

Canadian Healthcare Payers

*An Overview of the Healthcare
Reimbursement and Pricing Landscape*

*Information to Discern Market Research
Design and Sample Selection for Pricing and
Market Access Considerations*



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Audience: This paper is intended for market research services buyers and health business directors who want to better understand who to conduct research with influencing and making decisions for healthcare products on or intended for the Canadian market.

Scope: The paper focuses on the pharmaceutical market, even though both authoring companies have project experience in medical equipment and supply markets. The paper is also oriented towards market access topics based on those products having achieved Health Canada review and decisions.

Contents

Contents	iii
Overview – Canadian Healthcare System.....	1
The Current Canadian Reimbursement and Pricing Landscape	2
Important Research Considerations based on Product Life Stage	16
Stakeholders Involved with Product Decisions	17
About HealthViews and Pricing Solutions	18

Overview – Canadian Healthcare System

In Canada, healthcare is delivered through a publicly funded system that is supervised by the government with regulation set by the Canada Health Act.

Each province may opt out, though none currently do. Canada's system is known as a single payer system, in which basic services are provided by private doctors (since 2002, they have been allowed to incorporate), with the entire fee paid for by the government at the same rate.

There is no day-to-day care or patient information collected; it all remains confidential between patient and physician. The physician in turn handles the claim at a provincial level, and so the patient does not have to worry about billing and claims. Private insurances play a smaller part. The costs are covered from income taxes, although some provinces impose a monthly premium that may be waived or reduced for those with low incomes.

The federal government negotiates drug prices with suppliers to control costs.

Healthcare Spending in Canada

The amount Canadians spend on healthcare has increased every year between 1975 and 2009, from \$39.7 billion to \$137.3 billion. This represents more than a doubling of per-capita spending, from \$1,715 to \$4,089.

The increase in healthcare costs has been mostly covered by public funds. Hospitals get the greatest proportion of this money (\$51B), followed by pharmaceuticals (\$30B), and physicians (\$26B). The proportion spent on hospitals and physicians has declined between 1975 and 2009, while the amount spent on pharmaceuticals has increased.

In 2009, the government funded about 70% of Canadians' healthcare costs, covering most hospital and physician costs, while dental and pharmaceutical expenses were paid for by individuals.

When it comes to drug purchases, 10% of distribution is via hospital pharmacies and 90% via retail pharmacies. Manufacturers need to understand the decision-making levels for hospital pharmacy channels, as well as the drivers of demand and access for the retail pharmacy distribution channel.

On an annualized basis, there is an average of 12 prescriptions per person at an average cost of \$46 each, or \$564 per person per year.

The Current Canadian Reimbursement and Pricing Landscape

Objectives

- The objective of this section is to provide an overview of the reimbursement and pricing environment in Canada to assist the pharmaceutical market researcher in conducting analyses of new and existing medications. Market research in the pharmaceutical industry has become more complex due to greater reimbursement and pricing challenges. In order to optimize market research, many of these issues should be considered early in the process.

Reimbursement and Pricing

- Challenges to reimbursement are many and varied. Overcoming the hurdle of a successful submission to a national review body is only the first step in a long process.
- There are two federal review bodies in Canada that act as gatekeepers to reimbursement: Pan-Canadian Oncology Drug Review, or P-CODR, specifically for oncology products; and Common Drug Review, or CDR, for all others.
- Nine out of 10 provinces, two territories, and the First Nations and Inuit Health Branch follow the recommendations of P-CODR and CDR. Quebec does not participate in either review process, and has its own review and decision-making process.
- The CDR reviews new drugs, new combination products, and drugs with new indications. Individual provincial review committees still review line extensions.
- Participating provinces wait for a positive or negative recommendation from the CDR before they make a listing decision.
- The reimbursement process can take anywhere from nine months to two years, depending on the province. Not all provinces list the same products, which points to an inequity across jurisdictions.
- Hospital contracts are often negotiated through Group Purchasing Organizations (GPOs) via a Request for Proposal (RFP) process.
- The two biggest players in the GPO arena in Canada are Medbuy and HealthPRO.
- The Patented Medicine Prices Review Board (PMPRB) has jurisdiction over pricing of any medicine that is patented and sold. The PMPRB does not set prices,

but determines the maximum allowable or non-excessive price at which a patented medicine can be sold.

- In January 2010, the PMPRB issued new Guidelines that impose greater challenges to the pharmaceutical manufacturer, and that could serve to reduce prices of patented medicines over time.

Summary

- The pricing and reimbursement processes in Canada are dynamic. They are dependent on many variables, including the political party in power, the presence of advocacy groups, the politics around specific disease states, budgetary issues, etc.
- It is important to keep abreast of changes to the drug approval system in Canada, as these changes will inform future reimbursement and marketing strategies for manufacturers.

