represent approximately 70% of the overall private market. The Forecast is based on a quantitative and qualitative analysis of the pharmaceutical phase III pipeline and the distribution of molecule types. Actual historical volume trends were pulled from the IMS Brogan Private Drug Plan databases.

The Forecast (2013-2017) indicates that contrary to some predictions, growth in private drug costs will remain sustainable into the foreseeable future. The overall private market will experience low, single digit drug cost growth at a compounded annual rate of between 1.6% and 2.8% during the five year forecast period.

Upon examination of the pharmaceutical industry Phase III pipeline, there remains a substantial mix of both small and large molecule medicines entering the market. Many of these new innovations will be priced based on existing drugs within their class and displace the use of less effective medications. Prices for existing drugs will continue to remain flat and below the rate of inflation as they have for the past decade.

Loss of exclusivity of brand name medicines and generic pricing reforms will continue to put considerable downward pressure on overall drug costs over the entire five year forecast period with a projected saving of between \$1.2 billion and \$1.6 billion in 2017. Fifty-seven medicines projected to lose exclusivity during the forecast period accounted for almost \$1 billion in private market drug costs in 2012 alone.

It is also important to note that these projections do not include any additional cost containment measures beyond those already implemented. In addition, it does not incorporate any cost savings resulting from market entry of Subsequent Entry Biologics which could potentially reduce costs even further.

It is understandable that some private payers have concerns about the growth in specialty products. However, these concerns must be put in perspective with the evidence that their utilization is often within small patient populations in the overall market and that they confer dramatic improvement in outcomes to employees and their families, enabling greater productivity in the workplace.

While the predicted growth in private drug plan drug costs overall will be in the low single digits and sustainable, the experience of individual plans may be different based on industry, region, size, demographics and other factors. To manage these risks, solutions for individual plans to consider include drug cost pooling agreements, patient-centred plan design as well as health promotion strategies.

Through promotion of good health, adherence and prevention, and appropriate risk management, these costs can be sustained and value generated. This is an area where collaboration can achieve improved outcomes.

We can all agree that the sustainability of the drug plans and access to the appropriate treatments that keep Canadians healthy and productive is something that concerns us all. It is hoped that this Forecast will provide additional guidance and context in finding solutions that will ensure that private drug plans are sustainable now and in the future.