Hospital Drug Review Process

In general, the process within hospitals for reviewing drugs for inclusion on the hospital formulary lists has little or nothing to do with the pharmaceutical industry manufacturers. Although the review process does differ between teaching hospitals and community hospitals, one thing remains common – hospitals and/or physicians are the initiators of the drug reviews.

When a physician or hospital staff member initiates a request for review, a pharmacist on staff will prepare a binder that summarizes key clinical information. The pharmacist will present the data to the hospital Pharmacy and Therapeutics (P&T) committee for consideration (the Director of Pharmacy sits on the P&T committee). The P&T committee will make a recommendation to the hospital on whether the drug is safe and effective. The focus of the P&T committee is clinical in nature. If a product is deemed clinically efficacious and safe, the next hurdle is the cost. Generally, funding decisions are left to the “C-Suite” of the hospitals (the CFO, CEO, etc.).

Interestingly, teaching hospitals will go to the Ministry of Health (MoH) for additional funding if their budget deems this necessary, but it is the requesting physician, not the P&T committee members, who is responsible for making the request to the MoH. The community hospitals rarely, if ever, go to the MoH to secure additional funding; these initiatives have not been successful in the past. Securing money at the start of the budget year has proven to be more successful.

If a manufacturer sends in a binder of information, community hospitals would briefly look at the contents, paying particular attention to the budget impact analysis. However, in all likelihood, the pharmacist on staff would re-do the analysis. Similarly, teaching

hospitals would briefly look at the contents, but anything received from industry would be considered biased, and all analyses would be re-created by staff. Hospitals cannot guarantee that the information contained in a submission binder will be kept confidential. Often, in provincial submissions, manufacturers include proprietary and/or unpublished information. This is something for the manufacturer to consider when populating the hospital binder.

In general, teaching hospitals have more expertise in the area of pharmacoeconomics than do community hospitals. With either customer, it is important that the analysis that the manufacturer prepares be simple, with clear messages on the value of the drug. Along with pharmacoeconomic analyses, health technology assessment is also top of mind for decision- and policy-makers in the hospital setting. In a March 2010 report from CADTH (Canadian Agency for Drugs and Technologies in Health), the feature article focuses on the use of Health Technology Assessments (HTAs) in hospitals. It notes that HTAs are becoming increasingly important in the hospital environment, and suggests that the expertise within the hospitals is increasing as well.¹ A history of opportunity lost as a result of poor decisions related to reimbursement and utilization of health technology (including drugs, devices, and systems) is pushing the popularity and inclusion of pharmaco-economics and HTAs in the healthcare sector.

The value of hospital-based HTA units has been recognized in many provinces. As mentioned previously, the Quebec government has begun to take a closer look at the results of HTAs in relation to public plan listings via the Conseil du médicament. In Quebec hospitals, HTAs have been ongoing for some time. The network of five university teaching hospitals is now expanding to other centres. These HTA units conduct appraisals, not only of treatments (which include drugs) and delivery of healthcare, but also of medical devices (a future trend that will become important to provincial payers as well). The results of the HTAs inform the development of health policy within and outside of the institutions.² Between 2002 and 2007, HTAs have resulted in policy changes and rejection or partial reimbursement of 19 technologies, which has saved the overall healthcare system in Quebec approximately \$12.8 million.³

Alberta and Ontario are also operating hospital-based HTA systems, but not on the same scale as Quebec. In Ontario, the teaching hospitals tend to follow the listings on the Ontario Drug Benefit Formulary/Comparative Drug Index (ODBF/CDI), which considers HTAs in the public domain. The ODBF/CDI is the list of drugs for which the Ontario Drug Programs Branch will provide reimbursement for its clients.⁴ It is possible that hospitals, in the future, might work together on a common review of drugs. This is already being seen with a group of eight smaller hospitals in Barrie, Ont., that are providing forums for their P&T committees to meet and discuss as a group the merits of reimbursing particular compounds.

¹ Murphy G., Morrison A., Berube A., Husereau D. *Health Technology Update*, Issue 13, Ottawa: Canadian Agency for Drugs and Technology in Health; 2010.

² *Ibid.*

³ *Ibid.*

⁴ Ontario Ministry of Health website. Accessed March 31, 2010.
http://www.health.gov.on.ca/english/providers/program/drugs/odbf_mn.html

Group Purchasing Organizations

Group purchasing in the pharmaceutical industry refers to the increased buying power that a large group can wield versus that of a small group. For example, if one community hospital were to approach a pharmaceutical company to negotiate a contract price for a product, it might not have much leverage. However, if it were to partner with a very large teaching hospital, then its buying power, and therefore its ability to negotiate a better pricing deal, might be enhanced based on the increased volume associated with the price. Therefore, the more hospitals that join the group, the better the collective purchasing power of that group will be. It is on this principle that Group Purchasing Organizations (GPOs) or Hospital Buying Groups (HBGs) are formed. Members of the group share in the operating/administrative costs of the GPO, and enjoy the benefits of the group purchasing power.

Medbuy and HealthPRO are the leading GPOs in Canada. Medbuy's supplier list is extensive, and includes all the major players in the pharmaceutical industry in Canada.⁵ Members of the Medbuy GPO in Ontario include Sick Kids, the London Health Sciences Centre, the Canadian Diabetes Association, St. Michael's, and more. A more complete list can be found here: <http://www.medbuy.ca/en/aboutus/members.asp>. Medbuy is active in Ontario, British Columbia, Nova Scotia, and New Brunswick. According to its website, in 2008, Medbuy returned more than \$33.9 million in rebates to members in those four provinces. In Ontario, Medbuy partners with the St. Joseph Health System GPO. St. Joseph's has more than 160 members (healthcare facilities), 131 of which are in Ontario.

According to HealthPRO's website, it is Canada's largest GPO, with over \$1 billion in leveraging power.⁶ HealthPRO has locations across the country – in the Yukon, the Northwest Territories, Nunavut, British Columbia, Alberta, Manitoba, Ontario, Newfoundland and Labrador, and Nova Scotia.

In Quebec, a company called Approvisionnement Montréal is reputed to be a GPO. However, its website refers only to medical devices and equipment, and is closed to the general public. McKesson Canada, another player in this arena in Canada, has to date been considered primarily a wholesaler. However, it recently acquired a pharmacy drug chain in Quebec called Proxim, and may be seeking to join the ranks of Canadian GPOs by capitalizing on a possible marketplace gap in Quebec.

GPOs do not generally influence the listing process with public payers. The reimbursement decisions are made exclusive of any contract negotiations being established. In hospitals, the P&T committee would make a reimbursement recommendation. Once that recommendation has been made, a listing decision is made and contract negotiations begin. The contracting process may occur concurrently with the listing decision.

⁵ Medbuy website. Accessed March 31, 2010. <http://www.medbuy.ca/en/aboutus/oursuppliers.asp>

⁶ HealthPRO website, accessed April 1, 2010. <http://www.healthprocanada.com/>

GPOs function by sending out RFPs to manufacturers. The manufacturer has the choice whether or not to participate in the bid. The RFPs could be sent to multiple manufacturers for similar products (e.g., proton pump inhibitors), or to specific companies for specific brands (e.g., JOI and risperidone). The bidding opportunities could be published on one or more websites in the public domain (i.e., Biddingo, BC Bids, Bids.ca, Alberta Purchasing Connection, etc.). Depending on the contract stipulations, the GPO may have to sell a certain pre-specified amount in order to obtain maximum rebates on a product or group of products.

Private Payer Drug Review Process

Typically and historically, private-payer coverage and associated uptake of products has been much more rapid than that of public insurers. However, like public insurers, private insurers are becoming increasingly concerned about the cost of brand-name medications, especially with the recent cost-shifting that is taking place from the public to the private market (oral chemotherapeutic agents is a good example of this cost shifting).

The private payers do not wait for the results from the CDR review. Sometimes, private payers will follow the provincial reimbursement approval or denial, but most often, they are quicker than the provinces to list products, since their clients pay into the systems and therefore are not willing to wait for coverage.

Key trends to monitor in the private-insurer environment include: 1) drug reviews becoming more rigorous, leading to increased utilization of managed care plans; 2) an increased emphasis on the need to present and discuss the product with insurers pre-NOC; and 3) movement toward PLAs. In summary, private payers are taking control over access to medicines, and will not just list everything as they used to in the past. As recently as a few years ago, pharmaceutical manufacturers assumed that any product that was submitted to a private payer would gain rapid reimbursement. While it is certainly true that the private payers generally list products more quickly than public payers do, the lag times are increasing. The private payers are aware of the deals being struck with the provincial payers, and are also active in discussions around rebates of generic medications. Although they have not yet determined or implemented the adjudication systems required to manage product listing agreements, they are moving toward that objective. When conducting market research with private payers, it is increasingly important to identify how pricing of your medication will impact listing. Of particular importance is an understanding of how private payers manage other medications in the same therapeutic class, particularly with respect to: i) pricing; ii) whether they tier medications based on price; and iii) any rebates, deals, or programs they have in place. This information will help identify optimal price as well as challenges you may face if you are priced outside of the optimal range.

Rigorous Reviews

As private insurers are taking a closer look at the quality of the data provided in submissions for reimbursement, they are considering the value of the clinical data in relation to the price. We have seen several recent examples of products for which the data is not compelling and the price is high. While private payers generally do not say no to reimbursement, they are increasingly placing these types of products in tiered positions with respect to comparative products. For example, they will reimburse the product, but only after two or three other products have been tried; or they will attach a form of reference-based pricing to the listing, whereby the product will be reimbursed, but only up to the value of a competitive product that has better clinical data and a lower price.

Gaining Buy-In Early in the Process

There is a trend toward meeting with private insurers earlier in the process, and to tailoring the submission toward the private insurer by planning for workplace data collection (in time for submission), and organizing the content of the submission so that it is relevant to the private insurer market. It is important to meet with the private insurers early on to discuss the product with them, and to gain their buy-in on the type of data being presented. That helps to pave the way for a rapid and smooth review process.

Product Listing Agreements

Preferred partnerships, or negotiated agreements between drug plans and manufacturers, are rapidly becoming the new way of doing business as both public payers and private insurers look to clamp down on healthcare expenditures. Canadian private insurers, unlike their U.S. counterparts, have not yet pursued Product Listing Agreements (PLAs) with pharmaceutical manufacturers. This is primarily because the infrastructure (both human and systems) for the administration, adjudication, and tracking associated with managing PLAs has not yet been developed.

The larger tier of Canadian insurers, capturing 70% of the market, has not moved to invest in the system changes that would be required to manage the adjudication of PLAs. At this time, it is impossible to implement a PLA based on the structure of some insurance contracts and the capacity of adjudication systems. Both of these issues can be resolved, and much of the work is reported to have been completed on the systems side. On the federal side, the insurers are currently working through internal revisions to have the capability to adjudicate and administer PLAs in the near future.

To date, PLAs have been attempted only by larger insurers, with mixed success. Following are some examples of recent activities on the private-insurer side related to PLAs:

- ESI attempted (and has since abandoned) a formulary designed on preferential access gained by rebating branded products. Brand pharmaceutical companies did not submit tenders, partly because the plan was “theoretical”; because it didn’t

have any lives attached to it yet, ESI could not estimate the risk to the manufacturers in terms of revenue lost.

- Medavie Blue Cross has successfully signed a PLA (non-transparent discount) with Nycomed for access to Tecta[®]. The insurer told Nycomed that it liked the drug, but not at that price. Nycomed had to deal in order to gain coverage for the product.
- Towers Perrins (a benefits consultant) has issued an RFP to insurers, looking for a partner to negotiate multi-source and branded prices for their employers. The intent is to have an insurer negotiate on their behalf and present the negotiated opportunities to employers for their choice of adoption. All large insurers have declined participation, and three smaller insurers are responding. This is a weak plan, with no expected outcomes in the near term. However, it is a sign of employer concern around the management of their plans.
- GreenShield announced (July 2009) a “negotiated formulary” for five specific brands. Typically, these PLAs are done around multi-source products, and in this case, GreenShield approached brand-name pharmaceutical manufacturers and asked them to rebate their brand-name products to the cost of the generics. In return, manufacturers would get exclusive coverage on the GreenShield formulary. Five companies agreed and signed on. Others did not because the return on investment was not there. Already, there has been some negative reaction from several pharmacies. Rexall has announced that in specific locations (which just happen to be in the Windsor area where there are large numbers of GreenShield clients), it will no longer accept the GreenShield drug card (which means patients must pay out of pocket and seek reimbursement on their own).

Despite mixed success so far, it is reasonable to assume that private insurers will continue to work toward acceptance (internally and externally) of PLAs. Private payers have recognized the advantages that public payers are enjoying with respect to PLAs, and want the same benefits for their insured members. As a part of the Ontario Drug Renewal Process, private insurers have submitted responses collectively, and four payers have submitted independently. There is a common call for transparency on PLAs and an end to two-tiered pricing of multi-source products. The latter point is the focus, as there is little expectation of the former one being addressed. Claims of multi-source products to private insurers are averaging approximately 75% of the branded molecules.

Private insurers are actively lobbying for government policies on the pricing of multi-source products to be extended to them. A part of Bill 34 in Alberta does just that – as of January 1, 2010, multi-source products must be priced at 45% of the brand price to be listed on the Alberta Health and Wellness formulary, and these prices must be extended

[®] Tecta[®] is a registered trademark of Nycomed Canada Inc.

to private plans as well. This was attempted in Ontario when Bill 102 was enacted, but it didn't hold, due to the effective lobbying and pushback from the generic manufacturers and pharmacists.

Major Differences between Private Payers and Public Payers

In general, the differences between private payers and public payers can be summed up as follows:

Private Payers

- About 60% of Canadians are covered by private drug plans.⁷
- Private-payer plans take less time to review drugs because they are not dependent on federal review bodies.
- The clients of private payers pay into their drug coverage plan, either via their company (workplace) sponsor or via monthly fees if they are paying for the plan themselves. As a result, these clients expect coverage to be more rapid and comprehensive, since they are contributing to the cost of the program.
- Since private plans are most often funded by employers, budget impact analyses for private payers should use workplace data as a base. For the same reason, private plans are more interested in data around lost productivity.
- Clients of private plans generally enjoy good and rapid access to drugs.

Public Payers

- Public-payer plans take longer to review drugs because they are dependent on federal review bodies (with the exception of Quebec).
- The clients of public payers do not generally pay into their drug coverage plan (clients do contribute in certain provinces such as Manitoba, but the contribution is income-based and adjusted).
- Listing decisions for public plans are based on the money available in government drug budgets. Government payers seek PLAs in an attempt to cap spending on drugs where possible (for example, when generic medications are available, provinces might employ reference-based pricing), to ensure money is available to reimburse other, more expensive brand-name drugs.
- Clients of public plans can sometimes influence the government decision-makers by effective lobbying through patient advocacy groups (the recent Avastinⁱ® listing in Ontario is a good example of this⁸).

⁷ Drugcoverage.ca, accessed March 31, 2010.

http://www.drugcoverage.ca/p_private_insurance.asp?language=1

⁸ Google search: Ontario Avastin® Ombudsmen – accessed March 31, 2010.

<http://www.ombudsman.on.ca/media/119853/avastin%20statement%20oct%201%2009.pdf>.

<http://www.ombudsman.on.ca/en/media/press-releases/2009/ministry-decision-to-restrict-cancer-drug-%E2%80%9Cverges-on-cruelty%E2%80%9D-ombudsman-finds-cap-on-avastin-funding-unreasonable-and-wrong.aspx>

Quebec

In Quebec, all patients are covered for drugs; therefore, all patients pay into the drug plan (based on income and tracked via income-tax returns). If patients do not have access to medications via a private drug plan, they are then eligible for the public plan, administered by the Régie de l'assurance maladie du Québec (RAMQ).⁹

The Impact on Patients

Often, clients of private drug plans are covered faster and better than those of public drug plans. But there are also major differences in public plans across provinces. A recent study by Demers et al (2008)ⁱⁱ examined the differences in the annual costs of drugs to patients according to the province in which they lived. There were significant differences in the provincial plans in terms of details around co-payments (cost-sharing) and eligibility criteria to be covered by the plans. In their summary of results, they note that in two provinces, seniors pay 35% co-payment toward their drug costs, but in other provinces, the co-payment might be as high as 100%. Even with patients on social assistance, the differences are marked. In five provinces, patients covered under social assistance pay 35% (or less) toward co-payment, and in the other five provinces, they pay nothing. The authors highlight an example of a patient with congestive heart failure who, depending on where he or she lives, might pay between \$74 and \$1,332 out of pocket for drugs alone.

This has been illustrated recently in the news around the coverage of cancer medications, whereby patients in Canada have physically moved to British Columbia from Ontario to enjoy better and faster access to oncology medications.

⁹ Drugcoverage.ca, accessed March 31, 2010. http://www.drugcoverage.ca/p_benefit_qc.asp

The Current Pricing Landscape

Pricing Challenges

The Canadian pricing environment presents many challenges to pharmaceutical manufacturers, particularly as a result of an increased level of scrutiny imposed by the Patented Medicine Prices Review Board (PMPRB), a federal regulatory body with a mandate to ensure that prices charged by pharmaceutical manufacturers for patented medicines sold in Canada are not excessive. In June 2009, the PMPRB completed a four-year-long consultation with stakeholders on the modernization of its Excessive Price Guidelines (the Guidelines), implemented on January 1, 2010.¹⁰ This section outlines the challenges that pharmaceutical manufacturers face with respect to pricing in the context of these new Guidelines, as well as provincial considerations for price increases.

The Role of the PMPRB

The PMPRB is an autonomous quasi-judicial body that draws its authority from the Patent Act as last amended in 1993. The PMPRB has jurisdiction over *patented medicines* that have been *sold* and have the “merest slender thread” of a patent. This means that if a brand-name medicine has been genericized, PMPRB jurisdiction may still apply (i.e., in the case where the medicine has other patents).

Prices of patented medicines do not need to be approved by the PMPRB before the medicines are sold in Canada. The PMPRB does not set the prices, but determines the Maximum Average Potential Price (MAPP) and the Non-Excessive Average Price (NEAP) at which these medicines can be sold. The price of a patented medicine is considered excessive if the Average Transaction Price, or “ATP” (the manufacturer’s price net of any rebates and discounts), is greater than the MAPP or NEAP, nationally or in any sub-market. Manufacturers need to set their initial pricing carefully, since this will be used as a benchmark for any future price increases, which are limited by inflation rates.

For new medicines, the manufacturer generally makes a submission to the PMPRB. That body conducts a scientific and price review to determine whether the ATP is within guidelines or “non-excessive.” If the PMPRB deems a new or existing medicine excessive, the medicine is put under investigation.

There are several possible outcomes of an investigation:

- The medicine is deemed non-excessive, and the investigation is terminated;
- The medicine is deemed to be excessive, and the patentee is given the option to sign a Voluntary Compliance Undertaking (VCU), which includes adjusting its price to a non-excessive level and making a payment to offset excess revenues;
- The medicine is deemed to be excessive, and the patentee does not submit an acceptable VCU. In that case, the matter will be referred to the chairperson of the

¹⁰ Patented Medicine Prices Review Board (PMPRB) Compendium of Policies, Guidelines and Procedures. Final Revised Guidelines were issued in June 2009 for implementation in January 2010.

PMPRB, who has the authority to call a public hearing. If a hearing is called, the chairperson assigns members of the PMPRB to preside over the hearing.

The decisions of the PMPRB are subject to judicial review by the Federal Court (FC). If the pharmaceutical manufacturer is not in agreement with the hearing outcome, it can appeal to the FC. After the FC reviews a PMPRB ruling, either side can seek an appeal from the appeals court.

PMPRB Guidelines

The PMPRB has the authority to develop policies, procedures and guidelines outlining how it will carry out its statutory duties in a fair and effective manner. In 2005, the PMPRB began a consultation process with stakeholders on the modernization of the Guidelines. The new Guidelines, which were implemented on January 1, 2010, contain some items that could be seen as positive changes, and others as additional challenges for pharmaceutical manufacturers.

Potential Opportunity

The previous Guidelines included three levels of therapeutic improvement for new medicines:

- Category 1: line extension/“me too” products
- Category 2: breakthrough/substantial improvement
- Category 3: moderate/little/no improvement

The category assigned to a new medicine determines the level of pricing the manufacturer would be able to achieve for that medicine. The new Guidelines recognize the value of “moderate improvement” by including four levels of therapeutic improvement:

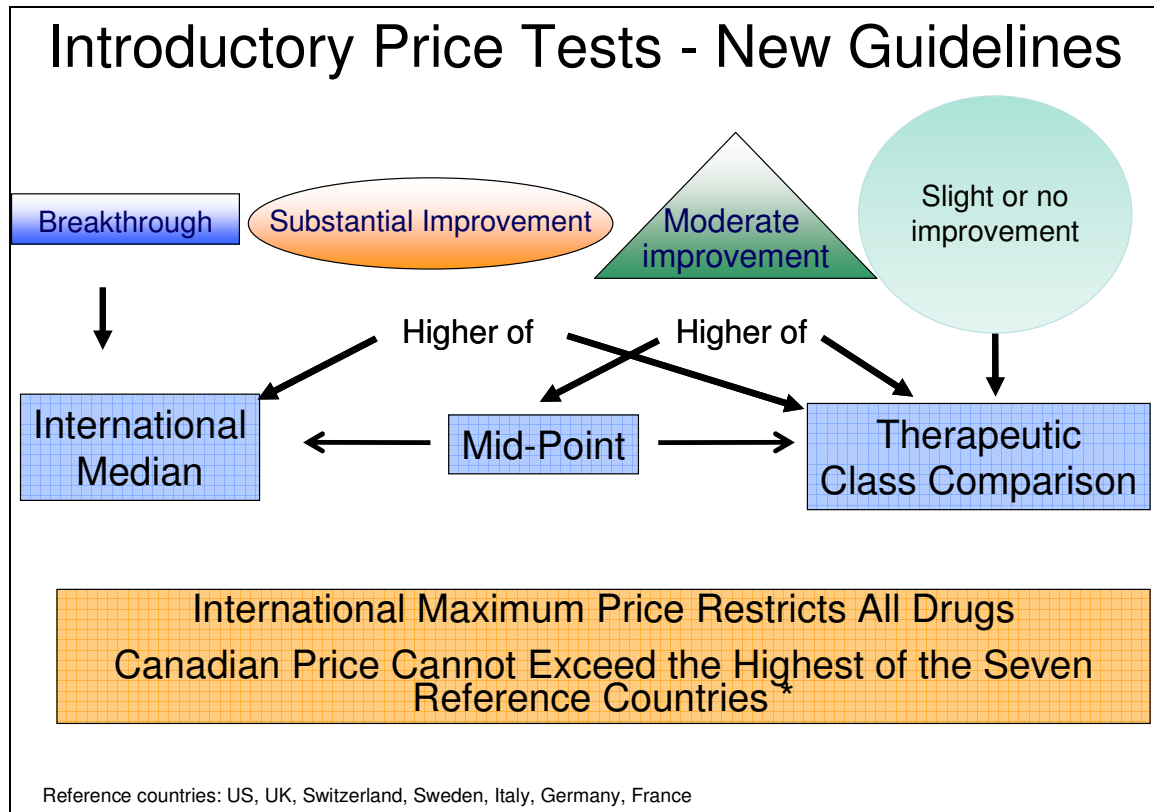
- Breakthrough
- Substantial improvement
- Moderate improvement
- Slight or no improvement

This allows for a medicine with *some improvements* over current therapies to benefit from a potentially higher price.

Figure 4 shows how new price tests allow for price premiums based on therapeutic improvement. A “breakthrough” medication is allowed to price at the level of the international median (IM), which is the median price of seven countries referenced by the PMPRB (U.S., U.K., Switzerland, Sweden, Italy, Germany, France). A product classified as “substantial improvement” is allowed the higher of the IM and the highest Therapeutic Class Comparator (TCC). Referencing the IM generally allows for higher prices. Provided a TCC can be established, the new category of “moderate improvement” is allowed the higher of: i) the midpoint of the IM and the highest TCC; or ii) the highest

TCC. A product that offers slight or no improvement is allowed to price at the highest TCC.

Figure 4: Introductory Price Tests Adapted from the PMPRB Guidelines



Potential Challenges

In addition to assigning a category to a new patented medicine, the PMPRB selects comparative medicines that are used to determine the maximum non-excessive pricing of the new medicine. The new Guidelines no longer reference the highest publicly available price; they now reference the *lowest* available public price. This change is seen as inconsistent with the notion of non-excessiveness, and appears to be a shift away from the Board’s mandate.

This and other changes to the Guidelines are expected to present challenges to pharmaceutical manufacturers. The changes could serve to inappropriately reduce prices of patented medicines over time, possibly resulting in barriers to entry for some medicines. Some speculate that these changes would be a disincentive for pharmaceutical Research and Development (R&D) in Canada, and could reduce the number of innovative medicines in Canada over time. As well, the new Guidelines are increasingly onerous, and are expected to result in administrative burden for both the pharmaceutical industry and the PMPRB. Finally, changes may lead to more disagreements between the PMPRB and patentees, resulting in more hearings and greater expense to the Canadian taxpayer.

Price Increases

Price increases for patented products are limited to the inflation rate, whereas increases for non-patented products are limited to what the market can bear (payers, hospitals, and consumers). Provinces vary in the notification required for price increases, along with the dates that price increases are implemented. (See *Figure 5* for a detailed illustration.) Quebec is unique in that it issues its own maximum allowable price increase annually, and only products listed on RAMQ for two years or more prior to implementation are eligible for price increases.

Figure 5: Provincial Notification and Implementation Times

Province	Notification Required	Implementation Date
BC, Manitoba, NS, NB, PEI	Require 60 days notice	Any time of year
Alberta, Saskatchewan	Inform by RFQ in October	April 1
Quebec	Inform by RFQ in December	April
Nfld	Inform by RFQ in Oct and Apr	Jan 1 and July 1
Ontario	Require 2 months notice Must inform by deadline as follows: <ul style="list-style-type: none">• Inform by April 1 for increase b/w April 1 and Sep 30• Inform by Oct 1 for increase b/w Oct 1 and Mar 31	Any time of year when ODBF is published (on a monthly basis)

Summary

Market research has become more complex with the changing reimbursement and pricing environment of the Canadian pharmaceutical industry. Historically, the researcher would consider the opinions of the physician or other healthcare practitioners in the retail or hospital market, depending on where the medication was going to be sold. Today, for a new product coming to market, there is much more for the researcher to evaluate and consider. The added complexity of conducting market research in the pharmaceutical industry is influenced by a number of factors:

- The product's therapeutic classification. (Is it a life-saving, unique medication in high demand, or a "me-too" drug in a saturated market? Is coverage in this class public, private, or cash-paying? What is the willingness of payers and consumers to pay? Will it generate patient advocacy?)
- Where it is being sold. (Which provinces? In the retail or hospital market, or both? What is the opinion of the various members of the hospital formulary committee?)
- The clinical data. (What, if any, are the clinical advantages over competitors?)
- The competition. (Who are the competitors, and how are they priced, positioned, and reimbursed?)
- PMPRB limitations.
- The manufacturer's desired pricing.

These and other questions should be addressed early on in the market research process. All of these factors need to be considered as pharmaceutical manufacturers attempt to determine their optimal positioning and pricing. Conducting market research in the pharmaceutical industry is much more complex now, and with a thorough understanding of the Canadian reimbursement and pricing climate, the researcher will be better equipped to add value and provide strategic business insights.

Important Research Considerations based on Product Life Stage

Clients can consider research requirements at distinct product life stages – the pre-market, close-to-market, and on-the-market stages.

Pre-Market

At this stage, primary research considerations may be to understand the competitive landscape, the market size and complexities, and the requirements of the prescribers. Pre-market research can also include the assessment of decision-making criteria for a particular drug, and identifying the stakeholders who are involved with access decisions.

Close to Market

Once the product has been approved by the various regulatory and decision-making bodies, research can facilitate needs identification for go-to-market preparations. This includes key message understanding, educational requirements for the product, receptivity to creative materials, and detailed information preferred for product prescribing.

On the Market

Once the product is on the market, research can facilitate insights on possible distribution gaps and market-acceptance factors. Numerous other research applications include usage and attitude tracking, new indication considerations, regional analysis and differences, competitive insights, sales force access and message tracking.

Stakeholders Involved with Product Decisions

The pricing environment section identifies the many professionals involved with the pricing and product listing decisions. These include:

- Health Canada and provincial health authorities
- Insurance benefit providers
- The hospital market – key personnel
 - Formulary Committee members
 - Physicians
 - Administrator/Purchasing-procurement managers
 - Pharmacy directors
 - Other clinical evaluators
 - Group buying organizations
- The prescription market – key personnel
 - Public health authority decision-makers
 - Private 3rd party payers (insurance managers, etc.)
 - Key opinion leaders
 - Physicians

Pricing Solutions offers consultative services and pricing expertise with health authorities and insurance providers. HealthViews has expertise in sourcing all healthcare professionals for fielding qualitative or quantitative market research studies.

About HealthViews and Pricing Solutions

About HealthViews

HealthViews is the leader in healthcare professional sample to marketing research and panel companies. Our exclusive focus within the health-industry ensures we have the panel breadth, depth and experience to consistently deliver even the most difficult to reach healthcare professionals.

The HealthViews Market Research Panel is comprised of physicians, nurses, pharmacists, and many other health professions. Our panels are of the highest integrity as we offer 100% validation of professionals with regulatory bodies and all panelists are double opted-in. We are also an accredited Gold Seal Member of the Marketing Research and Intelligence Agency and the Pharmaceutical Marketing Research Group.

In addition to providing healthcare professional sample, HealthViews also offers a full array of field services that includes, survey programming and hosting, an on-demand healthcare professional omnibuses, and qualitative research services.

About Pricing Solutions

Pricing Solutions Ltd. (PSL) is an international pricing strategy consultancy dedicated to helping clients achieve World Class Pricing™ competency. Pricing Solutions Ltd. has conducted pricing work for almost every major company in the Canadian pharmaceutical and medical devices market.

As pricing strategy specialists, Pricing Solutions has developed a wide range of proprietary tools, processes, and research techniques for studying and analyzing our clients' pricing problems. Our pricing practice and pricing management approach is built on two fundamental concepts. The first, Value-Based Pricing, means setting prices based on the value customers realize by doing business with the firm. This leads to the second fundamental concept, World Class Pricing™. This is the continuous improvement of tools and processes to cultivate pricing knowledge and tap into it on a day-to-day basis. Pricing Solutions is dedicated to providing our clients with the tools and support they need to make more profitable pricing decisions.

Pricing Solutions' core services include:

Pricing research, Pricing management, Pricing training, Pricing systems, Pricing advisory

Pricing Solutions is a Gold Seal member of Canada's Marketing Research and Intelligence Association, and adheres to all industry codes of conduct and privacy.

ⁱ Avastin® (bevacizumab) is a registered trademark of Hoffmann-La Roche Canada.

ⁱⁱ Demers V, Melo M, Jackevicius C, Cox J, Kalavrouziotis D, Rinfret S, Humphries KH, Johansen H, Tu JV, Pilote L. *CMAJ*. 2008 Feb 12;178(4):405-9. Comparison of provincial prescription drug plans and the impact on patients' annual drug expenditures.